CRADLE TO CRADLE CERTIFIED™

THE PRODUCT QUALITY STANDARD FOR THE CIRCULAR ECONOMY

A PROGRAM OF

CRADLE TO CRADLE PRODUCTS INNOVATION INSTITUTE

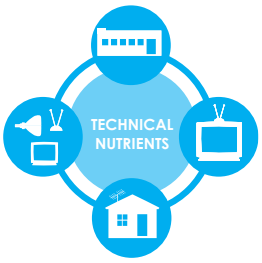
OVERVIEW PREPARED BY

MBDC
THE LEADING ACCREDITED ASSESSOR

CRADLE TO CRADLE

In their 2002 book *Cradle to Cradle: Remaking the Way We Make Things*, architect William McDonough and chemist Michael Braungart presented an integration of design and science that provides enduring benefits for society from safe materials, water and energy in circular economies and eliminates the concept of waste.

The book put forward a design framework characterized by three principles derived from nature:



Everything is a resource for something else. In nature, the "waste" of one system becomes food for another. Everything can be designed to be disassembled and safely returned to the soil as **BIOLOGICAL NUTRIENTS**, or re-utilized as high quality materials for new products as **TECHNICAL NUTRIENTS** without contamination.

Use clean and renewable energy. Living things thrive on the energy of current solar income. Similarly, human constructs can utilize clean and renewable energy in many forms—such as solar, wind, geothermal, gravitational energy and other energy systems being developed today—thereby capitalizing on these abundant resources while supporting human and environmental health.

Celebrate diversity. Around the world, geology, hydrology, photosynthesis and nutrient cycling, adapted to locale, yield an astonishing diversity of natural and cultural life. Designs that respond to the challenges and opportunities offered by each place fit elegantly and effectively into their own niches.

Rather than seeking to minimize the harm we inflict, *Cradle to Cradle* reframes design as a positive, regenerative force—one that creates footprints to delight in, not lament. This paradigm shift reveals opportunities to improve quality, increase value and spur innovation. It inspires us to constantly seek improvement in our designs, and to share our discoveries with others.

WHAT IS CRADLE TO CRADLE CERTIFIED™?

The Cradle to Cradle Certified™ Products Program is becoming a globally recognized "gold standard" science-based quality certification. It acknowledges continuous improvement and innovation of products and processes towards the goal of being not just "less bad" but also "more good" for people and the planet.

The certification program is based on the Cradle to Cradle® framework and methodology, which has been developed and implemented by MBDC over the past two decades. MBDC created the certification program in 2005 to recognize achievement in applying Cradle to Cradle principles. In 2010, MBDC donated to the Cradle to Cradle Products Innovation Institute an exclusive license for the certification program and methodology, and the Institute now administers the program and manages the Product Standard as a third-party, nonprofit organization.

Cradle to Cradle Certified™ Products
Products or materials from any industry or country are eligible to apply for certification. Since the program began in 2005, more than 150 companies from over 15 countries have participated in the Cradle to Cradle Certified™ program. The Istitute has issued over 400 certificates covering more than 2,900 certified products in a variety of categories, including building materials, interior design products, textiles, fabrics, cosmetics, home care products, paper, packaging, and polymers.

Levels of Achievement
The Cradle to Cradle framework has outlined a vision to guide product design and manufacturing, and the certification program recognizes multiple levels of achievement towards that vision. Under Version 3 of the program, there are five levels of product certification: Basic, Bronze, Silver, Gold, Platinum. In order to be certified at a certain level, a product must meet the minimum criteria for that level in all five criteria categories. The criteria in each category becoming increasingly demanding with each level of certification.

THE PRODUCT STANDARD

The Cradle to Cradle Certified™ Product Standard takes a comprehensive approach to evaluating the design of a product, the practices employed in manufacturing the product and its use and reuse potential.

The Cradle to Cradle Certified™ Product Standard is managed and updated by the Institute's Certification Standards Board. Products are assessed in five categories:

Material Health
Product ingredients are inventoried throughout the supply chain and evaluated for impacts to human and ecological health. The criteria at each level build towards the expectation of eliminating all toxic and unidentified chemicals and becoming nutrients for safe, continuous cycling.

Material Reutilization
Products are designed to either biodegrade safely as a biological nutrient or to be recycled into new products as a technical nutrient. At each level continued progress must be made towards increasing the recovery of materials and keeping them in continuous flows.

Renewable Energy & Carbon Management
The criteria at each level progress towards the goal of completely carbon-neutral manufacturing operations that are powered with 100% renewable energy.

Water Stewardship
Manufacturing processes are designed to regard water as a precious resource for all living things and at each level progress is made towards the goal of all effluent being clean enough to drink.

Social Fairness
Company operations are designed to celebrate all people and natural systems and progress is made towards the goal of having a wholly beneficial impact on the planet.

BENEFITS OF CRADLE TO CRADLE CERTIFIED™

Cradle to Cradle Certified™ is more than a recognized mark of product quality; it is a process that leads companies to make better products, better companies and better communities.

Results of the Certification Process

- **Benchmarking of a product's design** for safety to human and environmental health, sustainability of manufacturing processes and future use cycles
- **Defined trajectory for optimizing product design** and manufacturing processes
- **Expert evaluations** of product ingredients throughout the supply chain for toxicity hazards and risks in context of use
- **Third-party assessments** that can provide data to verify claims about your products, to meet regulations or to contribute to other certifications

Advantages of the Cradle to Cradle Certified™ Program

- **Joining a community of innovative companies** that make certified quality products and that use the power of business to provide social and environmental benefits in the circular economy
- **Use of the Cradle to Cradle Certified™ marks** on product packaging and marketing materials to indicate commitment to continuous improvement and total quality
- **Recognition in green building certification programs** (USGBC's LEED V4 Rating System, BREEAM-NL 2014 v1.0) and preference for use in certain Cradle to Cradle-inspired buildings, communities, and developments, including Park 20|20 in the Netherlands and Make It Right's homes in New Orleans
- **Becoming "products of choice"** for numerous environmentally preferable purchasing programs

GETTING CERTIFIED

1.CONFIRM ELIGIBILITY

Step 1: Determine if your product is appropriate for certification

- Is it within the scope of certification?
- Does it comply with the Banned Chemicals Lists?
- Is there a commitment to continuous improvement?
- Does your product meet eligibility requirements in the Cradle to Cradle Certified™ Product Standard?

2. SELECT AN ASSESSOR

Step 2: Select an Accredited Assessment Body for the testing, analysis, and evaluation of your product

- Select from the list of Accredited Assessment Bodies
- Develop a certification plan including cost, timeline and necessary resources

3.INVENTORY, ASSESS & OPTIMIZE

Step 3: Work with your assessor to compile and evaluate data

- Work with assessor and supply chain to collect data
- Assessor evaluates data against the Product Standard criteria
- Work with assessor to develop optimization strategies
- Submit an Assessment Summary Report, assembled by your assessor, to the Institute for final review

Step 4: Receive certification for your product

- The Institute reviews Assessment Summary Report to ensure completeness and accuracy and makes the final certification decision, conferring a certificate and the use of the Cradle to Cradle Certified™ mark, per the requirements of the Trademark Use Guidelines
- Applicant signs a Trademark License Agreement and pays a certification fee to the Institute

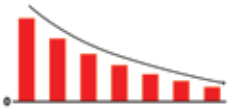
5. REPORT PROGRESS

Step 5: Report your progress

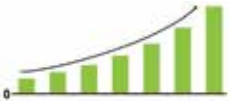
- Every two years, work with the assessor and supply chain to gather new data for re-certification
- Assessor evaluates data and progress on optimization strategies

THE UPCYCLE:
INNOVATION AND CONSTANT IMPROVEMENT

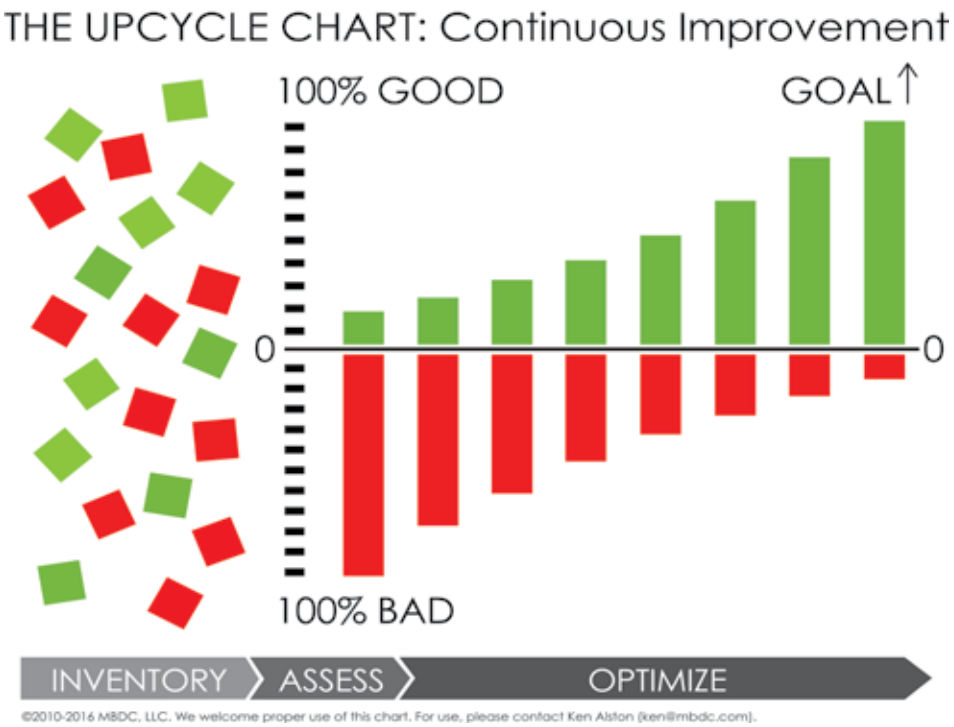
The Upcycle Chart enables many industry sectors, including product manufacturers, to 1) inventory, 2) assess, and then 3) optimize products, processes and systems with positive intentions and beneficial goals.



Industry can do better than conventional eco-efficient approaches which seek to reduce or minimize damage and typically portray reducing a negative footprint.



By adding eco-effective approaches and integrating positively defined goals based on Cradle to Cradle® values and principles, we are able to direct innovation in a coherent and positive trajectory.



MBDC

DESIGN + CHEMISTRY + LEADERSHIP + INNOVATION

Founded in 1995 by architect William McDonough and chemist Dr. Michael Braungart, MBDC has been advocating for endlessly resourceful, Cradle to Cradle® approaches, working with companies to intentionally design products which eliminate the concept of waste, use clean energy, value clean water and celebrate diversity for over 20 years.

MBDC's services can help you and your organization understand and implement the Cradle to Cradle® Design Framework on multiple levels, from materials and products to corporate leadership and your entire organization.

WE ARE LEADERS IN MATERIAL HEALTH ASSESSMENTS
Our chemists have been providing material and product assessments, down to the parts per million, for over two decades.

WE DEVELOPED THE CRADLE TO CRADLE® DESIGN FRAMEWORK
and have inspired and guided companies around the world to remake the way they make things.

WE CREATED THE CRADLE TO CRADLE CERTIFIED™ PRODUCTS PROGRAM
and donated a license to the Institute to make it available to the public as an independent third party peer reviewed program in order to spur innovation on a global scale.

HOW CAN WE HELP YOU?

MBDC: A LEADING ASSESSOR

MBDC has many years of experience in working throughout the supply chain to collect formulations, in evaluating product and manufacturing data to meet the requirements, and in supporting clients through the process.

Accredited Assessors are organizations approved by the Cradle to Cradle Products Innovation Institute to conduct third-party evaluations of products and their manufacturing processes. These organizations lead and manage the data collection and assessment process, guide manufacturers in meeting the certification requirements and submit the summary report to the Institute for approval.

With MBDC as your Accredited Assessor, you have the team that has the most extensive experience in the Cradle to Cradle Certified™ program to serve as your guide. We will:

- Provide an assigned project manager to provide guidance throughout the process
- Support in collecting and evaluating the necessary data to meet requirements
- Conduct assessments of the material health of each product ingredient or material
- Perform site visits at the manufacturing facilities of final assembly
- Develop recommendations to optimize products and improve certification level
- Create a final summary report submitted to you and the Institute

Investment in Certification

Investing in the Cradle to Cradle Certified™ program will provide tremendous value to your company and brand. Both pricing and timing for the certification process depend on complexity of the product, depth of the supply chain and the level of certification being pursued. Cost for MBDC's services can range from $1,700 for a Product Screen to $75,000+, for a complex industrial product. Length of the certification process may range from 2-6+ months.

INVENTORY + ASSESSMENT + OPTIMIZATION

MBDC has been providing material and product analysis, down to the parts per million, for over two decades. We are an internationally recognized authority on material health and product optimization.

In addition to providing Assessments for the Cradle to Cradle Certified™ Products Program, our services include:

Material Health Assessments
The MBDC Material Health Assessment (MHA) is based on the Material Assessment Methodology published as part of the Cradle to Cradle Certified™ Products Program. It goes beyond a simple supplier declaration of ingredients, to provide an in-depth, detailed report covering homogeneous materials inventoried to 100 parts per million and assessed for toxicity to human and environmental health. The report details the presence of hazardous materials; chemicals known to be carcinogens, mutagens or reproductive toxins; endocrine disruptors; and any incomplete data.

Product Screens
MBDC's product screens evaluate products for their potential for becoming Cradle to Cradle Certified™ and can provide valuable guidance in selecting and procuring materials from several potential suppliers for use in the built environment.

Product Optimization
MBDC will analyze the results of a product inventory and assessment and guide you to improve product design and manufacturing operations to minimize negative impacts, optimize positive impacts, and work towards being 100% good for people, planet, and profits.

For any new or existing product or packaging design, MBDC can help you rethink and redesign it using the Cradle to Cradle® Design Framework, select optimal materials, and plan for the future use cycles for the component materials.

CRADLE TO CRADLE® TRAINING

MBDC conducts inspiring, value-added, actionable workshops worldwide on applying the Cradle to Cradle® Design Framework and The Upcycle Chart to business audiences.

MBDC also facilitates hands-on design workshops where design teams work in groups to apply the Cradle to Cradle® design principles to real world product designs. The workshops can be tailored to suit your organization's needs. Corporate environmental and sustainability programs can be mapped using the proprietary Upcycle Chart to help identify additional value-added opportunities.

"The relationship forged with MBDC has been a potent catalyst for inspiration and innovation. Simply stated, the things we've learned as a result of our early relationship with [MBDC] have driven us to become a more sustainable, innovative, fit and relevant company. It has changed us, and continues to change us, profoundly and for the better." - STEELCASE

In the early 2000's, following a keynote speech given by William McDonough, MBDC hosted a Cradle to Cradle® workshop for the executives of Steelcase, Inc. Inspired by the concepts presented at these events, Steelcase invited a project manager from MBDC to join Steelcase's design team on the development of a new chair which would be a technical nutrient - designed to be easily disassembled with common hand tools and able to be returned for remanufacturing and endless reuse. The resulting product was the Think® chair, launched in 2004 as the first product to become Cradle to Cradle Certified™. Think became a global best-seller, and one of the company's most popular selling products.

Think® Chair Disassembled ©Steelcase, Inc.

MATERIAL HEALTH

MBDC launched in 1995, after William McDonough (an architect) and Dr. Michael Braungart (a chemist) worked together to design a compostable textile for Designtex, a Steelcase company. The manufacturer, Rohner Textil (now owned by Gessner AG), had been treating product scraps as hazardous waste due to the use of problematic and toxic dyes that were regulated in Switzerland.

In order to evaluate all ingredients for toxicity to human and environmental health, the team asked Rohner Textil's dye suppliers to share the full formulation of all dyes they'd been using. Ciba-Geigy was the only one to agree to share its proprietary formulations. Upon the analysis of hundreds of chemicals, 16 nontoxic dyes were selected for use in the new fabric line. The resulting compostable textile, Climatex® LifeCycle, uses only rapidly renewable, natural materials (wool and ramie) and nontoxic dyes. Instead of becoming hazardous waste, the scraps are now shredded into a felt-like sheet and sold to local farmers and gardeners as mulch.

EXECUTIVE VISION

VALUE MATERIALS AS NUTRIENTS FOR SAFE, CONTINUOUS CYCLING.

"Cradle to Cradle helps us to fulfill our corporate vision through a rigorous sustainability protocol, and enables us to create products that make buildings better."

Howard Williams,
Vice President & General Manager,
Construction Specialties

MANAGEMENT STRATEGY

Develop a plan to design products and optimize ingredients that are biological nutrients, which can be safely recovered and either reused or composted to improve soil health, or technical nutrients, which can be safely returned and reused in new products.

Assess the impacts of existing materials and processes to human and environmental health.

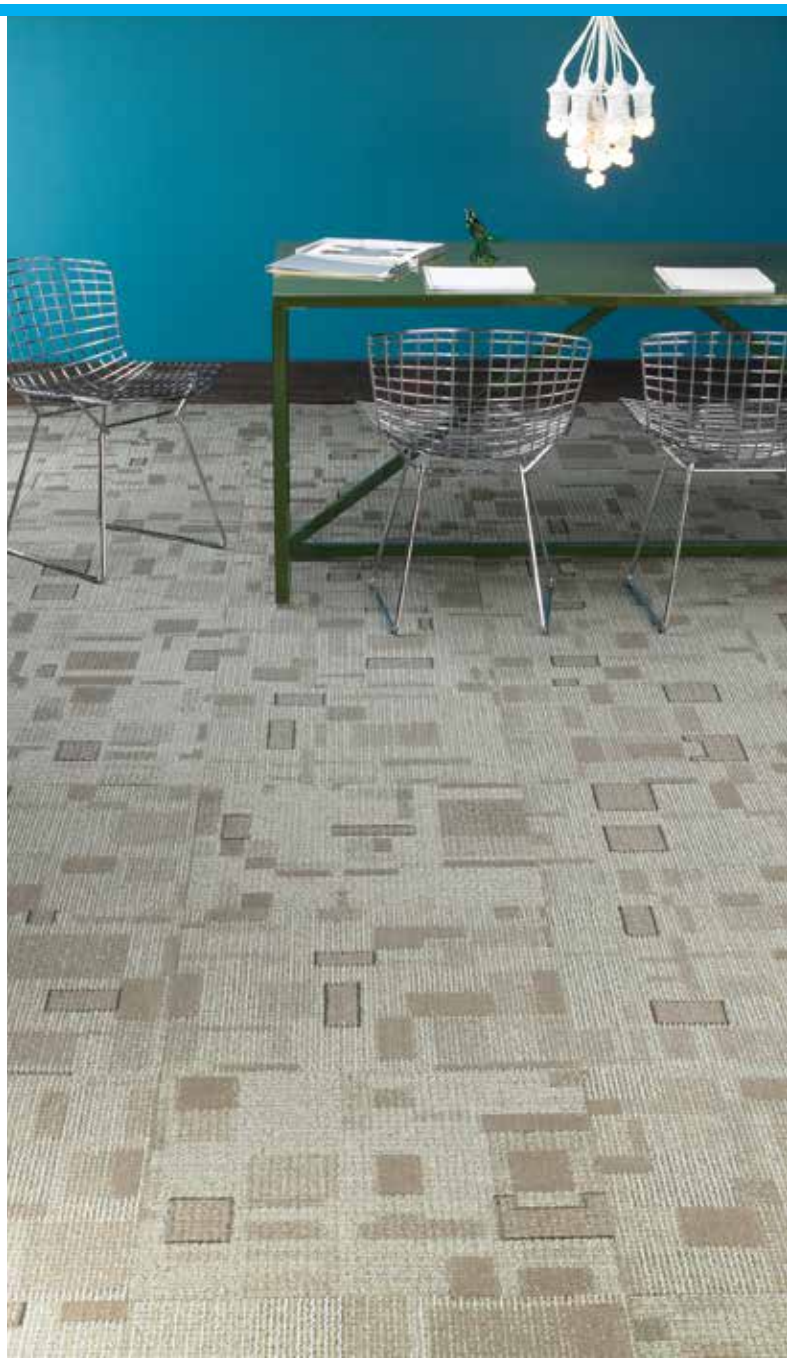
Identify ingredients to optimize and then work with suppliers to reformulate them.

Where hazardous ingredients cannot be replaced immediately, ensure they are safely managed while continuing to innovate for optimization.

MATERIAL REUTILIZATION

In 1995, MBDC worked with Shaw to apply the Cradle to Cradle® Design Framework in the design of the world's first PVC-free commercial carpet tiles that are separable into component materials and can be endlessly reused. Each tile is labeled with a toll-free number that customers can call to have used tiles picked up for recycling. Shaw worked with MBDC to assess the human and environmental health attributes of all ingredients and identify preferred substitutes.

William McDonough has collaborated with Shaw on the design of several Cradle to Cradle Certified™ flooring collections. *Essay of Clues*, inspired by William McDonough + Partners' architecture and planning work, was the first carpet to feature EcoWorx Broadloom backing. *A Walk in the Garden* features completely recyclable carpet tiles using EcoWorx and Eco Solution Q. In 2013, McDonough worked with Patcraft, a division of Shaw, to design another carpet tile collection, *Butterfly Effect*. Two percent of proceeds go directly to St. Jude Children's Research Hospital to help fund their life-saving treatments and ground breaking research in pediatric cancer.



EXECUTIVE VISION

MAINTAIN CONTINUOUS FLOWS OF BIOLOGICAL AND TECHNICAL NUTRIENTS.

"Nearly two decades ago, Shaw designed the world's first Cradle to Cradle Certified™ flooring product. Today, more than 60 percent of Shaw's sales are from Cradle to Cradle Certified™ products. As we work toward our goal to design all of our products to Cradle to Cradle® protocols by 2030, our company, our customers and our communities benefit from this rigorous, holistic approach."

Paul Murray, Vice President
Sustainability & Environmental Affairs,
Shaw Industries, Inc.,
a division of Berkshire Hathaway

MANAGEMENT STRATEGY

Create a plan to recover used products safely and continuously reuse materials as biological or technical nutrients.

Design products so that biological and technical nutrients can be easily disassembled and separated for recycling or composting.

Create and support systems to educate customers, recover products from them after the use phase is done, and safely direct the flow of all component materials for their next use.

RENEWABLE & CLEAN ENERGY

Companies in the office furniture industry—from early adopters Herman Miller and Steelcase to other brands such as Keilhauer—use the Cradle to Cradle® Design Framework to define and improve their sustainability footprint.

Herman Miller applied savings gained from energy efficiency measures towards renewable energy certificates and purchase agreements with energy generators to achieve 100% renewable energy for its worldwide operations. Steelcase purchases non-emitting renewable energy certificates equivalent to 100% of its global energy consumption—the first for a major commercial furniture company.

Mirra® Chair ©Herman Miller, Inc.

EXECUTIVE VISION

POWER ALL OPERATIONS WITH 100% CLEAN ENERGY.

"Our commitment to renewable energy is reflective of our passion for innovation and the environment. We're helping grow an industry that will ultimately benefit the entire world."
Jim Keane, President and CEO, Steelcase, Inc.

MANAGEMENT STRATEGY

Develop and implement a plan to transition into a renewably powered enterprise.

Collect data on the current mix of electricity sources and potential for generating clean energy on-site, nearby and/or remotely.

Identify cost effective clean energy programs to integrate with production and operations.

Monitor local and remote opportunities for using clean energy and begin implementing as soon as cost-effective.

Complete the shift to powering operations with 100% clean energy, as costs and infrastructure allow.

CLEAN WATER

DesignTex successfully eliminated hazardous ingredients from textile manufacturing and the effluent now sustains water quality rather than degrades it. Similarly, Method® uses the Cradle to Cradle® Design Framework to evaluate and optimize cleaning product ingredients to be as safe as possible for use in the home and in water systems. Method's laundry detergent (one of their 60+ Cradle to Cradle Certified™ formulations) is designed to contain significantly less water in the bottle (eco-efficiency) and is being optimized for human and environmental health (eco-effectiveness).

EXECUTIVE VISION

REGARD WATER AS A PRECIOUS RESOURCE.

"Obtaining external verification from MBDC, the people who wrote the book on Cradle to Cradle® design, reinforces the work we're doing to make our products safe for people and the environment, and it reflects our authentic mission of sustainability at a time when many companies talk about being green."

Adam Lowry,
Co-founder, Method

MANAGEMENT STRATEGY

Define a trajectory that signals and achieves a goal to optimize water quality.

Adopt a set of principles to guide efforts in protecting and enhancing water quality.

Conduct a water audit of facilities to characterize current water sources, discharges and impacts.

Implement process improvements to cleanse effluent water and/or reduce water consumption, and monitor performance over time.

Demonstrate water stewardship throughout facilities and products by achieving safe reuse flows, promoting healthy ecosystems and addressing local impacts.

SOCIAL FAIRNESS

IceStone has integrated the Cradle to Cradle® Design Framework into durable surface design and manufacturing operations to show leadership in social and environmental responsibility, promote green-collar jobs and support the green building industry. Within IceStone's repurposed and day-lit facility in Brooklyn, NY, 100% of wastewater is recycled and 50% of manufacturing energy is offset with renewable energy credits. IceStone believes that all employees are partners in the company who receive living wages, health benefits and job training. IceStone has completed a third-party social audit by Verite and is a founding Certified B Corporation.

EXECUTIVE VISION

CELEBRATE ALL PEOPLE AND NATURAL SYSTEMS.

"Identifying a third-party certification that considered all aspects of IceStone's operations was imperative. Any company can design products with recycled content and off-set their energy use with carbon credits, but the difference is how those companies treat their employees and the impact those companies have on the local and global community."

Dal LaMagna
CEO & CFO, IceStone

MANAGEMENT STRATEGY

Develop a process and timeline to realize your organization's social fairness vision.

Exceed and lead in the creation of standards for health, safety, ethical performance, and social fairness.

Engage stakeholders through open communication that integrates their creativity, ideas, and feedback.

Obtain third-party accreditation for social fairness practices.

Partner with surrounding communities, regions and interest groups.

Demonstrate leadership by honoring employees, customers, communities and ecosystems, and report publicly and transparently on your ongoing achievements and challenges.

DESIGN + CHEMISTRY + INNOVATION
WWW.MBDC.COM

CRADLE TO CRADLE CERTIFIED™

PRODUCT STANDARD

VERSION 3.1

PROGRAM ADMINISTERED BY

DOCUMENTS PREPARED BY:

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

THE *CRADLE TO CRADLE CERTIFIED* STANDARD REVISION HISTORY

REVISION	SECTION	TYPE OF CHANGE	DATE	AUTHORIZED BY
3.0	Initial Release		11/2012	MBDC & C2CPII
3.1	3	The cyclability assessment has been removed from the Material Health Assessment Methodology.	12/2014	C2CPII Certification Standards Board
3.1	4	The requirement that only A, B, and C assessed materials may count as recyclable or compostable in the Material Reutilization Score has been removed (i.e., X and GREY assessed materials may now count as recyclable or compostable when calculating the Material Reutilization Score).	12/2014	C2CPII Certification Standards Board
3.1	all	The information from both the Cradle to Cradle Certified Product Standard, Version 3.0 and its associated guidance document, Supplemental Guidance for the Cradle to Cradle Certified Product Standard, Version 3.0, has been consolidated into this document. Tables and passages that contained information that was available elsewhere in a more accessible or up-to-date form have been removed. The original intent has been further clarified; inconsistencies and typos that were contained in Version 3.0 have been corrected throughout.	1/2016	C2CPII
3.1	3	Information previously covered in both the Cradle to Cradle Certified Product Standard, Version 3.0 and Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.0 has been removed so that it is only present in the Assessment Methodology document.	1/2016	C2CPII

FOREWORD

Document Purpose
This version of the Cradle to Cradle Certified™ Product Standard (Version 3.1) represents a minor revision of Version 3.0.

In December 2014 the Cradle to Cradle Products Innovation Institute's Certification Standards Board approved the development of version 3.1 of the Cradle to Cradle Certified Product Standard. The main purpose of developing version 3.1 was to remove the overlap in the Material Health and Material Reutilization categories that was introduced in version 3.0 of the standard. These requirements were added to version 3.0 to discourage the re-use of materials that contain harmful substances; however, in practice this resulted in unforeseen problems that ran counter to the intent of the standard and the continuous improvement goal of Cradle to Cradle in general. The Institute and the Certification Standards Board felt it was important to address these issues immediately in a revised version of the standard. Further, a number of minor modifications were made to reduce redundancy and enhance clarity of the standard (see '*The Cradle to Cradle Certified Standard Revision History'* above).

The Cradle to Cradle Products Innovation Institute (C2CPII)
The Cradle to Cradle Products Innovation Institute administers the Cradle to Cradle Certified Products Program. The Certification Standards Board, using the Cradle to Cradle framework, is responsible for reviewing and approving revisions and/or amendments to the Cradle to Cradle Certified Product Standard and ensuring continuous improvement of products based upon five categories: material health, material reutilization, renewable energy and carbon management, water stewardship, and social fairness. Products that meet the criteria of this rating system will receive the Cradle to Cradle Certified certification mark for one of five levels. (http://c2ccertified.org)

MBDC, LLC
MBDC originated the Cradle to Cradle design framework and has 20 years of experience helping clients go beyond minimizing harm and move towards creating a wholly positive impact on the planet. MBDC partners with innovative clients within various sectors and industries to spur creativity, differentiate their brands and recognize their market leadership, attract and retain customers, enhance competitive advantage, and reduce long-term risks. MBDC leads companies towards sustainable growth by helping clients optimize corporate strategy, communications, operations, supply chains, and product designs. MBDC is an Accredited Assessment Body in the Cradle to Cradle Certified Products Program. (http://mbdc.com)

Environmental Protection Encouragement Agency, GmbH
Founded by Professor Dr. Michael Braungart in 1987, the Environmental Protection Encouragement Agency (EPEA) Internationale Umweltforschung GmbH works with clients worldwide to apply the Cradle to Cradle methodology to the design of new processes, products, and services. Materials are applied with respect for their intrinsic value and their useful afterlife in recycled or even "upcycled" products, which have value and technological sophistication that may be higher than that of their original use. EPEA is an Accredited Assessment Body in the Cradle to Cradle Certified Products Program. (http://epea-hamburg.org)

Together, we take on the challenge of scientifically evaluating and innovatively designing products according to a unique design practice.

SUPPORTING DOCUMENTS

The following documents are to be used in conjunction with the Cradle to Cradle Certified Product Standard:

- *Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.1 or Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.0* and *Supplemental Guidance for the Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.0.*
- *Cradle to Cradle Certified Policies and Procedures.*

All supporting documents can be downloaded from the Cradle to Cradle Products Innovation Institute website (http://c2ccertified.org).

1 INTRODUCTION TO CRADLE TO CRADLE®

Cradle to Cradle was developed by William McDonough and Michael Braungart, two pioneers merging intentional design, chemistry, and products for industry. Originally used loosely as a term with different meanings as contraindication to "cradle to grave,"[1] Cradle to Cradle is a beneficial design approach integrating multiple attributes: safe materials, continuous reclamation and re-use of materials, clean water, renewable energy, and social fairness.

William McDonough began his career as an architect in New York pioneering approaches to building design and concepts—such as *"a building like a tree, a city like a forest"*—which became foundational to the green building movement. His projects included building the first green office in New York for the Environmental Defense Fund in 1984, design of a solar-powered daycare center operated by children (1989), and a strategy for carbon balance and offset that garnered front-page coverage in the *Wall Street Journal* three years before the 1992 Rio Earth Summit. He was a founding member of the American Institute of Architects Committee on the Environment (COTE) and a charter member of the United States Green Building Council (USGBC).

Michael Braungart formed the Environmental Protection and Encouragement Agency (EPEA) Internationale Umweltforschung GmbH[2] in 1987, and soon afterward launched the Intelligent Products System (IPS), which defined materials as nutrients with the unique characterization that such materials could be continually reused in biological and technical cycles. The IPS was based on the European precautionary principle and brought a new perspective: that materials can be seen as key parts of technical and biological metabolisms.

McDonough and Braungart met in 1991 and began to share ideas. Together they merged the concept of materials as nutrients within biological and technical cycles with the concept of intentional design. This would later become the Cradle to Cradle design framework, which is the practical approach to product design in which all materials are biological and technical nutrients with coherent use periods and reverse logistics, renewable power, safe water, and social fairness.

In 1991, William McDonough was commissioned by the City of Hannover, Germany, at the suggestion of Dr. Michael Braungart, to craft sustainable design principles for Expo 2000, The World's Fair. *The Hannover Principles: Design for Sustainability*[3] were received and honored by Jaime Lerner, mayor of Curitiba, at the World Urban Forum of the Rio Earth Summit (UNCED) in 1992. They were delivered as a gift from the state of Lower Saxony by McDonough, who attended as the Official Representative for Architecture and City Planning for the International Union of Architects and the American Institute of Architects (dual role). In 1995, McDonough and Braungart co-founded McDonough Braungart Design Chemistry, LLC (MBDC).[4]

The Atlantic magazine published an article by McDonough and Braungart entitled "The Next Industrial Revolution"[5] in October 1998. This article chronicled the rise of *"eco-efficiency"* (doing more with less) as the main environmental strategy of many leading businesses and introduced the idea of *"eco-effectiveness"* to determine the right thing to do before doing it efficiently. In this article the terms

"downcycling" and *"upcycling"* were used to show how, by design, we can return product materials with improved, rather than degraded, quality over time.

By 2001 several case studies on the integration of the Cradle to Cradle design principles in product design by leading businesses were made available in video and DVD form by Earthome Productions.[6] Included in this compilation were stories from Designtex (Steelcase), Herman Miller, Ford, and Nike. In 2002, the book *Cradle to Cradle: Remaking The Way We Make Things* was published.[7]

MBDC launched the Cradle to Cradle Certified™ Program[8] in October 2005. As the program grew worldwide, the desire for an independent certification body was identified to bring the program into the public sphere. In August 2010 an exclusive, worldwide license was granted to the Cradle to Cradle Products Innovation Institute[9] as a third party not-for-profit organization to manage the certification program.

1.1 WHAT IS CRADLE TO CRADLE® DESIGN?

The Cradle to Cradle design principles provide a positive agenda for continuous innovation around the economic, environmental, and social issues of human design and use of products and services. Specifically, the purpose of the product certification program is to improve the way we make, use, and re-use things recognizing two metabolisms, the *biological metabolism* and the *technical metabolism,* with a goal to leave a beneficial footprint for human society and the environment.

The aim is to set a positive course for product and process design and development in a way that will allow natural and technical systems, products, and processes to support the diverse living population on earth. Cradle to Cradle design mirrors the healthy, regenerative productivity of nature, and considers materials as assets, not liabilities.

Management theorist Peter Drucker has said that it is a manager's job to do something the right way—to be efficient—but it is an executive's job to do the right thing—to be effective. To date, global efforts by businesses have been focused on becoming more efficient and reducing the (bad) environmental "footprint" by optimizing existing systems, which may be wrong designs. Cradle to Cradle design is about choosing the right thing to do and then doing that thing the right way to achieve positive outcomes. In other words, to become *"more good,"* not just *"less bad."*

For example, while it makes sense to slow down the use of fossil fuels, this is not the goal. Cradle to Cradle is a continuous improvement process design tool that starts with the positive or beneficial end in mind and executes efficiently towards achieving this goal. In this example the Cradle to Cradle goal is a move to renewable energy sources.

Long-Term Goals, Short-Term Actions, and Transitions

We start by defining long-term Cradle to Cradle goals and then develop transitional strategies to achieve them. In the short term, we can make successive design-based decisions that will move us to a more sustaining condition. The short-term actions for product development start with complete identification of the materials and chemicals that make up the product and process in order to assess them for human and ecological impacts.

In the medium term the goal is for designs that are positive or beneficial in terms of cost, performance, aesthetics, material health, and material (re)utilization potential with continuous use and reuse periods. Additionally, moving renewable energy forward in a cost-effective way, celebrating clean water as a human right, and honoring social systems are part of the holistic Cradle to Cradle approach.

The long-term goals can be wholly positive and intended to support 10 billion people and other species. For example, McDonough and Braungart's long-term goal is:

> "*Our goal is a delightfully diverse, safe, healthy and just world, with clean air, water, soil and power - economically, equitably, ecologically and elegantly enjoyed.*"

Cradle to Cradle provides a unique frame of thinking that is based on the precautionary principle and trust in the product supply chain. This is not a framework based on guilt or intended as an opportunity for taking legal actions. Rather it is the basis for building up a support system.

We work with humility and recognize that checking single chemicals in materials and products does not give the complete picture and that there may be unintended consequences, but it is a good start. In focusing attention on chemicals it is not our intention to promote more animal testing. If a chemical bio-accumulates we would rather see alternatives substituted.

The question becomes one of design intention and we can ask, "What type of products do we want to see?" Chemists become designers and designers become chemists. As humans, we accept the limitations of our knowledge and we will make mistakes, but these mistakes need to be reversible by future generations.

The product certification program is a QUALITY statement using QUANTITY indicators. Each level represents a higher quality indicator using multiple attributes. Today the program is primarily oriented from a Western cultural perspective. Longer term, the program is expected to evolve and quality indicators respecting and celebrating cultural diversity are anticipated.

1.2 THE CRADLE TO CRADLE® PRINCIPLES

In nature, there is no concept of waste. Everything is effectively food for another organism or system. Materials are reutilized in safe cycles. There are no persistent, bio-accumulative materials that can lead to irreversible changes. The earth accrues biota grown from the energy of the sun. We celebrate the diversity of people and of species. We become native to place, celebrating abundance and honoring every child that is born. In short, the design of goods and provision of services can be achieved with three principles in mind:

1. Eliminate the Concept of Waste

- Nutrients become nutrients again. All materials are seen as potential nutrients in one of two cycles – technical and biological cycles.
- Design materials and products that are effectively "food" for other systems. This means designing materials and products to be used over and over in either technical or biological systems.
- Design materials and products that are safe. Design materials and products whose nutrient management system leaves a beneficial legacy economically, environmentally, and equitably.
- Create and participate in systems to collect and recover the value of these materials and products. This is especially important for the effective management of scarce materials.
- Clean water is vital for humans and all other organisms. Manage influent and effluent water streams responsibly, and consider local impacts of water use to promote healthy watersheds and ecosystems.
- Carbon dioxide (CO_2) should be sequestered in soil. Our current practice where carbon dioxide ends up in the oceans and in the atmosphere is a mismanagement of a material.

2. Use Renewable Energy

- The quality of energy matters. Energy from renewable sources is paramount to effective design.
- Aligning with Green-e's list of eligible sources, renewable energy sources are solar, wind, hydropower, biomass (when not in competition with food supplies), geothermal, and hydrogen fuel cells.

3. Celebrate Diversity

- Use social fairness to guide a company's operations and stakeholder relationships.
- Encourage staff participation in creative design and research projects to enhance your Cradle to Cradle story.
- Technological diversity is key for innovation; explore different options in looking for creative solutions.
- Support local biodiversity to help your local ecosystem flourish; strive to have a beneficial social, cultural, and ecological footprint.

Under the Cradle to Cradle design approach, products that result in materials flowing into the biosphere (either from the product contents or the packaging) are considered to be "products of consumption." Materials that are recovered after use can be considered to be "products of service." (Note: some materials such as paper or bio-plastics are products of consumption as they ultimately return to the biosphere after a number of post-use cycles.)

1.3 COMPLEMENTARY METABOLISMS

The Cradle to Cradle Certified™ Program focuses on the characteristics of sustainable materials, products, and systems. As a result, this method places a major emphasis on the human and ecological health impacts of a product's ingredients at the chemical level, as well as on the ability of that product to be truly recycled or safely composted. The quality of energy used to create a product, water

quantity and quality, and social fairness also are essential Cradle to Cradle characteristics and focus areas in this certification process.

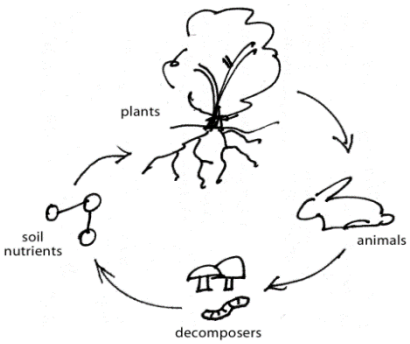
Cradle to Cradle design draws on knowledge from the fields of environmental chemistry and material flows management (broadly termed Industrial Ecology), and the fields of industrial and architectural design. It includes the *Intelligent Product System* (IPS) pioneered by chemist Dr. Michael Braungart in 1986.

Cradle to Cradle is an innovative approach that models human industry on the processes of nature's *biological nutrient metabolism* integrated with an equally effective *technical nutrient metabolism*, in which the materials of human industry safely and productively flow within the two metabolisms in a fully characterized and fully assessed way. Products that are designed as services are made from materials that cycle in the technical metabolism at the end of their use cycle. Consumption products, those that naturally end up in the environment (biological cycle) during or post-use, are made from materials that are inherently safe for the biosphere.

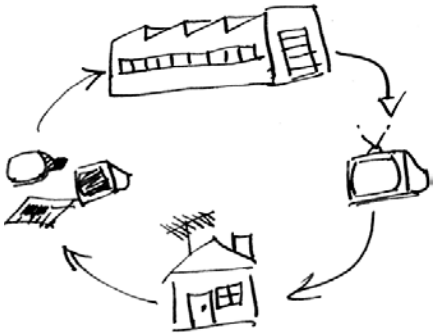
Nature's metabolism runs on renewable energy and returns all materials safely in cycles for reuse. Everything can be considered a nutrient with future value. All of our man-made designs exist in this metabolism and many products will result in the nutrients connecting with, and flowing directly into, this system during and after use. These materials need to meet a standard for "biological nutrients" with the highest level of safety designed in.

Products that have achieved positive design milestones along the continuum of improvement are shown to be suitable for cycling perpetually on Earth, using ingredients that are safe and beneficial – either to biodegrade naturally and restore the soil, or to be fully recycled into high-quality materials for subsequent product generations, again and again. This allows a company to eliminate the concept of waste and recover value, rather than creating a future of solid waste liability. Cradle to Cradle design turns contingent liabilities into assets.

Figure 1 Depiction of Biological and Technological Nutrient Cycles



Biological Nutrients



Technical Nutrients

1.3.1 Effective Material Cycles

Products of Consumption

A product of consumption is a material or product that is typically changed biologically, chemically, or physically during use and therefore enters the biosphere either by nature or by human intention. As a result, products of consumption should consist of biological nutrient materials.

Biological cycle materials and products need to be designed for safe combustion without the need for filters. Biological cycle products such as paper or bio-plastics may go through a series of technical cycles (e.g., recycling) before finally going safely into biological systems (e.g., composting or incineration for energy recovery).

A biological nutrient product is usable by defined living organisms to carry on life processes such as growth, cell division, synthesis of carbohydrates, energy management, and other complex functions. Any material emanating from a product of consumption that comes into intentional or likely unintentional and uncontrolled contact with biological systems is assessed for its capacity to support their metabolism. Metabolic pathways consist of oxidation, catabolism (degradation, decrease in complexity), and anabolism (construction, increase in complexity), both occurring generally in a coupled manner. The classification of products as biological nutrients (or source of nutrients) depends on the biological systems with which they interact. These systems can be more or less complex along the following organizational hierarchy:

- Organisms (nutrients for predators).
- Organic macromolecules and combinations thereof (nutrients for fungi, microorganisms, vegetarian animals; oral, dermal or olfactory nutrients).
- Minerals (nutrients for autotrophic plants).

For example, a detergent that is comprised of readily biodegradable materials could be designed such that the material or its breakdown products provide nutrition for living systems. Products like tires and brake shoes that abrade in use are also products of consumption, but have yet to be designed with biological nutrient materials.

Products of Service

A product of service is a material or product designed to provide a service to the user without conveying ownership of the materials. Products of service are ideally comprised of technical nutrients that are recovered at the end-of-use phase.

Technical nutrients (TNs) are products or materials that "feed" technical systems. While they may or may not be suitable to return to air, soil, or water, technical nutrients are never consumed but instead are catabolized (deconstructed) and anabolized (constructed) according to the following hierarchy:

- (Dismantle and) reuse.
- (Dismantle and) physical transformation (e.g., plastic remolding).
- (Dismantle and) chemical transformation (e.g., plastic depolymerization, pyrolysis, gasification).

Technical nutrients can therefore be managed with service contracts or leasing models so that users benefit from the product service without owning the materials. In the case of scarce materials, it is

especially important to use them in products of service so that they remain available over the long term as useful materials.

Externally Managed Components (EMCs)

An EMC is a sub-assembly, component, or material within a product that is exempt from the general requirement of full characterization to the 100 ppm level because it is managed in a technical nutrient cycle as part of a supplier or manufacturer commercialized nutrient management program.

To be considered an EMC, the sub-assembly, component, or material within a product must meet the following criteria:

1. The supplier of the EMC has provided the applicant with a guarantee for take back and appropriate nutrient management. The supplier may designate a third party or parties for implementation.
2. The supplier has signed a declaration that chemicals in the EMC will not negatively impact humans or the natural environment during the intended and unintended but highly likely use of the product for which the EMC is a component. This guarantee may be provided if the EMC is Cradle to Cradle Certified (Gold level or higher), or other appropriate evidence.
3. The EMC has undergone testing by an accredited analytical laboratory to ensure that harmful substances are not being emitted from the EMC above the chemicals' analytical detection limits. Off-gas testing is required for all EMCs (See Section 3.9 for more information on volatile organic compounds [VOCs] emission testing). Migration and leaching testing may be required depending on the type of EMC.

Note that EMCs are not exempt from banned list declarations. Also note that if during use of the product for which the EMC is a component a user is exposed to any part or chemical within the component, or if any part or chemical within the component is released to the environment, the component is not considered an EMC and will be assessed and inventoried like the other materials in the product.

EMCs were introduced in version 3.0 of the Cradle to Cradle Certified Product Standard as a way to include product components that do not need to be assessed the same way as the rest of a product because they are managed as a whole by the supplier or a third party. The EMC concept was invented by the founders of the Cradle to Cradle® framework to encourage manufacturers to design complex components that are completely managed after their use phase. As of the release date of version 3.0 of this Standard, an EMC had not yet been included in a Cradle to Cradle Certified product. Examples of potential EMCs are a pneumatic cylinder in an office chair, the motherboard in a computer, the electric motor inside an automated window shade product, and a solar panel.

2 OVERVIEW OF THE STANDARD

2.1 PRODUCT SCOPE

This certification program applies to materials, sub-assemblies, and finished products. Materials and sub-assemblies can be considered "products" for certification purposes.

This program does not address performance measures associated with any products that qualify for the Cradle to Cradle Certified™ Products Program. Product compliance with all applicable laws and regulations is assumed. Some rules in the program address activities that are also subject to regulation by local, state, or federal authorities. However, nothing contained herein changes legal regulatory requirements or prescribes how compliance is to be achieved. Documentation of compliance with certain key regulations may be included in some sections of the Standard, but this in no way changes the underlying regulatory requirements.

There are a number of product attributes that may exclude a manufacturer from seeking certification. The following list depicts some cases and issues that are out of the scope of this program. The purpose of this list is to create a threshold to prevent unreasonable products from entering the system and to protect the positive values around products, as well as their usefulness. The scope of the program does not include the following:

- The presence of any chemicals from the Cradle to Cradle Certified "Banned List" (See Appendix for lists).
- Processes in and of themselves.
- Food, beverages, pharmaceuticals, or fuels and other products intended for combustion during use.
- Buildings, countries, cities.
- Products from rare or endangered species (e.g., ivory).
- Products with ethical issues (e.g., weapons, tobacco, electric chair, etc.).
- Products leading to or including animal abuse.
- Products with apparent safety concerns related to physical and chemical characteristics.
- Products from companies involved in rain forest damage, child labor, blood metals, or blood diamonds.
- Applicant involved in terror support or racism/discrimination.
- Nuclear power and/or products used to produce nuclear power.
- Products that may be contrary to the intent of the Cradle to Cradle principles.

Product Packaging

Packaging material may be certified as a separate product or may be considered part of a product and thus included in the product certification. However, though it is encouraged, the packaging material is not required to be included in the product assessment. If the packaging material was included in the

assessment, the achievement level assigned to the packaging is provided on the product's certificate and in the entry in the Product Registry (http://c2ccertified.org/products/registry). If the certificate and the entry in the Product Registry do not address packaging, then the packaging is not included in the certification. Note that when packaging materials are included in the assessment, only the requirements in the Material Health and Material Reutilization categories are addressed.

Though not required to be included in the product assessment, materials in the product's primary packaging are subject to the same banned list requirements as the materials in the product and thus may not contain chemicals on the banned lists (see definition of 'primary packaging' below). Signed declarations stating that banned list chemicals have not been intentionally added at concentrations >0.1% (>1000 ppm) must be obtained for each homogeneous material used in the primary packaging, including inks, adhesives, and any materials used to label the package. Banned list declarations may be obtained from the supplier, the product manufacturer, or the assessor (see Section 3.3 of this document for more information). For primary packaging made from recycled materials, analytical testing for banned list chemicals may be required if all of the material ingredients cannot be defined with current information.

Primary packaging refers to the container that envelops a liquid, gel, paste, or powder and is intended to be kept with the product during its use or up until the moment of application (e.g., surface cleaner spray bottle, paint can, dishwasher powder box, nail polish bottle, wet-wipe pouch/packet/tub). Any materials that are intended to be removed prior to the product's use are not considered primary packaging (e.g. pallet, shrink wrap, carton). All materials meeting this definition are considered part of the primary packaging, including inks, adhesives and any materials used to label the package. Primary packaging is not in scope for products that are sold exclusively as material inputs for other products (rather than being sold to the general public).

2.2 STANDARD CATEGORIES AND THEIR SCOPE

Products seeking to be Cradle to Cradle Certified™ are evaluated against criteria in the following five categories:

Material Health – The ultimate goal is for all products to be manufactured using only those materials that have been optimized and do not contain any X or Grey assessed materials/chemicals. As such, products are able to achieve increasingly higher levels of certification as the percentage of assessed and optimized materials in the finished product increases.

The boundaries of review are drawn at the product leaving the direct production facility. The process chemicals associated with the production of certain inputs are included, where applicable (e.g., textiles, plated parts, paper, foam).

Material Reutilization – A key component of Cradle to Cradle design is the concept of technical nutrients and biological nutrients flowing perpetually in their respective metabolisms. Products are evaluated for their nutrient potential and nutrient actualization, as well as the role the manufacturer plays in material/nutrient recovery.

The intention of this category is to provide a quantitative measure of a product's design for recyclability and/or compostability. The larger the percentage of a product and/or its components that remain in a technical and/or biological metabolism, the better the score for this category.

Renewable Energy and Carbon Management – Cradle to Cradle products are manufactured in a way that positively impacts our energy supply, ecosystem balance, community, and ultimately strives to keep carbon in soil and earth vegetation where it belongs.

The intention of this category is to provide a quantitative measure of the percentage of renewably generated energy that is utilized in the manufacture of the product. Purchased electricity and direct on-site emissions associated with the final manufacturing stage of the product, as well as embodied energy associated with the product from Cradle to Gate, are considered, depending on the level of certification.

Water Stewardship – Water is a scarce and valuable resource. Product manufacturers are evaluated against their understanding of (and responsibility for) water withdrawals, consumption, and releases within the local ecology, and are rewarded for innovation in the areas of conservation and quality of discharge.

The intention of this category is to provide a quantitative and qualitative measure of water usage and water effluent related directly to the manufacture of the certified product.

Social Fairness – Cradle to Cradle product manufacturers strive to ensure that progress is made towards sustaining business operations that protect the value chain and contribute to all stakeholder interests, including employees, customers, community members, and the environment.

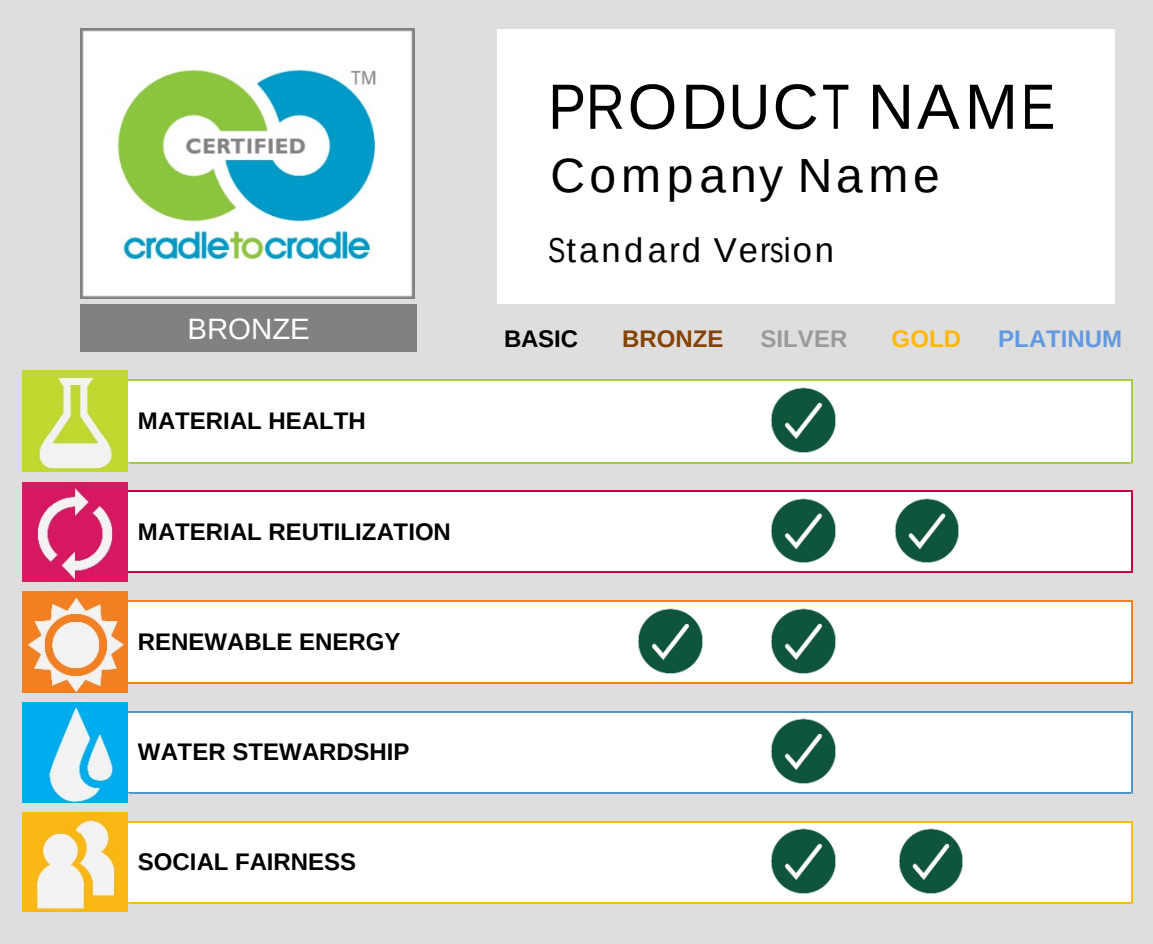
The intention of this category is to provide a qualitative measure of the impact a product's manufacture has on people and communities, and it includes some measures of general environmental impacts. Requirements apply to the facility or facilities where the final product is manufactured unless otherwise noted.

2.3 CERTIFICATION LEVELS

Because this program is not based on the binary, pass/fail model, but instead incorporates the concept of continuous improvement, the certification results are split into a **5-Level System of Basic, Bronze, Silver, Gold, and Platinum**. The minimum level of achievement in any of the five categories ultimately determines the final certification level.

When products qualify for certification, the manufacturer will receive a certificate and a scorecard that can be used to educate consumers on the level of achievement attained in all five categories. In addition, the product and its related certification level and scorecard will be listed on the Cradle to Cradle Products Innovation Institute's website (http://c2ccertified.org). An example scorecard is shown in Table 1.

Table 1 Example Product Scorecard



Publication of Product Scorecard

Publication of the product scorecard on the Certified Products Registry or in a company's marketing material is encouraged, but not required. Manufacturers can opt out of having their full scorecard published on the Certified Products Registry along with their overall level of certification.

Basic Level Is A Provisional Certification

At the Basic level, a product is just starting out on the path to certification. A company must conduct a rudimentary inventory of materials used to make the product, energy use, water stewardship, and social fairness issues affecting their industry and production region. The Basic level of certification has been designed to recognize a company's intent to improve the way their product is made, establishing a commitment to ongoing assessment and optimization.

As such, the Version 3.1 Basic level certification is a 'provisional' certification. A product may be certified only once at this level, and must re-certify at a higher level once the two year certification has expired or be delisted from the program. In addition, products certified at the Basic level under Version 3.1 may not use the certification mark on their product, but may refer to it in web and print marketing materials.

2.4 SUMMARY OF STANDARD REQUIREMENTS

Table 2 lists the Standard requirements for each of the five categories by certification level.

Table 2 Cradle to Cradle Certified™ Product Standard, Version 3.1

1. MATERIAL HEALTH	Basic	Bronze	Silver	Gold	Platinum
No Banned List chemicals are present above thresholds.	●	●	●	●	●
Materials defined as biological or technical nutrients.	●	●	●	●	●
100% "characterized" (i.e., all generic materials listed).	●	●	●	●	●
Strategy developed to optimize all remaining x-assessed chemicals.		●	●	●	●
At least 75% assessed by weight (Complete formulation information collected for 100% of BN materials that are released directly into the biosphere as a part of their intended use).		●	●	●	●
At least 95% assessed by weight (Complete formulation information collected for 100% of BN materials that are released directly into the biosphere as a part of their intended use).			●	●	●
Assessed materials do not contain carcinogenic, mutagenic, or reproductively toxic (CMR) chemicals in a form that may result in plausible exposure.			●	●	●
100% assessed by weight.				●	●
Formulation optimized (i.e., all x-assessed chemicals replaced or phased out).				●	●
Meets Cradle to Cradle VOC emission standards where relevant.				●	●
All process chemicals assessed and no x-assessed chemicals present.					●
2. MATERIAL REUTILIZATION	**Basic**	**Bronze**	**Silver**	**Gold**	**Platinum**
Defined the appropriate cycle (i.e., technical or biological) for the product.	●	●	●	●	●
Designed or manufactured for the technical or biological cycle and has a material (re)utilization score ≥ 35.		●	●	●	●
Designed or manufactured for the technical or biological cycle and has a			●	●	●

material (re)utilization score ≥ 50.					
Designed or manufactured for the technical or biological cycle and has a material (re)utilization score ≥ 65.				●	●
Well-defined nutrient management strategy (including scope, timeline, and budget) for developing the logistics and recovery systems for this class of product or material.				●	●
Designed or manufactured for the technical or biological cycle and has a material (re)utilization score of 100.					●
The product is actively being recovered and cycled in a technical or biological metabolism.					●
3. RENEWABLE ENERGY AND CARBON MANAGEMENT	**Basic**	**Bronze**	**Silver**	**Gold**	**Platinum**
Purchased electricity and direct on-site emissions associated with the final manufacturing stage of the product are quantified.	●	●	●	●	●
A renewable energy use and carbon management strategy is developed.		●	●	●	●
For the final manufacturing stage of the product, 5% of purchased electricity is renewably sourced or offset with renewable energy projects, and 5% of direct on-site emissions are offset.			●	●	●
For the final manufacturing stage of the product, 50% of purchased electricity is renewably sourced or offset with renewable energy projects, and 50% of direct on-site emissions are offset.				●	●
For the final manufacturing stage of the product, >100% of purchased electricity is renewably sourced or offset with renewable energy projects, and >100% of direct on-site emissions are offset.					●
The embodied energy associated with the product from Cradle to Gate is characterized and quantified, and a strategy to optimize is developed.					●
≥ 5% of the embodied energy associated with the product from Cradle to Gate is covered by offsets or otherwise addressed (e.g., through projects with suppliers, product re-					●

design, savings during the use phase, etc.).					
4. WATER STEWARDSHIP	**Basic**	**Bronze**	**Silver**	**Gold**	**Platinum**
The manufacturer has not received a significant violation of their discharge permit related to their product within the last two years.	●	●	●	●	●
Local- and business-specific water-related issues are characterized (e.g., the manufacturer will determine if water scarcity is an issue and/or if sensitive ecosystems are at risk due to direct operations).	●	●	●	●	●
A statement of water stewardship intentions describing what action is being taken for mitigating identified problems and concerns is provided.	●	●	●	●	●
A facility-wide water audit is completed.		●	●	●	●
Product-related process chemicals in effluent are characterized and assessed (required for facilities with product-relevant effluent). OR Supply chain-relevant water issues for at least 20% of Tier 1 suppliers are characterized and a positive impact strategy is developed (required for facilities with no product-relevant effluent).			●	●	●
Product-related process chemicals in effluent are optimized (effluents identified as problematic are kept flowing in systems of nutrient recovery; effluents leaving facility do not contain chemicals assessed as problematic) (required for facilities with product-relevant effluent). OR Demonstrated progress against the strategy developed for the Silver-level requirements (required for facilities with no product-relevant effluent).				●	●

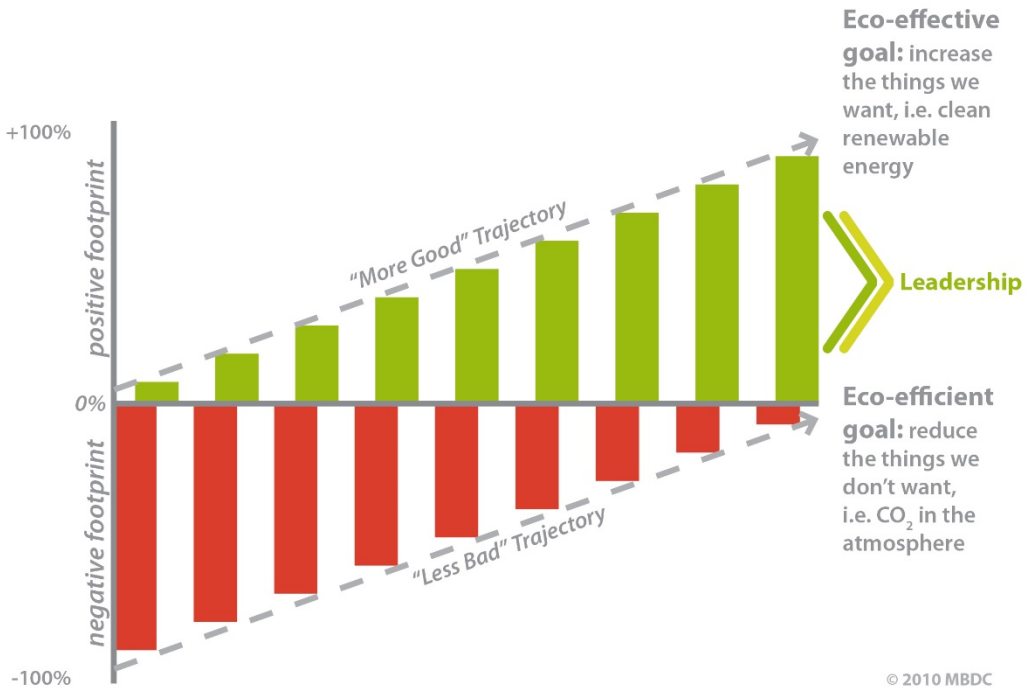
All water leaving the manufacturing facility meets drinking water quality standards.					●
5. SOCIAL FAIRNESS	**Basic**	**Bronze**	**Silver**	**Gold**	**Platinum**
A streamlined self-audit is conducted to assess protection of fundamental human rights.	●	●	●	●	●
Management procedures aiming to address any identified issues have been provided.	●	●	●	●	●
A full social responsibility self-audit is complete and a positive impact strategy is developed (based on UN Global Compact Tool or B-Corp).		●	●	●	●
Material-specific and/or issue-related audit or certification relevant to a minimum of 25% of the product material by weight is complete (FSC Certified, Fair Trade, etc.). OR Supply chain-relevant social issues are fully investigated and a positive impact strategy is developed. OR The company is actively conducting an innovative social project that positively impacts employees' lives, the local community, global community, or social aspects of the product's supply chain or recycling/reuse.			●	●	●
Two of the Silver-level requirements are complete.				●	●
All three Silver-level requirements are complete.					●
A facility-level audit is completed by a third party against an internationally recognized social responsibility program (e.g., SA8000 standard or B-Corp).					●

2.5 CONTINUOUS IMPROVEMENT AND OPTIMIZATION

It is expected that certification holders will make a good faith effort toward optimization in all five categories. Program conformance requires that all applicants outline their intention for the eventual phase-out/replacement of problematic substances (i.e., those materials or chemicals with X ratings) as part of certification. The plan constructed is meant to lay the foundation for prioritizing the phase-out of problematic product inputs in order to move along the Cradle to Cradle® continuum. The Accredited Assessor will help gauge whether significant progress has been made on the optimization of x-assessed substances to maintain or improve the certification level.

The continuous improvement chart shown in
Figure 2 clearly shows how the goal is not "zero" but instead to combine the progressive reduction of "bad" with the increase in "good" to reach a beneficial Cradle to Cradle goal.

Figure 2 Continuous Improvement Chart



2.6 CERTIFICATION MARKS

Companies receiving certification will have the opportunity to license the Cradle to Cradle Certified™ Marks. This Mark signifies to the global marketplace that the company has chosen a positive path toward using chemicals, materials, and processes for production that are healthy and fit in perpetual use cycles.

The Certification Mark(s) may only be used under license and in direct association with the certified product or that product's marketing materials. The Certification Mark(s) depicted below may be printed on the product with the exception of products certified at the Basic level. Because product

certification at the Basic level is a two-year provisional certification, the Certification Mark for Basic may not be used on the products. In general, the certification mark may not be used as a general-purpose mark associated with the company and its products. A style guide is available to demonstrate correct usage.

Figure 3 Cradle to Cradle Certified™ Marks

2.7 CERTIFICATION CYCLE AND RECERTIFICATION REQUIREMENT

Each product certification is valid for two years under Version 3.1 of the Standard. Certification holders must renew each certification prior to its expiration date to maintain Cradle to Cradle Certified™ product status. As part of the recertification process, certification holders must work with an accredited assessor to submit an updated assessment summary, which reports a good faith effort towards continually improving the product in accordance with Cradle to Cradle principles.

3 MATERIAL HEALTH

Safe and Healthy Materials

The review for Material Health generates material assessment ratings based on the hazards of chemicals in products and their relative routes of exposure during the intended (and highly likely unintended) use and end-of-use product phases. The ultimate goal is for all products to be manufactured using only those materials that have been optimized and do not contain any X or Grey assessed materials. As such, products are able to achieve increasingly higher levels of certification as the percentage of optimized materials in the finished product increases.

Table 3 lists each requirement within the Material Health category. To achieve a given level, the requirements at all lower levels are to be met as well. The sections that follow provide interpretation and suggested methods for achievement.

Table 3 Material Health Requirements

LEVEL	ACHIEVEMENT
BASIC	The product is 100% characterized by its generic materials (e.g., aluminum, polyethylene, steel, etc.) and/or product categories and names (e.g., coatings). The appropriate metabolism (i.e., technical nutrient (TN) or biological nutrient (BN) is identified for the product and its materials and/or chemicals. The materials subject to review in the product do not contain any Banned List chemicals above allowable thresholds based on supplier declarations.
BRONZE	The product is at least 75% assessed (by weight) using ABC-X ratings. Externally Managed Components (EMCs) are considered assessed and contribute to the overall percentage of the product that has been assessed. Complete formulation information needs to have been collected for 100% of BN materials that are released directly into the biosphere as a part of their intended use (e.g., cosmetics, personal care, soaps, detergents, paint, etc.). A phase-out or optimization strategy has been developed for those materials with an X rating.
SILVER	The product has been at least 95% assessed (by weight) using ABC-X ratings. Externally Managed Components (EMCs) are considered assessed and contribute to the overall percentage of the product that has been assessed. Complete formulation information needs to have been collected for 100% of BN materials that are released directly into the biosphere as a part of their intended use (e.g., cosmetics, personal care, soaps, detergents, paint, etc.). The product does not contain substances known or suspected to cause cancer, birth defects, genetic damage, or reproductive harm (CMRs) in a form that may result in plausible exposure.
GOLD	The product has been 100% assessed (by weight) using ABC ratings. All EMCs are considered assessed as non-X.

	The product contains no X assessed materials (optimization strategy is not required). Product meets Cradle to Cradle VOC emissions standards where relevant
PLATINUM	All process chemicals have been assessed and none have been assessed as x.

3.1 GENERIC MATERIAL TYPE AND INPUTS SUBJECT TO REVIEW

Standard Requirement

The product is 100% characterized by its generic materials (e.g., aluminum, polyethylene, steel, etc.) and/or product categories and names (e.g., coatings).

Applicable Levels of Certification

This requirement applies to all levels of certification (Basic, Bronze, Silver, Gold, and Platinum).

Intent

The intent of this requirement is to identify the generic materials used in the product and list them in a Bill of Materials. The Bill of Materials will be used at higher levels of certification to guide the identification of the chemicals present in those materials that will be assessed for their potential to impact human and environmental health. The intent of this requirement is also to assist a manufacturer with understanding all of the materials that are present in the product that may be subject to review.

Methods

Use a Bill of Materials to record the information below. The Bill of Materials should include the following column headings: part number, part description, number of parts per product, generic material, part weight, total weight (all parts), and percent of total weight. Some of these may not be relevant depending on product configuration.

Trade names and grades for purchased materials (exact material specification), color of polymers, finish type information, supplier name, location, and contact information are additional columns that will be useful if the applicant is applying at certification levels above Basic and/or if an assessor will be assisting with data collection from the supply chain.

1. List all homogeneous materials that are present in the product by generic material type and/or product categories and names within the Bill of Materials. Parts and components of assemblies and sub-assemblies of non-homogeneous (i.e., heterogeneous) materials are to be broken down to the homogeneous material level.
    a. Homogeneous materials are defined as materials of uniform composition throughout that cannot be mechanically disjointed, in principle, into different materials. Examples of homogeneous materials are polypropylene, steel, shampoo, glass cleaner, nylon yarn, finish, and coating.
    b. Examples of non-homogeneous materials are powder-coated steel, a printed bottle label, plywood, laminate, and chair casters.

Material safety data sheets (MSDSs) may be useful in completing this first step of characterizing the breakdown of the product; however, it will likely be necessary to consult with material suppliers. ***It cannot be assumed that MSDSs contain complete materials information even at a generic level.***

2. Weigh each material and record the weights in the Bill of Materials. When more than one of a single product input is used, remember to multiply the weight of a single material by the total number of items used in the product.

3. Determine the materials subject to review. First, weigh the entire product. Divide the weight of each material in the product by the total product weight to calculate the percentage of total weight for each material. All homogeneous materials present at ≥0.01% (≥100 ppm) are subject to review, with the following exceptions: finishes (coatings, plating, paints), blowing agents, textile auxiliaries, paper bleaching agents, and plating chemistry are subject to review at any concentration level when the part these are relevant to is itself present at ≥0.01% in the product. For example, a blowing agent used to manufacture foam that is present at <0.01% within the overall product does not need to be reviewed. The blowing agent does need to be reviewed for foam present at ≥0.01%, even if the blowing agent itself is present at levels below 0.01%.

Required Documentation

Ideally, separate Bills of Material will be provided for each product configuration under review. This may, however, be very difficult in the case of complex product systems. A single Bill of Materials can only be used for a product or group of products that share all of the same materials (or chemicals) in the same concentrations, with the exception of material (or chemical) components that can be substituted into the product (or Bill of Materials) without substantially changing the concentrations of each material (or chemical) in the product (e.g., a chair in different color styles or patterns, or soap in different fragrances; not an office set that includes a cabinet that is 95% "Alloy A" and a desk that is 10% "Alloy A"). For multiple products featuring various concentrations of materials (or chemicals), each product configuration is required to be reported.

3.2 IDENTIFYING APPROPRIATE METABOLISM(S)

Standard Requirement

The appropriate metabolism (i.e., biological or technical) has been identified for the product and its material components.

Applicable Levels of Certification

This requirement applies to all levels of certification (Basic, Bronze, Silver, Gold, and Platinum).

Intent

The intent of this requirement is to identify the intended nutrient cycle (i.e., biological or technical) for the product and its components, which can then be used to guide the development and implementation of an appropriate nutrient management strategy required for higher levels of certification.

Methods

For each homogeneous material subject to review, as determined according to the process described in Section 3.1, identify in the Bill of Materials whether it is part of a technical or biological nutrient

cycle. It may be that a material still needs to be designed for the most appropriate metabolism; the goal at this stage is to simply define what is appropriate. The following definitions and examples will aid in categorizing each material as well as the overall product.

Technical Nutrients (TNs)

- Materials or products that are capable of "feeding" technical systems: they may be dismantled and reused, or physically or chemically transformed, but are not consumed (i.e., materials that do not enter the biosphere).
- Materials or products that generally cannot be processed by biological systems.
- Materials or products that are items used as Products of Service. A Product of Service is a material or product designed to provide a service to the user without conveying ownership of the materials.
- Metals and plastics are examples of TNs. Bio-plastics, although they are from the biosphere, may be designed as TNs (i.e., kept in technical cycles).
- Externally Managed Components (EMCs) are a type of TN defined in Section 1.3.1.3.

Biological Nutrients (BNs)

- Materials or products that are usable by living organisms to carry on life processes.
- Materials or products that are items used as Products of Consumption, which are typically changed biologically, chemically, or physically during use and therefore enter the biosphere either by nature or human intention. Such products should be designed for the biological system and thus are categorized and evaluated as biological nutrients. For example, brake pads, which abrade into the environment upon use, should ideally be designed for the biological cycle and will be reviewed with that intention in mind.
- Cleaning products, cosmetics, personal care products, and paper are examples of BNs.

Note that the classification as TN or BN will determine which Banned List applies to the product, and will be considered in the material health assessment.

Required Documentation

Clearly identify in the Bill of Materials whether each material is part of a technical or biological nutrient cycle. This may be accomplished by adding a column in the Bill of Materials.

3.3 DETERMINING ABSENCE OF BANNED LIST CHEMICALS

Standard Requirement

The materials subject to review in the product do not contain any Banned List chemicals above the allowable thresholds based on supplier declarations.

Applicable Levels of Certification

This requirement applies to all levels of certification (Basic, Bronze, Silver, Gold, and Platinum). However, in cases where an applicant is applying for levels above Basic, full material disclosures (as described in Section 3.4) may be used in place of Banned List declarations.

Intent

The intent of this requirement is to ensure, to the extent possible, that chemicals considered harmful to humans or the environment are not intentionally added to materials in the certified products above a designated threshold. By requiring suppliers to submit declarations, the onus for confirming absence of Banned List chemicals is placed on the supplier to give them some responsibility for understanding the chemical composition of their materials and removing an additional obligation from manufacturers to test for all Banned List chemicals.

Methods

1. Refer to the Banned Lists of Chemicals for the Cradle to Cradle Certified™ Products Program (Appendix). Note there are two banned lists, one for technical nutrient (TN) materials and one for biological nutrient (BN) materials. See Table 4 for a guide to determine where Banned List chemicals are often used, and where to expect and look for their presence.
2. For each homogeneous material identified in the product, gather supplier declarations stating that Banned List chemicals have not been *intentionally added* above the allowable threshold (generally 1000 ppm, with the exceptions noted below). An *intentionally added* substance is a substance that has been added to the material for a specific purpose. A substance is also considered to be intentionally added to a material if a manufacturer chooses to use a material coming from a source that is likely to contain the substance. 'Intentionally added' also means 'known to contain.' Also note the following:
    a. The concentration of the banned chemical within each homogeneous material, and not the concentration of each banned chemical within the overall product, is the basis for this review.
    b. Exceptions to the TN Banned List and the 1000 ppm allowable threshold are as follows:
        i. Lead, PTFE, and PAHs are substances that are on the Biological Nutrients Banned List but not the Technical Nutrients Banned List. While these substances can be used in some materials as technical nutrients where exposure is not expected to occur (e.g., lead in aluminum, PAHs in carbon black), they are harmful chemicals and should not be present in materials that may result in exposure to humans and the environment. The following therefore applies:
            a. When present above 1000 ppm, lead, PTFE, and PAHs are also banned for use in TN materials where direct exposure to humans or the environment is highly likely to occur. Examples of these materials include paints, coatings, and finishes that are used on the surface of products such as toys or other children's products and jewelry.
            b. PTFE is banned in TNs if it is the primary component of the product. PTFE is considered a primary component when it represents more than 50% of the product (not material) by weight.
        ii. The thresholds for metals in BN materials are 2 ppm for cadmium, 90 ppm for lead, 100 ppm for chromium, 1 ppm for mercury, and 10 ppm for arsenic. With the exception of the lead threshold, these are the lowest soil screening values (SVs) among those of eleven European countries whose SVs are compared in Armiento et al. (2011) [www.tandfonline.com/doi/abs/10.1080/02757540.2010.534085]. The lead threshold is based on the legal threshold for paint in the US (90 ppm), which is lower than the lowest SV for the metal [www.cpsc.gov].

c. EMCs are not exempt from Banned List declarations.

d. Banned list declarations are also required for each homogeneous material used in the product's primary packaging (if any), including inks, adhesives, and any materials used to label the package (see Section 2.1 of this document for more information).

e. Analytical testing for Banned List chemicals is not accepted in lieu of supplier declarations, but is required in the following situations:

   i. To ensure absence of Banned List chemicals from recycled content when full data cannot or will not be gathered. See section 3.3.1 for further information.

Required Documentation

A signed statement from each supplier must be obtained and submitted to the assessor to verify that the product or material does not contain banned chemicals. Product manufacturers or the assessor may also sign these declarations if they have detailed knowledge of the material's chemical constituents. A supplier may submit a Banned List declaration that broadly covers all inputs provided to a manufacturer. At a minimum, these statements must:

1. Clearly identify the supplier and the material by product identification number, trade name, and/or grade as appropriate.
2. Include the full listing of Banned List chemicals (ensure that the correct list is used depending on whether each item has been categorized as a BN or TN).
3. Include the statement that such chemicals have not been intentionally added at >0.1% (lower levels apply for BN).

A convenient way to track whether materials contain Banned List chemicals and/or whether signed supplier declarations have been received for the inputs is to add a column to the Bill of Materials where comments can be included to that effect.

Table 4 Major Uses and Primary Human Health and Environmental Issues Associated with Banned List Chemicals

Banned List Category	Major Uses and Contamination Concerns	Primary Issues
Metals: Lead, cadmium, chromium VI, mercury	Intentional inputs to some metal alloys, inks, colorants and stains. Lead and cadmium are used in batteries. Chromium VI may be used as a wood preservative, in leather tanning, and as a metal coating. Mercury is used in fluorescent bulbs and other specialty applications. These metals are contaminants found in many materials including polymers, paper, metals, glass, paint and coatings, etc.	Lead: potent neurotoxin, possible carcinogen (IARC). Cadmium and chromium VI: carcinogenic to humans (IARC). Mercury: potent neurotoxin, highly toxic to the respiratory system and kidneys.
Metals: Arsenic	Alloying agent and/or impurity of copper, brass and bronze, wood preservative (chromated copper arsenate).	Carcinogenic to humans (IARC).

Banned List Category	Major Uses and Contamination Concerns	Primary Issues
Flame Retardants	Additive to polymers used in electronics, appliances, and automotive applications, carpet, furniture foam, upholstery, and textiles.	Environmental persistence, bioaccumulation, endocrine disruption, liver and neurodevelopmental toxicity. TDCP/TDCPP: Known carcinogen (CA Prop 65).
Phthalates	Used as plasticizers (to increase softness and flexibility) in PVC and other polymers, inks, and adhesives, personal care products such as nail polish and hair gels, and medical devices. May be found as contaminants in recycled polymers and paper at low levels.	Endocrine disruption, reproductive development toxicity.
Halogenated Polymers	PVC is widely used in a variety of products from packaging to construction. It is somewhat common for PET to be contaminated with PVC due to similar specific gravity. A common use of PVDC is in films (e.g., Saran Wrap). CPVC (chlorinated polyvinyl chloride) is used to manufacture pipes. Polychloroprene (neoprene) is used to manufacture wet suits, laptop sleeves, iPod holders, gaskets and hoses. PTFE (Teflon) is used in a wide range of products where low friction and/or scratch resistance is required, including cookware, inks, paints, coatings, textiles (Gore-Tex), etc.	Production and release of potent toxins including dioxins, furans, and hydrogen chloride upon combustion. Vinyl chloride monomer is carcinogenic to humans (IARC). Chloroprene monomer is possibly carcinogenic to humans (IARC) and a known carcinogen (CA Prop. 65). PFOA, used during manufacture of PTFE, may be released when PTFE is heated to high temperatures. (Also see below for more information; PFOA is also on the Banned List). PTFE is associated with pulmonary edema upon inhalation of fumes when heated to high temperatures. Additives such as phthalates used widely in halogenated polymers are also problematic.

Banned List Category	Major Uses and Contamination Concerns	Primary Issues
Chlorinated Hydrocarbons	The chlorinated hydrocarbons on the Banned List are primarily used as pesticides (insecticides, fungicides); some are banned for use in the U.S., EU, and other countries. Secondary uses of some compounds are solvents for waxes, gums, resins, tars, rubbers, oils, asphalts, dyes and intermediates. Hexachlorobenzene is used in the manufacture of synthetic rubber and as a plasticizing agent in PVC. SCCPs are used in lubricants, plasticizers, flame retardants. (Note: It is currently unlikely to find these as intentional inputs to consumer products.)	Toxicity concerns vary depending on the chemical and include carcinogenicity, reproductive toxicity, endocrine disruption, persistence, bioaccumulation, and aquatic toxicity at low concentrations.
Polycyclic aromatic hydrocarbons (PAHs)	PAHs are present in fossil fuels (coal, mineral oil, etc.). They are produced during incomplete combustion of organic materials and released in vehicle, factory, and other exhausts. PAHs are also found in a variety of consumer products as contaminants due to the use of extender oils and carbon black. PAHs may be found in soft polymers (rubber and elastomers) and black hard polymers.	Some are known carcinogens, mutagens, and reproductive toxins.
Pentachlorophenol (PCP)	Fungicide banned for use in the U.S. except as a wood preservative for telephone poles, pilings, and other heavy-duty applications. PCP may be used as a cotton and leather preservative. It is no longer produced in the EU and is banned in some countries.	Known carcinogen (CA Prop 65).
Octylphenol, Octylphenol ethoxylates; Nonylphenol, Nonylphenol ethoxylates	Surfactants and wetting agents used in cleaning products, paints, inks, adhesives, pesticides, textiles, and paper processing. Canada and the EU have restricted the use of NPEs.	Persistent in the aquatic environment, moderately bioaccumulative, extremely toxic to aquatic organisms, endocrine disruption.

Banned List Category	Major Uses and Contamination Concerns	Primary Issues
Triorganotin compounds (-butyl, -octyl, -phenyl)	Fungicides and bactericides that may be used in textile, leather, pulp and paper manufacturing. In this context they are primarily of concern due to their effects on aquatic organisms, as they may be released with process water. May also be used as PVC stabilizers, wood preservatives, and pesticide treatment for textiles and carpet. Use is restricted in the EU, U.S., and other countries.	Highly toxic to aquatic organisms, endocrine disruption
Perfluorooctane-sulfonate (PFOS), Perfluorooctanoic acid (PFOA)	PFOS: May be used as a stain repellent for textiles and carpet (phased out in U.S. and EU), mist suppressant in chromium VI metal plating process, fire fighting foam, photo-imaging, paper coating (repels oil and water) PFOA: Used in the production of PTFE and other fluoropolymers; PTFE may degrade to PFOA.	Persistent, bioaccumulative, present at low levels in the human body; PFOS and PFOA have been associated with a variety of toxic effects in mammals, including developmental toxicity and liver toxicity; human health effects are not fully understood.

3.3.1 Recycled Content

It may be necessary to test materials containing recycled content for Banned List chemicals. Analytical testing is required for certain material types and sources in cases where full ingredient data cannot or will not be gathered and where there are concerns about possible contamination. The intent of this requirement is to ensure the use of safe materials in recycling streams. The assessor, in consultation with the manufacturer, is responsible for determining whether a material is likely to contain Banned List chemicals based on its source, and requiring analytical testing when the presence of Banned List chemicals above the designated threshold is a concern.

Table 5 can be used as a reference for examples of materials with known issues with regard to Banned List chemicals.

Note that for metals, testing will generally not be necessary. Identification of the specific alloy grade being used will allow determination of the full chemical composition of the metal alloy down to 0.01%. Potentially useful references for looking up metal composition based on grade include www.matweb.com, www.efunda.com, and www.copper.org.

Table 5 Examples of Materials with Known Issues with Regard to Banned List Chemicals and Suggested Analytical Methods

Banned List Category	Recycled Material Types to Test	Method (suggested)
Metals: chromium VI, mercury	All materials.	Chromium VI: ICP/MS or ICP/AES (ICP/OES) with detection limits in the low ppm range. Note that if ashing digestion techniques are required, mercury, arsenic, and tin may volatilize from the sample, increasing detection limits, though an acceptable detection limit should still be attainable. If total chromium in the material is greater than that allowed for the desired certification level, then further testing will be required to determine the amount of hexavalent chromium present using alkaline digestion techniques (most cases). XRF testing methods are allowed for glass. Mercury: ICP or CVAA/direct mercury analysis with detection limits in the low ppm range.
Metals: lead, cadmium	All materials identified as biological nutrients, or in technical nutrients with no guaranteed management plan.	Same as above for chromium VI.
Metals: arsenic	Copper, brass, bronze, recycled wood where full data cannot be gathered.	Same as above for chromium VI.
Halogenated Flame Retardants (refers only to those on the Banned List)	Polymers sourced from electronic, appliance, and automotive sources, recycled carpet, upholstery foam, and textiles.	GC/MS; Detection limit <0.1% for Basic level and the Banned List chemicals; Detection limit <0.01% (100 ppm) for Bronze level and above. If flame retardants are not expected to be present (unlikely for these material types): oxygen bomb combustion sample preparation followed by ion chromatography with detection limits in the low ppm range (25 ppm max, ~5ppm or less preferred) may be used. This is a screen for all halogens including inorganic so will cover the halogenated polymer test as well. Request that bromine, chlorine, and fluorine be reported separately.

Banned List Category	Recycled Material Types to Test	Method (suggested)
Phthalates: DEHP, BBP, DBP	Flexible polymers other than PET, HDPE, and PP from standard post-consumer recycling streams. (Franz et al. (2004) found phthalate contamination in recycled PET in the 0.05-0.5 ppm range. Vinggaard et al. (2000) found the maximum concentration of phthalates in paper to be 28 ppm for DBP).	CPSC-CH-C1001-09.3 Standard Operating Procedure for Determination of Phthalates (or more recent version). GC/MS; detection limit <0.1% (1000ppm).
Halogenated Polymers: PVC, PVDC, CPVC, Polychloroprene, PTFE	All polymers	If flame retardants or other halogens are not expected to be present, this method is recommended: oxygen bomb combustion sample preparation followed by ion chromatography with detection limits in low ppm range (25 ppm max, ~5ppm or less preferred). This is a screen for all halogens including inorganic. Request that bromine, chlorine, and fluorine be reported separately. If flame retardants or other halogens are expected to be present: GC/MS; detection limit <0.1% for Basic level and the Banned List chemicals; detection limit <0.01% (100 ppm) for Bronze level and above. (Complete this test and the oxygen bomb screening test if applying above the Basic level and hoping to achieve an X or grey assessment for recycled content). Other common halogen sources that are not on the Banned List of chemicals: chlorinated pigments, additional flame retardants, UV stabilizers, and biocides. If these are expected to be present, it is recommended to use GC/MS methods to test for specific chemicals on the Banned List.

Banned List Category	Recycled Material Types to Test	Method (suggested)
Chlorinated Hydrocarbons (refers only to those on the Banned List)	Testing is not required unless applying at the Gold level.	The VOC testing required at the Gold level covers this requirement. Single materials will not need to be tested; instead the entire product is tested. See VOC Emissions Testing (Section 3.9).
Polycyclic aromatic hydrocarbons (PAHs)	Testing is not required.	Not applicable.
Pentachlorophenol (PCP)	Recycled wood from heavy-duty applications such as utility poles, railroad ties, etc., cotton and leather.	GC/ECD; (See Becker, Buge and Win. Determination of PCP I waste wood – method comparison by a collaborative trial. Chemosphere 47 (2002): 1001-1006). Detection limit <0.1% for Basic level and the Banned List chemicals; Detection limit <0.01% (100 ppm) for Bronze level and above.
Octylphenol, Octylphenol ethoxylates; Nonylphenol, Nonylphenol ethoxylates	Recycled textiles, reclaimed fibers, recycled leather.	LC/MS; detection limit <0.1% (1000 ppm).
Triorganotin compounds (-butyl, -octyl, -phenyl)	Recycled wood, carpet, textiles.	GC/MS; detection limit <0.1% (1000 ppm).
Perfluorooctanesulfonate (PFOS) Perfluorooctanoic acid (PFOA)	Recycled textiles, reclaimed fiber.	LC/MS; detection <0.1% (1000 ppm).

Testing Intervals

Testing of recycled content to ensure absence of banned substances is required when complete data cannot be obtained. At a minimum, testing is required at the time of the initial certification and again at each subsequent re-application.

An exception to this requirement is for materials containing recycled content for which a C or better material assessment is desirable (so that they may contribute to the percentage assessed to Gold certified products). In these cases, testing is required on a semi-annual basis (every six months). These semi-annual test results must be provided to the assessor immediately after testing is completed. If any test shows problematic chemicals present above the required thresholds, the material will no longer be assessed as C or better. This will affect the overall certification level immediately (i.e., demotion from Gold). For this reason it is recommended that only consistent and relatively clean material streams be used, especially in the case of Gold certified products. Note that testing is usually not required for steel, aluminum, and other metals.

Selecting a Testing Laboratory and Analytical Method

Laboratories conducting the analytical testing of recycled content must be certified to ISO 17025 and experienced in materials analysis. There are many laboratories that specialize in testing environmental samples (e.g., air, water, and soil); however, these labs may not have expertise in extracting and analyzing contaminants from other material types. It is recommended that applicants work with their assessor to select an appropriate laboratory to conduct the analyses.

Table 5 lists appropriate testing methods for common material types and contaminants. It may, however, be necessary to determine appropriate methods on a case-by-case basis. In addition, different laboratories may use somewhat different methods based on equipment availability and expertise. Some laboratories may also use proprietary sample preparation methods that they will not fully disclose. Instrumentation may include ICP/MS, ICP/AES, GC/MS, GC/ECD, or LC/LMS, among others. The appropriate method is dependent on the contaminant of interest, material type, and analytical laboratory. In some cases X-ray fluorescence (XRF) methods may be used (i.e., for glass elemental analysis). In speaking with and selecting a laboratory, it must be ensured that:

1. Detection limits are low enough.
    a. If applying only at the Basic level, detection limits of <1000 ppm for each contaminant are acceptable in most cases. Exceptions to this are metals in biological nutrients.
    b. If applying for levels above Basic, detection limits of <100 ppm are needed for the metals (lead, cadmium, mercury, chromium VI), flame retardants, and halogenated polymers (see Section 3.4.2). A detection limit of <100 ppm is sufficient for any other contaminant(s) that will be tested.
    c. Generally, detection limits of much less than 1000 ppm will be achievable.
2. Sample preparation and contaminant extraction methods are appropriate. Generally, solvent extractions will be necessary. Environmental laboratories experienced in testing air, water, and soil samples may use U.S. Environmental Protection Agency (EPA) standardized methods; however, such methods may not be appropriate for extraction of contaminants from materials such as polymers.

Required Testing Documentation

Test reports including contaminants tested for, detection limits, description of material sample(s) tested, test method(s), laboratory certification information, and laboratory contact information must be submitted to the assessor.

RoHS directive testing reports may be submitted to ensure conformance with the Banned List for metals (mercury, chromium VI) and some flame retardants (RoHS does not cover TBBPA or TDCP). RoHS compliance statements fully cover the Basic-level requirements for these contaminants.

To determine that metals and halogens are present at <100 ppm, as required at the Bronze level and above for assessing recycled content, full RoHS test reports including detection limits and contaminant concentrations should be provided (compliance statements alone are not sufficient). If detection limits are <100 ppm, the RoHS test report applies.

CONEG compliance statements (relevant to packaging in the U.S.) apply for lead, cadmium, chromium VI, and mercury testing for paper and other packaging materials with recycled content.

3.4 COLLECTION OF MATERIAL COMPOSITION DATA

Standard Requirement

Material ingredient data must be collected to generate ABC-X assessments for each material in a product.

Applicable Levels of Certification

This requirement applies to the Bronze level of certification and above (Bronze, Silver, Gold, and Platinum).

Intent

The intent of this requirement is to assist a manufacturer with understanding the chemicals that are present in the product so that they may be assessed for their potential to adversely impact human or environmental health.

Methods

1. Sign necessary confidentiality agreements with suppliers and sub-suppliers, if necessary. Confidentiality is a major concern for many manufacturers so it will often be necessary to sign confidentiality agreements assuring that ingredient data will be held as confidential. Three-way agreements may be necessary in cases where a consultant is gathering data and sending it on to an assessor.
2. Collect data for each homogeneous material subject to review (as determined in Section 3.1) until the desired percentage of the materials in the product have been assessed. It will often be necessary to collect data from multiple sequential tiers of a supply chain to identify all chemicals subject to review in each homogeneous material. The chemicals subject to review in each material are those present at a concentration ≥ 0.01% (≥ 100 ppm), and those subject to review at any concentration (see f. and g. below). Chemicals subject to review are limited to intentionally added inputs (see Section 3.1 for definition of intentionally added). Request the following information at each tier as necessary to identify all chemicals subject to review in each homogeneous material:
    a. Name of each chemical or specific manufacturer trade name and grade in the case of purchased chemicals or chemical mixtures.
    b. Unique CAS for all raw chemicals.
    c. Concentration or concentration range (e.g., 0-1%, 1-5%, etc.) of each chemical or chemical mixture (note the concentrations must add to 100% or a statement from the supplier that all ingredients are present is required).
    d. The function each chemical or chemical mixture serves within the material or product (i.e., resin, main polymer, catalyst, antioxidant, UV stabilizer, pigment, impurity, etc.; note this information is useful to have when conducting assessments but is not required).
    e. Percent recycled content, if any, including indication of type (post-consumer or post-industrial).

f. The concentrations of lead, mercury, hexavalent chromium, cadmium, pigments, dyes and other colorants, phthalates, halogenated organics, and scarce elements or substances specified in the *Material Health Assessment Methodology* document (i.e., indium, gold, diamond, etc.) when present at any concentration.

g. Process chemicals used that are metal plating agents (i.e., hexavalent chromium), textile auxiliaries (i.e., textile process chemicals), blowing agents, and paper bleaching agents. These process chemicals are subject to review even if they are not expected or known to be present in the finished product. Note that for paper, manufacturers may not know if process chemicals remain in the final product at ≥100ppm. If they are unsure, it is required that they provide data on process chemicals as well. Octylphenol, octylphenol ethoxylates, nonylphenol, nonylphenol ethoxylates, and triorganotin compounds (-butyl, -octyl, -phenyl) are Banned List chemicals that may be used in textile, paper, and pulp processing. Evaluation and optimization of process chemicals will extend into all product-relevant processes at the Platinum level.

3. Identify all chemicals present at 0.01% or greater in the material (or at any concentration for the exceptions listed in 2.f. and 2.g. above) if the goal is for a material to receive an A, B, or C assessment. If it has become clear that a material will be X assessed before the full chemical composition has been obtained, it is allowable to have incomplete data such as those reported on an MSDS. In such cases, a supplier declaration stating that no Banned List chemicals are present must be obtained.

There are analytical testing and other requirements for EMCs and materials containing recycled content, but analytical testing is generally not required for identifying chemicals subject to review. See Sections 3.4.1 and 3.4.2 for further information on EMCs and materials containing recycled content.

4. Common follow-up questions relevant to conducting assessments once data have been provided are:

   a. For polymers, what are the residual monomer concentrations (in cases where monomers are x assessed)?

   b. Have petroleum distillates been severely hydro-treated?

   c. In cases where chemical concentrations have been provided, what is the final concentration of that chemical in the product? Note that some chemicals that were added or used during the manufacturing process may not be present in the final product.

The applicant is required to provide the information to answer these common follow-up questions.

For polymers, the residual monomer concentrations must be reported in cases where the monomers are 'x' assessed or on the Banned Lists (e.g., PFOA and PFOS concentrations must be reported for materials containing PTFE). Analytical testing to determine the monomer concentration in the material is required if the monomer concentration cannot be obtained from existing information.

Knowing what ingredients to expect in different material types is helpful in determining whether accurate information has been provided. See Table 6 for guidance.

Table 6 Typical Ingredients in Common Materials

MATERIAL TYPE	DESCRIPTION	TYPICAL INGREDIENTS
Adhesives	Glues, tapes, binders, etc.	Resins, fillers, antioxidants, catalysts, film backers, preservatives, solvents, tackifiers, defoamers, etc.
Adhesives – Formaldehyde-based Binders	Melamine-Formaldehyde (MF), Phenol-Formaldehyde (PF), Urea-Formaldehyde (UF), Wet Strength, M-UF, P-UF, Non-Scavenged UF, etc.	Base resin, residuals, etc.
Fabric	Natural or synthetic fibers, yarn, etc. Woven and non-woven textiles.	Base fiber, dyes and/or pigments, recycled content, auxiliaries, flame retardants, residual pesticides or preservatives.
Fasteners (metal)	Screws, bolts, washers, rivets, etc.	Base metal alloy, recycled content, coatings or paint, trace contamination, waxes, lubricants/plating/finishes.
Finishes	Most metal (structural and fasteners) will have a finish: Zinc oxide, oil, chrome, etc.	Hexavalent chromium finishes, cadmium plating, etc.
Polyurethane Foam	Cushions, padding, insulation, etc.	Polyol and isocyanate, blowing agent, catalyst, additives, colorants, flame retardants, etc.
Glass, Fiberglass, Clay	Tempered glass, fiberglass.	Glass, colorants, recycled content, trace heavy metal contamination, other additives for fiberglass reinforcements such as sizing and coatings.
Inks, Dyes, Colorants, Pigments	Paper inks, fabric dyes, plastics and paint colorants, printing inks for paper, fabric, labels, etc.	Colorants, biocides, solvents, polymers, minerals, fillers, resins, etc.
Laminates	High-pressure or low-pressure decorative laminate.	Adhesive, kraft paper, wetting agents, resins, residuals from resins, abrasion additives, decorative paper, backers, etc.
Metal (not fasteners)	Table legs, arms, etc. Steel, aluminum, etc.	Base metal alloy, recycled content, coatings or paint, trace contamination.
Paints	Coatings on a variety of substrates.	Colorants, biocides, solvents, polymers, minerals, fillers, waxes, resins, etc.

Paper and Pulp	Labels, packaging, envelopes, etc.	Pulp, paper, biocides, inks, bleaching agents, residual process chemicals, recycled content, trace contamination, aluminum sulfate, etc.
Polymers	Including copolymers, nylon, ABS, polypropylene, polyethylene, PET, PU, PC, acetals, PVC, etc	Base resins, colorants, catalysts, fillers, recycled content, trace contamination, flame retardants, additives such as UV stabilizers, antioxidants, recycled content, trace, residual monomers (common problematic monomers: styrene, butadiene, acrylonitrile, bisphenol A, etc.).
Wood, Natural Fibers (treated or untreated)	Plywood, particleboard, veneers, oriented strand board, solid wood, jute fiber, etc.	Base material, adhesives, preservatives, flame retardants, etc.

Required Documentation

A Bill of Substances for each homogeneous material that includes the information listed above is required. Note that "Exact Material Specification" is required for this stage.

It is recommended to also obtain a signed statement from the manufacturer indicating that, to the best of their knowledge, all chemicals that are present at 0.01% or greater in the material have been provided (or to any level for the exceptions listed above) in the Bill of Material.

3.4.1 Externally Managed Components (EMCs)

The following information must be collected from the applicant or applicant's supplier if a sub-assembly is to be defined as an EMC (see Section 1.3.1.3 for definition and more information on EMCs):

1. The supplier of the EMC has provided the applicant with a guarantee for take back and appropriate nutrient management. The supplier may designate a third party or parties for implementation.
2. The supplier has signed a declaration that chemicals in the EMC will not negatively impact humans or the natural environment during the intended and unintended but highly likely use of the product for which the EMC is a component. This guarantee may be provided if the EMC is Cradle to Cradle Certified™ (Gold level or higher), or other appropriate evidence.
3. The EMC has undergone testing by an accredited analytical laboratory to insure that harmful substances are not being emitted from the EMC above the chemical's analytical detection limits. Off-gas testing is required for all indoor-use EMCs (See Section 3.9 for more information on VOCs emission testing). Migration and leaching testing may be required depending on the type of EMC.

If the above are completed, the general requirement for full chemical compositional identification and assessment of the EMC will not apply.

The intent of these requirements is for the supplier to indicate, to the best of their knowledge, that the sub-assembly is a sealed component that is manufactured in a way that prohibits the migration of

chemicals and materials from the component. If, during use of the product for which the EMC is a component, a user is exposed to any part or chemical within the component, or if any part or chemical within the component is released to the environment, the component is not considered an EMC and will be assessed and inventoried like the other materials in the product.

It is recognized that it is not possible to know with absolute certainty that chemicals and materials in the EMC will not negatively impact humans or the natural environment during all the possible use and re-use scenarios. The overall intent is to allow for the use of product components that do not need to be assessed the same way as the rest of a product because they are managed as a whole by the supplier or a third party. The EMC concept was invented by the founders of the Cradle to Cradle® framework to encourage manufacturers to design complex components that are completely managed after their use phase. Examples of potential EMCs are a pneumatic cylinder in an office chair, the motherboard in a computer, the electric motor inside an automated window shade product, and a solar panel.

Required Documentation

The following documents must be submitted to the assessor:

1. A signed statement from the manufacturer guaranteeing take back and appropriate nutrient management of the EMCs, including a full description of the take back program and how the product or material will be returned.
2. A signed declaration that chemicals in the EMC will not negatively impact humans or the natural environment, as detailed above (this guarantee may be provided if the assembly/part is Cradle to Cradle Certified (Gold level or higher), or other appropriate evidence).
3. Test results, including a description of the test methods used and laboratory contact information.

3.4.2 Recycled Content

The information below will aid in the collection of chemical ingredient data from the applicant or applicant's supplier if the product contains recycled content.

1. **Recycled content from a single stream source** -- In cases where recycled content is coming from a single stream source, it may be possible to gather ingredient data from the original manufacturer as described above for other homogeneous material types. For example, a single stream, post-industrial recycled material source may be made up of one or two materials of known trade name and grade. In this case, analytical testing is not required, assuming the actual material formulation has been obtained.
2. **Recycled content from an undefined source --** In many cases, it is not possible to obtain sufficient ingredient data on materials containing recycled content from undefined sources (the majority of post-consumer recycled materials are undefined) to ensure that Banned List chemicals are not present above allowable thresholds, determine whether toxic metals and organohalogens are present at ≤100 ppm, and to complete an A, B, C, or X material assessment. This may be done through a combination of analytical testing and ingredient disclosures as follows:
    a. Metals: Metals are some of the most highly recyclable and recycled materials known. Steel mills, aluminum plants, and other facilities that recycle metal alloys perform analytical tests for

the purpose of identifying and tightly controlling the elemental composition of the alloys being manufactured using recycled scrap. Therefore, the ingredient composition for metal alloys can usually be found in publicly available sources (e.g., AISI, JIS, Aluminum Association) or in the mill certificate provided by the metal supplier[1].

If possible, obtain the alloy grade and look up standard composition in the available databases or obtain the mill certificate with full composition information. Identifying the specific alloy grade being used will allow determination of the full chemical composition of the metal alloy down to the 100ppm (0.01%) level. The following websites are potentially useful references for looking up metal composition: www.matweb.com, www.efunda.com, and www.copper.org.

Alternatively, analytical testing can be used to obtain the full chemical composition down to 0.01% and then conduct the material assessment. Analytical methods with detection limits that are ≤100ppm (0.01%) for lead, mercury, cadmium, and chromium VI must be used. Analytical testing for lead is required in cases where available alloy composition data for recycled cast aluminum does not report the lead concentration.

b. Glass: Glass is also one of the most recyclable materials today. Similar to recycled metals, a series of simple and inexpensive analytical tests can be performed to identify the full elemental composition of the inorganic material.

   If possible, obtain an ingredient disclosure from the supplier to identify the full elemental composition of the glass material. If a disclosure cannot be obtained, conduct analytical testing with detection limits that are ≤100ppm (0.01%) to obtain the full chemical composition down to 0.01% and then generate the material assessment. XRF methods may be used for elemental analysis of glass.

c. Paper and Natural Cellulosic Fibers: Recycled paper and other natural fibers compose one of the largest recycled material pools by weight worldwide. In some cases, paper composition information can be obtained from the paper mill(s). Alternatively, analytical testing must be conducted.

   Identify chemicals that are present in the material at concentrations ≥100 ppm and pulp bleaching agents at any concentration (it is required that pulp suppliers disclose the type of bleaching process used). Data are to cover final product composition as opposed to input composition, if possible. In addition to pulp bleaching agents, a number of different process chemicals (e.g., de-inkers, sizing agents) may be used in the recycling of paper and natural fiber materials to make them suitable for manufactured products in their next use phase, and these must be considered. If it is unclear whether or not process chemicals remain in the final product, it is recommended to gather data on process chemicals as well. Analytical testing for metals (excluding arsenic) is required for the assessment of paper containing recycled content.

   To be eligible to earn an A, B, or C material assessment rating, the ingredients remaining on the finished paper must be fully identified and assessed. The assessor must then evaluate all ingredients that compose ≥0.01% of the finished paper product using the Cradle to Cradle Certified Material Health Assessment Methodology. For untreated post-consumer recycled paper, if the recycled paper remains in an untreated state (i.e., raw recycled paper), then it might not be possible to determine the full composition by weight for all ingredients. In these

[1] The user must have the specific alloy number for the metal before being able to identify its composition (i.e. AISI 1020 Steel; JIS G 3101 Steel; 6061 Aluminum).

cases, a material assessment cannot be performed and the material will earn a GREY assessment and is added to prioritized optimization plan.

d. Polymers: Plastics are an integral part of everyday life and are seen as valuable technical nutrients that need to be kept in closed-loop material flows rather than burned for energy or dumped in landfills. There are usually significant challenges in obtaining the full composition of a post-consumer recycled plastic due to contamination, varying grades of resin from different manufacturers, various product labels, and content residues. However, when a material comes from just one or two known sources, it may be possible to go back to the original manufacturer to gather full chemical ingredient data, as for virgin materials.

   Polymers must be from relatively consistent recycling streams in order to receive an A, B, or C material assessment. If an A, B, or C assessment is of interest:

   i. Define the recycling stream. For example, is the material sourced only from clear PET bottles, milk jugs, battery casings, etc.? How has the material been separated from other types of plastic? Discuss separation techniques with the material provider(s) and document any known contamination issues.

   ii. In addition to testing for the presence of Banned List chemicals above the allowable thresholds, testing for other contaminants may be required depending on discussions with material providers and knowledge of the specific material types. The goal is to determine if any chemicals that would result in an X assessment are present at ≥100 ppm. For example, in the case of recycled PET, antimony testing may be required as it is expected to be present. In these cases, testing regimens will need to be developed on a case-by-case basis. If total halogen concentrations are greater than 100 ppm based on a screening test, it will be necessary to identify the specific halogen compound or compounds present in the product to determine whether any one organohalogen compound is present at a concentration of 100 ppm or greater. Note that the total halogen test will also detect inorganic halides such as chloride salts, which are typically not problematic.

3. Materials subject to analytical testing are those containing recycled content from undefined sources (i.e., most post-consumer sources) for which full chemical ingredient data cannot be gathered and/or contamination is suspected. At a minimum, testing is to be done as described in Section 3.3.1 to determine the absence of Banned List chemicals above the allowable thresholds.

4. Note that it may not be possible to gather full chemical ingredient data on materials that contain recycled content from undefined sources. Recycled content that has passed testing for Banned List chemicals (see Section 3.3.1), but for which full ingredient data cannot be gathered or adequately determined (i.e., for polymers from inconsistent streams), will not count toward the total percentage assessed (it is considered "un-assessed" or GREY). This will be a common situation for post-consumer recycled plastics from variable and mixed streams and paper that has not been re-pulped but only shredded for reuse.

Required Documentation

See Section 3.3.1 for required documentation.

3.5 MATERIAL ASSESSMENTS

Standard Requirement

Materials in a product must be assessed using the ABC-X rating system. The required percentage of the product that is assessed is dependent on the certification level.

Applicable Levels of Certification

This requirement applies to the Bronze level of certification and above (Bronze, Silver, Gold, and Platinum).

Intent

The intent of this requirement is to assist the manufacturer with understanding the potential for the chemicals in their product to adversely impact human or environmental health (chemical hazard profiling), and whether or not the materials in the product support Cradle to Cradle® material health objectives. The intent is also to give designers a tool to evaluate and profile the hazards associated with a chemical by which they can make educated and informed decisions when creating products.

Methods

See the document entitled *Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.1* (available for download on the Cradle to Cradle Products Innovation Institute website at www.c2ccertified.org).

Required Documentation

A column in the Bill of Materials can be used to list and track assessment ratings for each homogeneous material. At a minimum, this level of information must be reported to the Cradle to Cradle Products Innovation Institute. Assessment ratings for each chemical ingredient in each homogeneous material may or may not be reported, although each assessor will be required to track this information for each project and for auditing purposes.

3.6 DETERMINING PERCENTAGE ASSESSED

Standard Requirement

Materials in a product must be assessed using the ABC-X rating system. The following percentage of materials in the product that are assessed is required for each certification level:

Bronze level	TNs and BNs are at least 75% assessed as A, B, C, or X. Complete formulation information needs to have been collected for 100% of BN materials that are released directly into the biosphere as a part of their intended use (e.g., cosmetics, personal care, soaps, detergents, paint, etc.).
Silver level	TNs and BNs are at least 95% assessed as A, B, C, or X. Complete formulation information needs to have been collected for 100% of BN materials that are released directly into the biosphere as a part of their intended use (e.g., cosmetics, personal care, soaps, detergents, paint, etc.).
Gold level	TNs and BNs are 100% assessed as A, B, or C.

Applicable Levels of Certification

This requirement applies to the Bronze level of certification and above (Bronze, Silver, Gold, and Platinum).

Intent

The intent of this requirement is to encourage manufacturers to identify the extent to which the materials in their product may adversely impact human or environmental health by increasing the percentage of materials that are assessed with each higher level of certification.

Methods

1. In order for a homogeneous material subject to review to be counted as "assessed," the following must be true:

    a. For materials assessed as A, B, or C, all chemicals subject to review have been identified and none of those chemicals were assigned an 'x' or 'grey' single chemical risk rating. This refers to chemical substances as present in the homogeneous materials of the finished product. For example, if the manufacturer mixes a base resin with a color masterbatch during production, the resin and masterbatch together are a single homogeneous material for the purpose of the assessment and this is where the 100ppm threshold is applied. If any substance subject to review in this homogeneous material receives a single chemical risk rating of 'x', the entire homogeneous material will be x-assessed, regardless of whether the substance was an ingredient of the base resin or the masterbatch. See Section 3.4 for more information on chemicals subject to review in each material.

    b. The concentrations of the following chemical ingredients in the material have been collected, regardless of their concentration in the material:

        i. Lead, mercury, hexavalent chromium, cadmium, pigments, dyes and other colorants, phthalates, halogenated organics, and scarce elements (i.e., elements such as indium and gold).

        ii. Process chemicals: metal plating agents (i.e., hexavalent chromium), textile auxiliaries, blowing agents, and paper bleaching agents.

    c. Analytical testing has been completed and thresholds have been met where relevant for EMCs and materials containing recycled content. See guidance in Section 3.4 for further information.

    d. The material has received an A, B, C, or X assessment, or it is defined as an EMC (Section 3.4.1).

2. The total percentage of materials in the product assessed equals the sum of the individual percentages by weight of each homogeneous material that meet the requirements listed above, with one exception as follows. In the case that the finished product is a single-material product, then the percentages for each input product/mixture and/or chemical are used in determining the percentage of the product assessed. For this purpose, a product is considered a single-material product if it is composed of:
    - a single homogeneous material, or
    - a single homogeneous material that is at least 95% of the final product by weight and 5% or less of other materials that are either a coating, finish, print, paint, ink, other surface treatment, film, or interlayer.

Note that the percentage assessed required for each certification level corresponds to the percentage of materials, not the chemicals, assessed by weight in the product. This is because:

- Only chemicals ≥100ppm in the material (plus exceptions noted above), and not all chemicals in the material, are subject to review. It is possible that a small percentage of the material contains chemicals that have not been identified and assessed.
- X-assessed materials may have one or more ingredients that have not been identified. The identification process may have been discontinued once a problematic ingredient was identified in the material.

Note also that in cases where the finished product is a single-material product, the percentages for each assessed chemical substance by weight are used in determining the percentage of the product assessed.

A material may be identified as GREY if the supplier refuses to provide the complete formulation, or expert judgment by the assessor concludes a substance has been omitted from the material formulation. A material may also be identified as GREY if certain hazard data are not available for one or more chemicals in the material (for more information on the chemical risk assessment process see the *Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.1).* Because there is not enough information to render an assessment, chemicals or materials assigned a GREY rating do not count toward the percentage assessed. Once the missing information is obtained, a GREY material may become an A, B, C, or X assessed material and count toward the percentage assessed.

In order for a material to count towards the percentage assessed at the Silver level, one of the following is required to ensure carcinogens, mutagens, or reproductive toxins (CMRs) are not present in those materials:

- All of the chemicals subject to review in the material have been identified (i.e., no GREY ingredients) and none received a single chemical risk score of 'x' as a result of being a CMR, OR
- In cases where an X-assessed material may have one or more ingredients that have not been identified (i.e., GREY ingredients), the material supplier or other party with knowledge of the chemical composition of the material has signed a declaration stating that CMRs are not present in the material.

Required Documentation

It is recommended that a column(s) in the Bill of Materials be used to tabulate and calculate the total percentage of the product that has been assessed.

3.7 MATERIAL OPTIMIZATION STRATEGY

Standard Requirement

A phase-out or optimization strategy has been developed for those materials with an X rating.

Applicable Levels of Certification

This requirement applies to the Bronze and Silver levels of certification. (By definition, Gold- and Platinum-level products will not contain any x-assessed substances and therefore will not need a material optimization plan.)

Intent

The intent of this requirement is to encourage the manufacturer to develop a plan for phasing out the use of all chemicals or materials in their product that may adversely impact human or environmental health and advance along the continuous improvement pathway to higher levels of product certification.

Methods

1. Each applicant will receive a certification report from their consultant or assessor. This report will include assessment comments, indicating as much as possible what the issues are with a given material. The report will also contain a recommendations section that may provide some guidance on which materials are most feasible to work on in the near term. Some consultants / assessors will also track optimization opportunities in the Bill of Materials. These documents are the starting point for developing an optimization plan. The following information will be needed to construct the optimization strategy:
    a. Assessment results (A, B, C, X, or Grey) and description/comments.
    b. Initial optimization recommendations and next steps.
    c. Indication of how difficult it will be to optimize each material.
2. All X (problematic) and Grey (data missing) materials are to be included in the optimization plan. The exception is for materials assessed as Grey only because of recycled content, which is difficult to define. These may be excluded from the plan.
3. Generally, optimization will be done through current suppliers.
    a. The first step in most cases will be to approach the suppliers to inquire if they would be willing to work on optimizing the materials that are purchased from them.
    b. When contacting suppliers, discuss with them the assessment results. Suppliers may also contact the consultants / assessors for further detail if needed, as much of their ingredient information is confidential and cannot be provided.
4. Include a plan timeline.
    a. It is recommended to divide the timeline into near-term optimization (next 1-2 years) and longer-term optimization (> 2 years).
    b. Focus near-term optimization on materials that are most feasible to optimize.
    c. It is acceptable to select only one or two materials to work on in the near term.
5. Include a plan budget.
    a. It is understood that this will be a rough estimate.
    b. Changes to materials may result in increased, decreased, or no change to a material's cost. Indicate what change in cost is expected, if possible.
    c. Any time needed to test potential new materials and staff time to work with suppliers on optimization may also be included in the budget, if significant.
6. **It is required that some optimization progress be made prior to each successive re-application.** Note, however, that X assessed items are allowed at the Basic to Silver levels of certification (excluding carcinogens, mutagens, and reproductive toxins at Silver). Complete phase-out of at least one X assessed item is preferable; however, it may not always be possible to fully substitute materials prior to re-application. Acceptable progress includes:

a. Work has been done towards the goal of fully characterizing materials previously assessed as Grey (i.e., new material ingredient information has been gathered).

b. Research has been completed and documented regarding possible alternative materials, including performance issues, costs, etc.

c. Performance testing has been completed on alternative materials.

7. For products that do not contain any X or Grey assessed materials, it is required that progress be made in other program categories (i.e., Material Reutilization, Renewable Energy and Carbon Management, Water Stewardship, or Social Fairness). See Section 8 (Continuous Improvement and Optimization) for further information.

Required Documentation

A complete strategy or plan addressing all items listed above for each X or Grey assessed material is required. This information may be provided in the form of a table, or as part of the original Bill of Material, with the following column headings: component, assessment, optimization recommendation (from consultants or assessors), opportunity (feasibility or difficulty), action plan including timeline (near term or long term), budget or cost, and progress (for reporting progress at re-application).

3.8 DETERMINING ABSENCE OF CMR SUBSTANCES

Standard Requirement

The product does not contain substances known or suspected to cause cancer, birth defects, genetic damage, or reproductive harm (CMRs) in a form that may result in plausible exposure during the product scenarios evaluated.

Applicable Levels of Certification

This requirement applies to the Silver level of certification and above (Silver, Gold, and Platinum).

Intent

The intent of this requirement is to prevent the use of chemicals that have been identified as CMRs in materials or products. These chemicals are considered to be particularly harmful to humans and wildlife.

Methods

The chemical hazard profiles are used to generate A, B, C, or X assessments and verify that any X assessed materials do not contain a chemical with a single chemical risk score of 'x' as a result of being a carcinogen, mutagen, or reproductive toxicant (CMR).

This requirement shall be interpreted to mean that the 95% or more of the materials in the product that have been assessed as A, B, C, or X do not contain known or suspected CMRs in a form that will result in plausible exposure to humans or the environment during the product scenarios evaluated. Because the A, B, C, X material health assessment methodology incorporates both hazard and exposure considerations, materials containing known or suspected CMRs may receive a C assessment, and thus be allowed for use in a Silver-certified product, if the assessor determined that relevant exposure to those CMRs is not plausible. If the assessor determined that plausible exposure to the CMR may occur as a result of its use in the material, the material receives an X assessment and is not

permitted for use in a Silver-certified product. Further details of the material health assessment methodology are available in a separate document (*Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.1*).

Note that all chemicals, including CMRs, are treated equally in the material health assessment methodology. Generally, the chemicals that are present at concentrations below 100 ppm in each homogeneous material are not subject to review, and the homogeneous materials that are present at concentrations below 100 ppm in a product are not subject to review either. Thus it is possible that CMRs are present in a certified product if they are below the concentration subject to review or are present in a material that is not subject to review. However, if a CMR is in a material, or is one of the chemical types that are subject to review at *any* concentration in the product, it is subject to review (see Section 3.4 for a complete list). When a material assessment is completed, the assessor will report back to the consultant and/or applicant regarding which materials contain these chemicals.

Required Documentation

Chemical hazard profiles are generally not fully documented with reports provided to applicants due to confidentiality reasons. In order to track and verify the presence or absence of CMRs for each homogeneous material, it is suggested that a column be added to the standard Bill of Materials.

3.9 VOLATILE ORGANIC COMPOUND (VOC) EMISSIONS TESTING

Standard Requirement

A product designed for indoor use, or one that could potentially impact indoor air quality, meets Cradle to Cradle Certified™ VOC emissions standards.

Applicable Levels of Certification

This requirement applies to the Gold level of certification and above (Gold and Platinum) and EMCs at all certification levels.

Intent

The intent of this requirement is to ensure that VOCs are not being emitted from products used indoors or products that impact the concentration of VOCs in the indoor environment.

Methods

Indoor-use products are those with intended or likely unintended use scenarios in interior spaces (i.e., inside a building).

Due to the short duration of exposure, consumable indoor products fully designed as biological nutrients (e.g., detergents, personal care products, toilet paper) are not subject to the VOC emissions testing requirement. Furthermore, VOC tests are not required for products that are sold exclusively as material inputs for other products (rather than being sold to the general public).

The VOCs with established Chronic Reference Exposure Levels (CRELs) listed in the California Department of Public Health's (CDPH) Standard Method v1.1-2010 must be included in emissions testing. CREL values are continuously updated by the California Office of Environmental Health Hazard Assessment (see http://oehha.ca.gov/air/allrels.html). If the assessor has reason to believe other

problematic substances may be present in the product (e.g., radioactive substances in granite), these may also be required for testing. Although 4-Phenylcyclohexene is not listed in the CDPH Standard Method v1.1-2010 as of the time of this writing, it must also be included in emissions testing of any carpet or flooring product seeking to fulfill this requirement.

To demonstrate compliance with emissions standards, a product must comply with the following requirements:

1. One of the following test methods to quantify emissions has been used:
    a. ASTM D5116 for small chamber or equivalent.
    b. EU standard.
    c. ASTM D6670 for large chamber or equivalent EU standard.
    d. ANSI/BIFMA M7.1 for office furniture or equivalent EU standard.
    e. ISO 16000 series for VOCs
2. One of the following loading scenarios to quantify emissions has been used:
    a. ANSI/BIFMA M7.1 for office furniture.
    b. California Department of Health Services section 01350 for all other products.
3. Emissions results
    a. VOCs that are considered known carcinogens, endocrine disruptors, mutagens, reproductive toxins, or teratogens are below detection limits (detection limits must be < 9.0 µg/m^3 for formaldehyde and < 2µg/m^3 for all other chemicals).
    b. TVOC must be < 0.5 mg/m^3.
    c. Individual VOCs that would receive an x assessment must be < (0.01) x [the lower of the TLV or MAK value].
    d. The time point used is 7 days for VOCs and IVOCs.
    e. The analytical laboratory used must be ISO 17025 accredited.

These thresholds were designed to reflect those required in the California Department of Public Health's Standard Method v1.1-2010.

Required Documentation

Testing reports, including a description of the samples tested, the analytical methods used, the method detection limits, and laboratory contact information must be submitted to the assessor.

3.10 PROCESS CHEMICALS

Standard Requirement

All process chemicals used during the final manufacturing stage of the product are assessed and none are assessed with an x rating (no GREYs).

Applicable Levels of Certification

This requirement applies to the Platinum level of certification only.

Intent

The intent of this requirement is to ensure that chemicals used in the product manufacturing process do not adversely impact human or environmental health.

Methods

All process chemicals used during the final manufacturing stage of the product are subject to review.

A process chemical is defined as any substance that comes into direct contact with the product or any of its material constituents during any of processes that constitute the final manufacturing stage of the product. It is used as an intentional part of any of these processes to fulfill a specific function or achieve a specific effect in the product or any of its material constituents. Within this definition, process chemicals are limited to pure chemical substances and chemical substances present in a mixture at a concentration of 1,000 ppm or above. Mixtures include liquids, sprays, gases, aerosols, solids, etc. The concentration threshold applies to process mixtures directly as received by the supplier and prior to any dilution that may take place at the manufacturing site(s). This definition does not include maintenance agents for machinery, effluent or wastewater treatment chemicals, chemicals used in steam boilers, or cleaning agents used for the production area, offices, and/or lavatories. Distilled water, tap water, and ambient air in their chemically unaltered state are excluded from the assessment.

The same methodology is applied in assessing process chemicals as for product inputs, although different exposure scenarios will be important to consider. The single chemical risk rating (as a, b, c, or x) must be reported for each process chemical identified. The single chemical risk rating considers the chemical's hazards and exposure via any relevant exposure scenarios determined by the assessor. Note that the assessment must be conducted using the final reacted form of the parent chemical resulting in exposure. For example, if the exposure is via effluent, the assessment must be conducted on the primary hydrolyzed or reacted form of the parent chemical that would appear in the effluent. See the *Material Health Assessment Methodology* document for further details on how the single chemical risk score is determined.

Required Documentation

If applying for the Platinum level in the Material Health category, a list of all process chemicals in the Bill of Materials is required. Indicate under the "generic material" that it is a process chemical. Also report the single chemical risk rating (a, b, c, or x) for each chemical.

4 MATERIAL REUTILIZATION

Eliminate the Concept of "Waste"

A significant focus of Cradle to Cradle® as a product design framework is to promote the creation of an optimized materials economy that eliminates the concept of "waste." This category of the program is intended to create incentives for industry to eliminate the concept of "waste" by designing products with materials that may be perpetually cycled to retain their value. The Program challenges companies to take more responsibility for creating the infrastructure and systems necessary for recovering and recycling materials as the nutrients necessary to fuel our global economies. There are many opportunities for companies to use products as part of the services they offer their customers.

Table 7 lists each requirement within the Material Reutilization category. To achieve a given level, the requirements at all lower levels are to be met as well. The sections that follow provide interpretation and suggested methods for achievement.

Table 7 Material Reutilization Requirements

LEVEL	ACHIEVEMENT
BASIC	Each generic material in the product is clearly defined as an intended part of a biological or technical cycle (this is covered by the Material Health requirement at Basic level; see Material Health guidance in Section 3.2).
BRONZE	The product has a Material Reutilization Score that is ≥ 35.
SILVER	The product has a Material Reutilization Score that is ≥ 50.
GOLD	The product has a Material Reutilization Score that is ≥ 65. The manufacturer has completed a "nutrient management" strategy for the product including scope, timeline, and budget.
PLATINUM	The product has a Material Reutilization Score of 100. The product is actively being recovered and cycled in a technical or biological metabolism.

4.1 MATERIAL REUTILIZATION SCORE

Standard Requirement

The following Material Reutilization Score is required for each certification level:

Bronze level: ≥ 35
Silver level: ≥ 50
Gold level: ≥ 65
Platinum level: 100

Applicable Levels of Certification

This requirement applies to the Bronze level of certification and above (Bronze, Silver, Gold, and Platinum).

Intent

The intent of this requirement is to increase the material reutilization potential of a product determined by using the Material Reutilization Scoring method described below.

Methods

1. For each homogeneous material subject to review (as determined according to the process described in Section 3.1), indicate the recyclable, biodegradable (including compostable), rapidly renewable, and recycled content as percentages. Note that it is not required to have reutilization data for all homogeneous materials subject to review. It is recommended to first gather data on higher weight inputs. Depending on the certification level of interest, gathering data on all homogeneous materials may not be necessary in order to achieve the required reutilization score. Note also that although it is highly recommended, it is not required that recyclable, biodegradable (including compostable), and recycled content be verified by outside sources in order to receive credit.

    a. Recyclable material: A recyclable material is a material that can be recycled at least once after its initial use phase somewhere in the world, at least at the pilot scale, in the intended end-of-use scenario the applicant aspires to, independent of current feasibility and implementation. It does not matter whether the product is likely to be recycled in this way based on current infrastructure and/or the regions in which the product is distributed. (Note: The plan to realize the intended end-of-use scenario is due at the Gold level, and implementation needs to be demonstrated for the Platinum level). The entire material needs be recyclable in order to be counted as recyclable in the Material Reutilization score.

    The material must also be separable under normal recycling conditions, commonly separated in practice by the consumer in order for recycling to occur (e.g., just because it's possible to strip a coating from a material does not mean that the user would commonly do this in practice in order to recycle the material), and/or separated by the manufacturer or contracted third party as part of an active product recovery/take back program. The separability requirement applies only in cases where separation would be necessary in order for recycling to occur. The portion of an EMC that is recyclable once take back has occurred applies.

    Renewably sourced materials that are incinerated to produce energy ('waste to energy') may be counted as recyclable (e.g., polyethylene made from sugar cane) in the Material Reutilization score if the assessor determines that incineration of the material does not lead to problematic by-products (i.e., scrubber technology has been demonstrated to efficiently remove the problematic by-products).

    Note that each homogeneous material counts either as fully recyclable (i.e. with all of its mass) or not. A homogeneous material cannot be partially recyclable. This extends also to single-homogenous material products, which will either be 0 or 100% recyclable. Conversely, biodegradability may be assessed on an individual chemical substance basis for liquid, gel, powder, or paste products.

    b. Biodegradable chemical or material: The OECD defines the appropriate testing methods for determining ready and inherent biodegradability. The entire material needs be biodegradable in order to be counted as biodegradable in the Material Reutilization score. If making biodegradability claims for materials that are not commonly known to be biodegradable, testing should be done according to these, or comparable, methods. Biodegradability of the material must be considered under the conditions of the material's intended end-of-use scenario.

c. Compostable material: A compostable material is a material capable of undergoing biological decomposition in a compost site as part of an available program, such that the material is not visually distinguishable and breaks down into carbon dioxide, water, inorganic compounds, and biomass at a rate consistent with known compostable materials. If making claims on the compostable nature of materials that are not commonly known to be compostable, testing is required according to the appropriate ASTM, ISO, CEN, or DIN standard (e.g., ASTM D6400-04 for plastics). The entire material needs be compostable and be separable from other materials in the product in order for that material to count as compostable in the Material Reutilization score.

   Renewably sourced materials that are incinerated to produce energy ('waste to energy') may be counted as compostable (e.g., wood) in the Material Reutilization score if the assessor determines that incineration of the material does not lead to problematic by-products (i.e., scrubber technology has been demonstrated to efficiently remove the problematic by-products).

d. Recycled material (combined percentage of post- and pre- consumer recycled materials).

   ii. Post-consumer recycled material is a material that has been collected for recycling after consumer use.

   iii. Pre-consumer recycled material is a material that has been collected for recycling prior to consumer use, comes from sources outside of the applicant manufacturer's facility, and has been modified before being suitable for recycling back into a manufacturing process. Waste materials directly incorporated back into the manufacturing process within the applicant facility do not apply.

d. Rapidly renewable material: A rapidly renewable material is a material that is grown and harvested in cycles of less than 10 years. FSC certified wood and wood products may also be counted as rapidly renewable, even if they are grown and harvested in cycles of more than 10 years.

2. In the case of steel parts, if it is not possible to determine the actual percentage of recycled content, the industry-wide average may be used. For other material types where it is not possible to determine recycled content, zero recycled content should be assumed. The following are the industry averages obtained from the Steel Recycling Institute (www.recycle-steel.org; 2010 data) for the basic oxygen furnace method (BOF) and electric arc furnace method (EAF). If the method is unknown, use the lowest value.

   a. BOF: 33.6%

   b. EAF: 89.9%

3. Sum the individual percentages of recyclable and biodegradable (including compostable) materials. This sum equals "% of the product considered recyclable or biodegradable/compostable" in the formula below.

4. Multiply the individual percentages (as proportions; e.g., 50%=0.5) of recycled and rapidly renewable content present within each homogeneous material by the percentage of those materials within the overall product and sum the results. This sum equals "% recycled or rapidly renewable content in the product" in the formula below.

5. Calculate the Material Reutilization Score as follows with percentages entered as proportions:

$$\frac{\left[\begin{matrix}\%\ recycled\ or\ rapidly\ renewable \\ product\ content\end{matrix}\right] + 2\left[\begin{matrix}\%\ of\ product\ recyclable \\ or\ biodegradable/compostable\end{matrix}\right]}{3} \times 100$$

Example: Product X contains 80% recyclable materials and 40% recycled materials

$$\text{Material Reutilization Score} = \frac{[(0.40) * 1] + [(0.80) * 2]}{3} \quad X\ 100 \quad = \quad 67$$

Special Considerations for Calculating the MR Score for Products Containing Water

With the exception of paints (see next section), water weight must be excluded from the product weight when calculating the Material Reutilization score. This means that water does not count as recyclable, biodegradable/compostable, rapidly renewable, or as recycled input, but that it also does not contribute to the denominator when determining the weight fractions of other chemical substances and inputs that do count as recyclable, biodegradable/compostable, rapidly renewable, or as recycled input.

Special Considerations for Calculating the MR Score for Paint and other Wet-Applied Products

How to Calculate Percent Cyclable

General purpose and wall paints and other wet-applied products must be regarded as Biological Nutrients, and are thus assessed based on their safety when released into the biosphere (by erosion, washing, leaching, burning, or similar processes) and their biodegradability. Because such products are formulated, single-material products, the percent biodegradable is not based on the percent of biodegradable homogeneous materials (as for multiple-material products). Instead, the '% biodegradable content' for the MR score is based on the individual product ingredients and must be calculated in the following manner:

1. Sum the percent weight of all substances that are biodegradable in their pure form, as per the relevant OECD (or comparable) tests and definitions.
2. Add the percent weight of water in the product and the percent weight of benign minerals commonly found in surface soils and sediments. Benign minerals are defined as those having a single chemical risk rating of a, b, or c (not x or GREY). Minerals commonly found in soils or sediments are limited to Al-, Ca-, Fe-, Mg-, Mn-, Na-, K-, or Zn-containing silicates, oxides, carbonates, or phosphates that can be commercially derived without chemical alteration from surface soil or sediments (no more than 2 m below the land surface or sea level). If the applicant feels that a non– Al-, Ca-, Fe-, Mg-, Mn-, Na-, K-, or Zn-containing silicate, oxide, carbonate, or phosphate should be counted as a benign soil/sediment mineral, they must submit a request to amend this guidance to the C2CPII.
3. The resulting percentage is used as the % cyclable ('recyclable/biodegradable') content to compute the MR score.

How to Calculate % Rapidly Renewable/Recycled Content

To derive the '% rapidly renewable content' of the product, water weight is excluded (e.g., if the paint is 15% rapidly renewable inputs by weight and 20% water by weight, the % rapidly renewable content used to derive the MR score would be 15% / (100%-20%) = 18.75%).

Required Documentation

For tracking and reporting of recyclable, biodegradable (including compostable), recycled, and rapidly renewable content, it is recommended that additional columns be added to the original Bill of Materials used to report and define homogeneous materials, as described in Section 3.1.

4.2 NUTRIENT MANAGEMENT STRATEGY

Standard Requirement

The company has completed development of a "nutrient management" strategy for the product, including scope, timeline, and budget.

Applicable Levels of Certification

This requirement applies to the Gold level of certification and above (Gold and Platinum).

Intent

The intent of this requirement is to challenge manufacturers to take more responsibility for creating the infrastructure and systems necessary for recovering and recycling materials as the nutrients necessary to fuel our global economies.

Methods

A nutrient management strategy is defined as a process for actively recovering or cycling the technological or biological nutrients in the product in a technical or biological metabolism. Nutrient management strategies will likely be very unique to each product. See Section 4.3 for examples of nutrient management methods.

The following must be addressed in the plan for development of a "nutrient management" strategy:

1. Commencement date of program.
2. Method of recovering, reusing, recycling, or composting individual materials within the product and the product overall.
3. Method of informing customers regarding disassembly of product, if needed.
4. Method of informing customers and the public about the program and access to recycling or other options.
5. Budget allocated to execution of the plan.
6. Initial and future targets and timeline for number of units or volume of materials to be collected and recycled or composted.
7. Recovery and recycling rate data, if available (for municipal recycling, provide average rates).

a. Partners in program (i.e., who will be recycling or composting).

b. Target end-markets for recycled goods.

c. Estimated market value of goods pre-recycling.

Required Documentation

A strategy outline and narrative addressing the points listed above are required.

4.3 NUTRIENT CYCLING

Standard Requirement

The product is actively being recovered and cycled in a technical or biological metabolism.

Applicable Levels of Certification

This requirement applies to the Platinum level of certification only.

Intent

The intent of this requirement is to ensure that manufacturers are actively recovering and recycling the product and thus working towards the goal of eliminating the concept of waste.

Methods

1. Methods of recovering and recycling products that qualify include:

   a. Company-sponsored collection program: The manufacturer has ownership of, and is in direct control of, creating the infrastructure for the recovery and recycling or industrial composting of the product.

   b. Municipal recycling: The product has been designed to be recycled using the municipal recycling systems. One hundred percent of the product's materials can be separated and recycled within municipal systems. Within the U.S. and where not otherwise clearly defined by regulations, the Federal Trade Commission's (FTC) definitions of "recyclable" apply (see FTC GreenGuide). The average recycling rates and references below for the material type(s) must be reported.

   c. Retail-sponsored collection program: A retail organization is partnering with one or more original equipment manufacturers to collect and recycle or compost selected products (e.g., recycling of electronic products through retail outlets).

   d. Manufacturing association-sponsored collection program: The original equipment manufacturers organize a program to collect and recycle or compost selected products.

2. Collect data on the recovery and recyclability or compostability rate at which the materials are managed based on percent of volume of units sold. It should be shown that recovery rates are balanced with use and installation timelines. For example, an architectural installation made of aluminum may be on a building well over 50 years old, but the company has not yet experienced any "recovery" due to the long timeline. Since aluminum is one of the most highly recycled materials, this case is exempt from meeting positive recovery rates. In most cases, however, at least some recovery and recycling must be occurring in order to meet this requirement.

3. Conduct compostability testing for materials that are not generally known to be compostable, if applicable. See Terms and Definitions for the definition of "compostable" and applicable testing standards.

Required Documentation

A description of the product stewardship program used to collect and recycle the product after its first use-phase must be provided. The description must address the points listed above for developing a strategy as required at the Gold level, in addition to the recovery and recyclability or compostability rate in the program. For compostable products, cite the relevant standard and provide test results.

5 RENEWABLE ENERGY AND CARBON MANAGEMENT

Eco-effective energy production

Cradle to Cradle® envisions a future in which industry and commerce positively impact the energy supply, ecosystem balance, and community. This is a future powered by current solar income and built on circular material flows. The Renewable Energy and Carbon Management category is a combination of these core principles of Cradle to Cradle design: *produce and use renewable energy* and *eliminate the concept of waste.* Renewable energy displaces energy produced from fossil fuels, which emit carbon. Changing the quantity and quality of energy used affects the balance of carbon in the atmosphere and ultimately the climate. Ideally, emissions are simply eliminated, and renewable energy is produced in excess to be supplied to local communities. When emissions do occur, they are managed as biological nutrients and balanced with an equivalent uptake by natural systems. If we are to reach the ultimate goal of net positive impact, it is critical to accurately measure energy use and emissions. By obtaining these measurements, we can identify and carry out effective plans for transitioning to renewable energy use, and achieving a balance of carbon in the atmosphere and as food for building healthy soil.

Table 8 lists each unique requirement within the Renewable Energy and Carbon Management category. To achieve a given level, the requirements at all lower levels are to be met as well. The following sections provide interpretation and suggested methods for achievement.

Table 8 Renewable Energy and Carbon Management Requirements

LEVEL	ACHIEVEMENT
BASIC	Annual electricity use and greenhouse gas emissions associated with the final manufacturing stage of the product are quantified.
BRONZE	A renewable electricity use and carbon management strategy is developed.
SILVER	For the final manufacturing stage of the product, 5% of electricity is renewably sourced or offset with renewable electricity projects, and 5% of GHG emissions are offset.
GOLD	For the final manufacturing stage of the product, 50% of electricity is renewably sourced or offset with renewable electricity projects, and 50% of GHG emissions are offset.
PLATINUM	For the final manufacturing stage of the product, >100% of electricity is renewably sourced or offset with renewable electricity projects, and >100% of GHG emissions are offset. The embodied energy associated with the product from Cradle to Gate is characterized and quantified, and a strategy to optimize is developed. At re-application, progress on the optimization plan is demonstrated. ≥ 5% of the embodied energy associated with the product from Cradle to Gate is covered by offsets or otherwise addressed (e.g., through projects with suppliers, product re-design, savings during the use phase, etc.).

5.1 QUANTIFYING ELECTRICITY USE AND EMISSIONS

Standard Requirement

Annual electricity use and greenhouse gas (GHG) emissions associated with the final manufacturing stage of the product are quantified.

Applicable Levels of Certification

This requirement applies to the Basic level of certification and above (Basic, Bronze, Silver, Gold, and Platinum). Annual electricity use and GHG emissions associated with the final manufacturing stage of the product must be re-calculated at re-certification.

Intent

The intent of this requirement is to assist manufacturers with understanding their baseline electricity use and GHG emissions.

Methods

1. Conduct a facility-level audit of electricity use and GHG emissions for all facilities involved in final manufacturing stage processes as follows:

    a. The electricity use and GHG emissions calculations must pertain to the final manufacturing stage of the product only, rather than to all of the product-relevant processes at the facility. The intent of this is to establish an even playing field for manufacturers with varying levels of vertical integration and to measure electricity used for similar processes. Processes that are considered to represent the final manufacturing stage by product category can be found in the Final Manufacturing Stage Guidance document, which is subject to periodic review based on assessor and applicant feedback. Please contact certification@c2ccertified.org if your product category is not represented or if you have comments regarding the listed processes.

    b. Calculate the amount of electricity used, including the percent on-site renewables and the percent renewables purchased from the grid and/or compliant renewable energy certificate (REC) sources. Note that if heat is purchased directly from a utility, include it in the calculations for GHG emissions (see next section). Also note that overhead operations, including facility air conditioning and lighting, may be considered non-attributable (see the Greenhouse Gas (GHG) Protocol Product Standard for detail). Even so, if it is not possible to separate these from the total, they may be included. Electricity use must be reported in terms of kilowatt hours (kWh).

    c. Calculate total carbon equivalent emissions from GHG emissions associated with the final manufacturing stage of the product. The GHG emissions in scope for this requirement are those that are (1) emitted directly during the product's final manufacture or on-site treatment of process wastes or (2) associated with purchased heat. GHG emissions associated with electricity generated off-site are out of scope. Be sure to include all on-site fuel uses such as gasoline for transport vehicles, propane, etc. when attributable to the product. If transport vehicles are used during the final manufacturing stage of the product, whether owned by the company or not, the emissions from the fuel used for the vehicles must be included in the total emissions calculation. Also be sure to include any relevant product-attributable, non-electricity-related emissions, such as methane from water treatment ponds, fugitive emissions from refrigerants, and/or carbon dioxide from cement production. Select a widely recognized method and guidance when calculating emissions. Appropriate references include GHG

Protocol Product Standard and the Intergovernmental Panel on Climate Change (IPCC). GHG emissions must be reported in terms of carbon dioxide equivalents (tCO_2e).

d. Allocate electricity and GHG emissions to the applicant product(s) (see definition of product-attributable processes in Chapter 7 of the GHG Protocol -- Product Life Cycle Accounting and Reporting Standard[1]). Select the most appropriate method for the product(s) under review. For example, if products are of similar weight across SKUs, a weight allocation is appropriate.

e. An applicant must work with their accredited assessment body to obtain the appropriate template for quantifying the product-allocated electricity use and emissions.

2. In addition to the requirements and questions described above and below, the following questions will help in evaluating whether all relevant GHG emissions sources have been accounted for and aid in making judgments about data accuracy:

   a. Have fugitive emissions been accounted for? These are emissions due to storage leaks or machinery leaks. In the case of refrigerants, this may be accounted for based on the amount of recharge required.

   b. Does the company own any vehicles that are directly relevant to product manufacture or transport? For transport using company-owned vehicles, if driving distances were employed in estimating emissions (as opposed to actual fuel use), was actual driving distance available, or was distance estimated based on straight line or shortest route distances? How does this estimate compare with actual distance?

   c. Does the company conduct on-site wastewater treatment relevant to the product? Has this been accounted for?

   d. Are other process-relevant GHG emissions of concern (e.g., in cement manufacture)?

   e. What reference sources have been used in selecting the emissions factors?

Required Documentation

Record the information listed below for each facility at which the product undergoes final manufacturing (see above for more information on determining the final manufacturing stage/processes).

1. Facility name.
2. Country and region.
3. Utility name.
4. Renewable electricity purchased (delivered) through utility. Note: This is not the same as the average utility or regional grid mix. The applicant may only claim renewable electricity that is delivered to them through renewable energy pricing programs, or assurance that claims to the use of renewable electricity in the utility mix may be made by customers of the utility.
5. Total amount of electricity required for the final manufacturing stage of the product in terms of kWh.
6. Total amount of GHG emissions generated for the final manufacturing stage of the product in terms of tCO_2e.
7. Total amount of renewable electricity generated on site for the final manufacturing stage of the product in terms of kWh.

8. Date range of data (calendar or fiscal year are acceptable).
9. Data source (e.g., utility bills and receipts; if other data source, please describe).
10. Indicate the GHGs that are included in this inventory. Note that carbon dioxide is to be included at a minimum. The widely used GHG Protocol stationary combustion tool also includes methane and nitrous oxide in totals.
11. Indicate and describe the method used to allocate electricity use and GHG emissions to the production of the applicant product (e.g., percentage of total production weight or volume).
12. Indicate and describe the method used to allocate electricity use and GHG emissions to the final manufacturing stage of the product.
13. Indicate guidance and/or tools used (e.g., GHG Protocol, Stationary Combustion Tool, etc.).
14. Supporting documents such as Excel worksheets from the GHG Protocol and electricity use bills may be provided and/or requested as well. These will allow the assessor to evaluate data quality and completeness.

5.2 RENEWABLE ELECTRICITY AND CARBON MANAGEMENT STRATEGY

Standard Requirement

A renewable electricity use and carbon management strategy is developed.

Applicable Levels of Certification

This requirement applies to the Bronze level of certification and above (Bronze, Silver, Gold, and Platinum).

Intent

The intent of this requirement is to challenge manufacturers to develop a strategy that not only increases renewable electricity use and reduces GHG emissions, but also achieves the ultimate goal of using > 100% renewable electricity and closing the carbon cycle for the final manufacturing stages of the product.

Methods

1. The strategy must cover facility-level electricity use and GHG emissions for at least the final manufacturing stage of the product.
2. The following should be included in a renewable electricity and carbon management strategy:
    a. Methods that are and/or will be employed to use renewable electricity and manage GHG emissions, including a description of whether the focus is on installation of renewables, absolute reductions (i.e., improved energy efficiency measures), and/or intensity initiatives (e.g., efficiency improvements defined as reductions in emissions normalized by total production), or carbon sequestration projects.
    b. Quantitative targets and timeline, including dates that individual initiatives went or will go into effect.

c. Progress made to date and what change in absolute emissions can be attributed to integration of renewables or efficiency improvements. If no progress has been made, explain why.

d. Budget allocated to execution of the plan.

Required Documentation

A strategy outline and narrative addressing the points listed above are required.

5.3 USING RENEWABLE ELECTRICITY AND ADDRESSING GREENHOUSE GAS EMISSIONS

Standard Requirement

A percentage of the electricity is renewably sourced or offset with renewable energy projects, and the same percentage of GHG emissions are offset. This requirement applies only to the electricity use and GHG emissions associated with the final manufacturing stage of the product.

The following percentages are required for each certification level:

Silver level:	5%
Gold level:	50%
Platinum level:	> 100%

Applicable Levels of Certification

This requirement applies to the Silver level of certification and above (Silver, Gold, and Platinum).

Intent

The intent of this requirement is to encourage manufacturers to participate in the demand for renewable electricity with the goal of producing > 100% renewable electricity for a product. With only a baseline investment in renewable electricity, subsequent energy efficiency measures may increase the percentage of overall renewable electricity use, thereby incentivizing efficiency as a path to effectiveness. The intent of the following methods is to designate appropriate strategies for making valid claims to renewable electricity generation, and appropriately managing GHG emissions.

Methods

Using Renewable Electricity

1. Calculate the annual electricity use associated with the final manufacturing stage of the product based on data from the previous year. If there is reason to expect that electricity consumption will be much higher in the subsequent year or for new products, different methods will have to be applied. For example, if it is known that there will be a significant increase in production volume for an existing product, the allocated electricity consumption and production volume estimates should be employed to estimate the total amount of electricity required for the coming year. Estimates for new products may be based on allocated electricity consumption estimates for existing products of similar type.

2. Note that renewable electricity that is already a standard part of the grid mix does not count toward this requirement unless the applicant is participating in a voluntary green pricing program or the applicant has verified that their utility is delivering renewable electricity that may be claimed by the utility customer without being double-counted elsewhere in the system.

Renewable electricity used as part of direct power purchase agreements (PPAs) with renewable energy producers may count toward the requirement as long as the purchased energy is derived from a source among those eligible (solar, wind, hydropower, biomass (when not in competition with food supplies), geothermal, and hydrogen fuel cells) and the associated attributes of renewable-based generation are also transferred as part of the purchase agreement and not claimed or counted elsewhere (i.e., sold to a third party in the form of RECs).

3. *On-Site Renewables:* Calculate the percentage of on-site renewable electricity generation as a proportion of the overall electricity attributed to the final manufacturing stage of the product based on data from the previous year. To meet the renewable electricity use requirement for a particular level, the remaining percentage of renewable electricity must be compensated for by the purchase of RECs or offsets.

4. *Unbundled Renewable Energy Certificates (RECs)*: If purchasing unbundled RECs to compensate for the percent of renewable electricity required, the RECs must be from voluntary programs (as opposed to compliance programs). In the U.S., Green-e RECs must be purchased. Outside the U.S., the use of equivalent, verified RECs is appropriate. It is important to ensure that RECs are not double-counted and the applicant has valid claim to the use of the renewable electricity attribute provided.

5. *Offsets supporting Renewable Energy*: Registered carbon offsets that support renewable energy projects may be used in place of RECs for electricity; however, in this case the electricity needs to be converted to metric tons CO_2 equivalents (tCO_2e) using the utility or regional grid electricity mix (this is referred to as the 'Alternative Energy Inventory' in the templates). Renewable electricity in a grid or regional mix will result in lower emissions overall, so that the amounts of offsets are less than if electricity was produced from fossil fuel sources.

    a. NUCLEAR POWER: When using carbon offsets in place of RECs for electricity to meet the renewable electricity requirement ('Alternative Energy Inventory'), the emissions value that the required offset amount is based on needs to be adjusted for the share of nuclear power in the electricity mix. For all electrical sources, calculate the amount of CO_2e attributed to nuclear power by using the average CO_2 emissions from coal. This is done because compared to energy from other fossil fuels, nuclear power is responsible for very low to zero greenhouse gas emissions, particularly when the supply chain is not considered. However, nuclear power is not a renewable source of electricity and the low CO_2 emissions would be an undue advantage to any manufacturer purchasing offsets for this requirement. As the environmental and human costs of nuclear energy are immeasurably high, an adjustment is made to the total GHG emissions prior to offset purchase. (Note: In most cases the conversion of electricity produced from nuclear energy to emissions is not necessary because this electricity may be treated like other non-renewable electricity sources and compensated for via the purchase of RECs.)

        i. Using data from the World Nuclear Association (http://world-nuclear.org), calculate the nuclear multiplier based on the country where each final manufacturing facility is located with the following formula: (Percent of Nuclear*891 grams CO_2e/kWh)/(1,000,000 g/ton). Be sure to enter the percentage as a proportion (e.g., 10%=0.1). The assumed emissions rate for electricity produced from coal is 891 g/kWh (value is from http://world-nuclear.org). The following website lists the most recent values for the percentage of nuclear shares of electricity generation: http://world-nuclear.org/info/Facts-and-Figures/Nuclear-generation-by-country/. Multiply the total *product-allocated* electricity by the nuclear multiplier and add this to the total *product-allocated* CO_2e, making sure all

units are in metric tons. The Excel-based worksheet made available to assessors by the Cradle to Cradle Products Innovation Institute for the collection of Energy and emissions data includes up-to-date nuclear values and the formula for adjusting emissions associated with electricity when conducting the Alternative Energy Inventory.

ii. Optional: It is allowable to use more local electricity mix information than national grid data. The formula remains unchanged in this case: (Percent of Nuclear*891 grams CO_2e/kWh)/(1,000,000 g/ton).

iii. Multiply total metric tons CO_2e, including nuclear carbon conversion, by the desired offset percentage to determine the amount of offsets that should be purchased.

6. For electrical sources, the carbon offset project types listed below (as defined by CDM methodologies) are recommended. Carbon credits generated by hydropower projects will ideally be offset using the Gold Standard to provide assurance that the environmental and community impacts have been accounted for and will be continually monitored.

   a. AM0019: Renewable energy projects replacing part of the electricity production of one single fossil fuel-fired power plant that stands alone or supplies to a grid, excluding biomass projects.

   b. AM0026: Methodology for zero-emissions grid-connected electricity generation from renewable sources in Chile or in countries with merit order-based dispatch grid.

   c. AM0052: Increased electricity generation from existing hydropower stations through decision support system optimization.

   d. AM0072: Fossil fuel displacement by geothermal resources for space heating.

   e. AMS-I.A.: Electricity generation by the user.

   f. AMS-I.B.: Mechanical energy for the user with or without electrical energy.

   g. AMS-I.C.: Thermal energy production with or without electricity.

   h. AMS-I.D.: Grid-connected renewable electricity generation.

   i. AMS-I.F.: Renewable electricity generation for captive use and mini-grid.

   j. ACM0002: Consolidated baseline methodology for grid-connected electricity generation from renewable sources.

<u>Addressing GHG Emissions</u>

For emissions originating from non-electrical resources (e.g., on-site natural gas, propane for forklifts, process emissions), projects supporting the sequestration of carbon into forests or soil or other carbon offset strategies are accepted. RECs are not appropriate for these emission types.

1. Calculate the annual GHG emissions associated with the final manufacturing stage of the product based on data from the previous year. On-site emissions must be calculated in terms of CO_2e and based on the emissions factor of the purchased fuel. GHG emissions that have been captured through carbon capture and storage or processes that sequester carbon in the product are not included in the emissions total. To meet the offset requirement for a particular level, the given percentage of emissions must be compensated for by the purchase of offsets or via use of renewables such as biomass (i.e., the given percentage of emissions must be compensated for by

the purchase of offsets, but the purchase of offsets for emissions resulting from the combustion of eligible renewable fuels, such as biomass, is not required).

Emissions from renewable fuels must be tracked and reported during the certification process; however, the emissions generated by eligible renewable fuels will not be included in the final quantity of direct on-site emissions for which offsets need to be purchased at the Silver level and above. By using eligible renewable fuels exclusively, it is thus possible to meet the Silver, Gold, and Platinum requirements without the purchase of offsets, since all direct on-site emissions from non-renewable sources will have been avoided (provided there are no other product-attributable greenhouse gas emissions during final manufacture). Similarly, no offsets need to be purchased if the final manufacture of a product does not generate any direct on-site emissions of greenhouse gases.

Eligibility of renewable fuels for this purpose is determined based on the definitions in Section II.A 5 in Appendix D of the Green-e National Standard. Renewable fuels that are not covered by the types (woody waste, agricultural crop residue, animal and other organic waste, certain energy crops, landfill gas and wastewater methane) and definitions in Section II.A 5 in the Green-e National Standard may be eligible, subject to a case-by-case review by C2CPII. The methodology presented to C2CPII must demonstrate that the eligible emissions are derived from the combustion of a fuel that can be considered renewable in accordance with the general definitions provided by Green-e. Additionally, it should be demonstrated that across its entire lifecycle, the qualifying fuel is expected to have a favorable impact on atmospheric greenhouse gas concentrations in terms of CO_2 equivalents.

2. To purchase offsets, navigate to the Verified Registry website of choice to set up an account and make a purchase. Offsets must be fully retired in a third party registry to meet this requirement. Below is a partial list of recommended registries.
   a. Clean Development Mechanism (CDM): http://cdm.unfccc.int/Registry/index.htm.
   b. Climate, Community, and Biodiversity: http://www.climate-standards.org/index.html.
   c. Verified Carbon Standard: http://www.vcsprojectdatabase.org/.
   d. Gold Standard: http://goldstandard.apx.com/index.asp.
   e. Green-e Climate Certified Carbon Offsets procured from an offset provider/retail seller or carbon credits procured directly from an offset project (or through a broker) certified by a Green-e Climate Endorsed Program: http://www.green-e.org.
3. There are some projects that do not take into account the surrounding natural resources and often can have adverse negative effects on humans and the environment. These projects will not be considered acceptable in the Cradle to Cradle Certified™ Products Program, although they may be verified carbon offsets. For non-electrical sources, it is recommended to avoid the following project types: carbon sequestration in the ocean, clean coal, methane sequestration, and any others that do not align with Cradle to Cradle®.
4. If it is determined that excess offsets or RECs were purchased in the prior year due to use of estimates, the excess may be credited toward the amount to be purchased at the next re-

application. If it is determined that insufficient offsets or RECs were purchased in the prior year, this is to be made up at the next re-application.

5. If a percentage of the facility's electricity use and GHG emissions is compensated for with renewable electricity use or offsets, that percentage may be claimed for all certified products produced at that facility. If renewable electricity or offsets compensate for the production of only the product being assessed for certification, those purchases may not be claimed for any other products.

Required Documentation

It is recommended to use the data template provided by a Cradle to Cradle Certified accredited assessment body to calculate electricity use and GHG emissions, and to track on-site renewable electricity, REC purchases, and offsets.

1. Update electricity use and emissions calculations performed at the Basic level with the most current prior year data. If electricity consumption and/or emissions are expected to change significantly, include estimates for the upcoming two years.
2. If converting electricity to CO_2e, report country, nuclear share, multiplier, nuclear carbon conversion, and total CO_2e, (nuclear carbon conversion + total product-allocated CO_2e calculated initially).
3. Report sources of on-site renewable electricity and annual generation attributable to the final manufacturing stage of the product.
4. Indicate the amount and percentage of RECs purchased, including registry and/or retailer.
5. If converting electricity to CO_2e, indicate the amount and percentage of carbon offsets purchased to offset electricity. Provide the name of the offset registry, project, and project description.
6. Indicate the amount and percentage of carbon offsets purchased to offset emissions. Provide the name of the offset registry, project, and project description.
7. Provide receipt of purchase for offsets and/or RECs as provided by the issuing body.
8. At re-application, indicate and make up for any differences between amounts of offsets and RECs purchased in the prior year as compared to actual emissions estimates for that year.

5.4 EMBODIED GHG EMISSIONS

Standard Requirement

The embodied greenhouse gas (GHG) emissions associated with the product from Cradle to Gate (i.e., up to final manufacturing stage) are characterized and quantified, and a strategy to optimize is developed. At re-application, progress on the optimization plan is demonstrated.

Applicable Levels of Certification

This requirement applies to the Platinum level only.

Intent

The intent of this requirement is to assist a manufacturer with understanding the impacts of energy use associated with their supply chains, which can be significant in many cases. Also, the intent is to honor the importance of a product's GHG emissions throughout its lifecycle and encourage the

development of a strategy to continuously improve beyond where a manufacturer has direct influence in the final manufacturing process.

Methods

1. Inventory carbon equivalent GHG emissions from resource extraction to production (applicant's gate) using primary and/or secondary data for input materials. Primary data are defined as those collected directly from suppliers and secondary data are published data that are aggregated to the material level. The use of primary data is ideal because it creates the most accurate energy and emissions profile associated with a product, but it is more resource-intensive. Secondary data for material types are more readily available as part of life cycle analysis (LCA) software or other online tools and datasets, but do not account for optimization efforts in a unique supply chain. Conducting a full life-cycle emissions inventory and analysis, including storage and transport, use, and recycling phases, is encouraged, but not required. Note that a variety of methods will be considered acceptable for fulfilling this requirement, as long as the methods are reported and described in detail. The importance is not on the detail of the study, but full disclosure of the methods used.
2. The inventory threshold is left to the applicant to determine and define as part of the boundary and scope decision; however, at a minimum, all inputs representing 1% or more of the product's total inputs must be included. Ideally, all inputs will be included, as it is difficult to know until data are gathered whether they will contribute significantly to total emissions or not. For guidance, refer to a widely recognized methodology such as the GHG Product Lifecycle Standard or PAS 2050.
3. The following should be included in a strategy to optimize the embodied energy of a product from Cradle to Gate.
    a. Identify the highest-impact emissions sources in the supply chain and develop an outreach strategy to identify renewable electricity and carbon management strategies already in place and opportunities for optimization.
    b. Methods that are and/or will be employed to use renewable electricity and manage GHG emissions among high-impact supply chain actors, including a description of whether the focus is on installation of renewables, absolute reductions (i.e., improved energy efficiency measures), and/or intensity initiatives (e.g., efficiency improvements defined as reductions in emissions normalized by total production), or carbon sequestration projects.
    c. A timeline including dates that outreach activities or initiatives went or will go into effect.
    d. Progress made to date and what change in absolute emissions can be attributed to integration of renewables or efficiency improvements. If no progress has been made, explain why.
    e. Budget allocated to execution of the plan.

Required Documentation

It is recommended to report the following information, at a minimum (taken from the GHG Protocol Product Standard, Chapter 14). Other product-relevant embodied energy standards may be used, as long as methodology, information source, scope, and boundary are reported.

1. Inventory Information (14.1.1)
    a. Product name and description.

b. Goal of inventory.

c. Product rules or guidance that influenced boundary set methodology choice, allocation procedures, data collection sources, and software system used.

2. Scope (14.1.2)
   a. Unit of analysis and reference flow.
   b. Flow diagram.
3. Boundary of Inventory (14.1.3)
   a. Assumptions made.
   b. Methodology choice (i.e. Cradle to Gate, Use, End-of-Life, Cradle to Grave).
4. Allocation Method (14.1.4)
5. Data Information Used (14.1.6)
   a. Primary data (% of total emissions).
   b. Secondary data (% of total emissions).
   c. Sources.
6. Inventory Results (14.1.7)
   a. Total CO_2e per unit of analysis.
   b. Percent of total CO_2e attributed to each life cycle stage (if applicable).
   c. Global warming potential metric(s) used and description of the source.
7. Use of Results
   a. Describe the significance of inventory results.
   b. How will it be used to educate internal or external stakeholders appropriately?

5.5 ADDRESSING EMBODIED ENERGY USE WITH OFFSETS OR OTHER PROJECTS

Standard Requirement

At least 5% of the embodied energy associated with the product from Cradle to Gate is covered by offsets or otherwise addressed (e.g., through projects with suppliers, product re-design, savings during the use phase, etc.).

Applicable Levels of Certification

This requirement applies to the Platinum level only.

Intent

The intent of this requirement is to begin to address embodied energy impacts of production that occur upstream of final manufacture, as these impacts may be significant sources of emissions.

Methods

1. It is necessary to first estimate embodied energy from Cradle to Gate, as described in Section 5.4.
2. The most likely method of managing embodied energy emissions is through the purchase of offsets. Other project types that will be considered for this requirement include, but are not limited to, projects with suppliers, product re-design, and savings during the use phase.

Required Documentation

1. Supporting documentation showing how total emissions were calculated (see the Required Documentation section in Section 5.4).
2. If carbon offsets are used, quantity of offsets purchased, name of offset registry and project, receipt of purchase, and certificate from the issuing body.
3. For project types other than offset purchase, documentation clearly showing reductions or sequestration should be provided.

6 WATER STEWARDSHIP

Treating Clean Water as a Valuable Resource and Fundamental Human Right

Water stewardship creates awareness and drive towards the treatment of water as a valuable resource by encouraging effective management and use strategies. Every product manufacturer has an important responsibility to care for this vital resource, and would be wise to effectively manage water resources. These goals are addressed within the program by encouraging an understanding of, and responsibility for, water withdrawals, consumption, and releases within local ecosystem(s), and awarding innovation in the areas of conservation, quality, and social fairness.

lists each unique requirement within the Water Stewardship category. To achieve a given level, the requirements at all lower levels must be met as well. The sections to follow will provide interpretation and suggested methods for achievement.

Table 9 Water Stewardship Requirements

LEVEL	ACHIEVEMENT
BASIC	The manufacturer has not received a significant violation of their discharge permit within the last two years. Local- and business-specific water-related issues are characterized (e.g., the manufacturer will determine if water scarcity is an issue and/or if sensitive ecosystems are at risk due to direct operations). A statement of water stewardship intentions describing what action is being taken for mitigating the identified problems and concerns is provided. At re-application, progress on action plans is demonstrated.
BRONZE	A facility-wide water audit is completed.
SILVER	Product-related process chemicals in effluent are characterized and assessed. OR Supply chain-relevant water issues for at least 20% of Tier 1 suppliers are characterized and a positive impact strategy is developed (required for facilities with no product-relevant effluent).
GOLD	Product-related process chemicals in effluent are optimized (chemicals identified as problematic are kept flowing in systems of nutrient recovery; effluents leaving facility do not contain chemicals assessed as problematic). OR Demonstrated progress on the strategy developed for the Silver level requirements (required for facilities with no product relevant effluent).
PLATINUM	All water leaving the manufacturing facility meets drinking water quality standards.

6.1 REGULATORY COMPLIANCE FOR EFFLUENT

Standard Requirement
The manufacturer has not received a significant violation of their discharge permit related to the final manufacturing stage of the applicant product within the last two years.

Applicable Levels of Certification
This requirement applies to the Basic level of certification and above (Basic, Bronze, Silver, Gold, and Platinum).

Intent
The intent of this requirement is to ensure, to the extent possible, that the product-relevant effluent discharged by manufacturing facilities does not degrade surface waters.

Methods
1. If the applicant is subject to well-developed and enforced regulations pertaining to effluent quality, the requirement is fulfilled if their facility has not received a significant violation of their discharge permit (related to the applicant product's manufacture) within the last two years (provided appropriate documentation is provided; see below). In the U.S., a manufacturer must not have been in "Significant Noncompliance" as defined in Title 40 Part 403.8(f) (2) (viii) of the U.S. Code of Federal Regulations, unless the violation was administrative. In other countries, the manufacturer must be in compliance with the equivalent regulation applicable to industrial or manufacturing facilities.
2. If there are no local regulatory requirements or regulations are poorly enforced, and the applicant's facilities discharge either process or sanitary effluent to surface waters, the applicant must develop an effluent management system, including analytical testing protocols, to meet contaminant threshold requirements specific to their business. The management system should be in place and within developed threshold compliance prior to certification.

Required Documentation
The following information must be provided to the assessor:

1. A qualitative description of how effluent is managed.
2. If applicable, a signed statement from the applicant stating that the facility or facilities at which the product is manufactured are subject to well-developed and enforced regulations pertaining to effluent quality and have not been subject to any significant product-relevant discharge violations in the past two years. If a significant discharge violation has occurred in the past two years at any final manufacturing stage facility, the applicant must demonstrate that it was due to processes unrelated to the final manufacture of the applicant product(s). This will require additional work to first document the reason for the violation, and then trace the source of that problem to show it was unrelated to the applicant product.
3. The required documentation to demonstrate regulatory compliance must be submitted with each application for certification, including recertifications. Note that an exception to this requirement is granted if the applicant provided a compliance statement to the assessor within the last 90 days (e.g., with a certification application for a different product manufactured at the same site).

If the final manufacturing stage of a product occurs at more than one facility, a regulatory compliance statement for each facility is required for certification. A single manufacturing site not meeting the requirement will result in the requirement not being met for the product applying for certification.

If the applicant is required to obtain permits and conduct periodic testing of effluent, the following may assist in determining if well-developed and enforced regulations pertaining to effluent cleanliness are in place:

a. Results of any required tests for biological oxygen demand (BOD), chemical oxygen demand (COD), total organic carbon (TOC), total suspended solids (TSS), ammonia as N, temperature, and pH.

b. A list of all chemicals known to be released to the biosphere via effluent discharges by chemical name and Chemical Abstract Service Registry Number (CAS #), including maximum and average allowable release limits by concentration and mass. The assumption is that this list will primarily, if not only, represent chemicals that are declared and tracked under existing permitting processes.

c. Reasons for the presence of the contaminants, an indication of which contaminants are currently covered by any required permits, and which discharges must be remediated prior to release to the publicly owned treatment works (POTW) or open water.

d. A description of any pre-treatment methods used to manage these contaminants.

e. A description of the analytical testing performed on water discharges that is required or conducted on a voluntary basis, including sample collection methods and analytic test methods for each contaminant.

f. An indication of which effluent chemicals are related to production of the applicant product or products.

3. If untreated or unregulated process and/or sanitary water is released to open water, the applicant is required to develop an effluent management system prior to certification. Required documentation includes a description of the rationale behind the plan, the reasons for selecting particular contaminants of concern, complete analytical testing protocols used to meet contaminant thresholds, and references indicating the basis for the plan, so that the plan's comprehensiveness and effectiveness can be evaluated by the assessor.

6.2 LOCAL AND BUSINESS-SPECIFIC WATER ISSUES

Standard Requirement

Local and business-specific water-related issues are characterized (e.g., the manufacturer will determine if water scarcity is an issue and/or if sensitive ecosystems are at risk due to direct operations).

Applicable Levels of Certification

This requirement applies to the Basic level of certification and above (Basic, Bronze, Silver, Gold, and Platinum).

Intent

The intent of this requirement is to assist the manufacturer with understanding the water-related issues near their facility and encouraging them to consider their potential impact on these issues.

Methods

1. Identify the watershed, drainage basin, or catchment in which relevant facilities are located, and list the major demands and stressors on water sources within the catchment (e.g., industrial, agriculture, ecosystems, municipal). Suggested references for finding this information include U.S. EPA Surf Your Watershed, World Business Council for Sustainable Development (WBCSD) Global Water Tool, and local governmental and non-governmental organizations focusing on water.
2. Determine if relevant facilities are located in areas where water resources are scarce or stressed. Suggested references include the WBCSD Global Water Tool and scarcity/stress categories therein and UN Aquastat.
3. Determine if relevant facilities are located in areas where significant portions of the population (i.e., greater than 10%) do not have access to fresh or clean water and improved sanitation. Suggested references for finding this information include the WBCSD Global Water Tool and access categories therein, UN Aquastat, WHO/UNICEF Joint Monitoring Programme for Water Supply and Sanitation, and the Social Hotspots Database.
4. Determine if relevant facilities are adjacent to impaired waterways, endangered wetlands, or water bodies seriously impacted by eutrophication (i.e., a process where water bodies receive excess nutrients that stimulate excessive plant growth). Suggested references for this information include the U.S. EPA list of impaired waterways, WRI interactive global map of eutrophication and hypoxia, and Ramsar Listed wetlands.
5. Describe any additional water-related issues that are relevant to the applicant's industry, business, or location and are not covered above. This should include both direct and indirect impacts, such as problems with POTW overflow or specific effluent quality issues relevant to the industry. References for this information include local government and non-governmental organizations focusing on water, and industry associations.

Required Documentation

The information listed below, including the data sources used, must be provided to the assessor. Include ratings where applicable (e.g., the Global Water tool provides red to green ratings for access to improved sanitation). The Global Water Tool may be provided as supporting documentation.

1. Watershed or catchment name.
2. Major water sources within the catchment.
3. Major demands on sources.
4. Scarcity/stress level.
5. Access to improved water (% of population) and risk category (SHdb) or rating (WBCSD).
6. Access to improved sanitation (% of population) and risk category (SHdb) or rating (WBCSD).
7. Impaired waterway, endangered wetland, or water bodies impacted by eutrophication, if any.
8. Other issues.

6.3 WATER STEWARDSHIP INTENTIONS

Standard Requirement

A statement of water stewardship intentions describing actions being taken for mitigating identified problems and concerns is provided. At re-application, progress on any action plans is demonstrated. Note: the "identified problems and concerns" mentioned here are those identified in the section above covering Local and Business-Specific Water Issues.

Applicable Levels of Certification

This requirement applies to the Basic level of certification and above (Basic, Bronze, Silver, Gold, and Platinum).

Intent

The intent of this requirement is to challenge manufacturers to develop an innovative plan for mitigating the water-related issues previously identified.

Methods

The following must be provided to the assessor for each local and business-specific water issue identified:

1. A description of what is already being done toward mitigating the identified issue.
2. An action plan for how each issue will be addressed in the future, including:
    a. A statement of intent and commitment.
    b. Measurable goals and timeline.
    c. A plan to address high or very high risk/opportunity categories (Social Hotspot Database) and red ratings (WBCSD Global Water Tool).
3. At re-application, a report on progress made against the action plan(s) developed at the initial certification. Progress on the plan(s) is required if local and business-specific issues that had not already been fully addressed were identified at the initial certification.

Required Documentation

Provide a strategy outline and narrative addressing the points listed above.
At re-application, provide the original plan and report progress on each individual action item.

6.4 WATER AUDIT

Standard Requirement

A facility-wide water audit is completed.

Applicable Levels of Certification

This requirement applies to the Bronze level of certification and above (Bronze, Silver, Gold, and Platinum).

Intent

The intent of this requirement is to assist manufacturers with understanding the amount of water used to manufacture the product and identifying opportunities for reduction in use.

Methods

Conduct a facility-wide water audit that includes the following information:

1. Total withdrawals by source, including water body type and name. Include all direct withdrawals and purchased municipal water. Be sure to include all water inputs, including those used in support of the facility (e.g., landscaping, sanitary use). Report each input and withdrawal in units of total volume per year. If possible, identify the ultimate sources of purchased municipal water.
2. Rainwater collection systems (total annual volume and percentage of total withdrawals).
3. Water recycling and reclamation systems (total annual volume and percentage of total withdrawals).
4. Quantification of effluent discharge into receiving water body or POTW.
5. Flow diagram illustrating facility inputs and outputs.
6. Total consumption per year due to evaporation and/or incorporation into the product.

   Consumption = Total Withdrawals – Total Discharge (include units/year)

   Consumption includes all water that evaporates during production processes, is incorporated into products, or is not returned to the source catchment.
7. Detail regarding use (e.g., process, cooling, landscaping, sanitary, etc.). A breakdown by specific use within the facility is not required, although it is encouraged.
8. **Optional** - Identification of areas in which water of lower quality could be used, with the goal of increasing recycling, is encouraged.
9. **Optional** - Allocate facility-level data to the applicant product or products using the most appropriate method. For example, if products are of similar weight across SKUs, a weight allocation is appropriate. If products are not of similar weight across SKUs, product value or volume may be appropriate. Indicate the method used to allocate water use to the production of the applicant product.

Useful references for obtaining the above information include the WBCSD Global Water Tool, GEMI, Carbon Disclosure Project – Water, and GRI water indicators.

Required Documentation

Provide facility-level data as outlined above for the most recent calendar or fiscal year. If the product is produced in multiple facilities, including contract manufacturing facilities, provide data separately for each facility. An applicant must work with their accredited assessment body to obtain the appropriate template for conducting the water audit. Many of the required data fields are also contained within the WBCSD Global Water Tool. A completed WBCSD workbook may be provided as backup documentation.

Add rows to the table if relevant source and receiving water bodies are not included. For example, if water is withdrawn and/or discharged to more than one surface water body, add an additional row and collect data for each water body separately. The addition of rows to break out totals by use (e.g.,

process, cooling, etc.) may also be useful. It may be preferable to transfer the table into an Excel spreadsheet so that calculations can be automated.

6.5 CHARACTERIZING AND ASSESSING PRODUCT-RELATED PROCESS CHEMICALS IN EFFLUENT

Standard Requirement

Product-related process chemicals in effluent are characterized and assessed, or product-related process chemicals are not discharged to water systems because wastewater is kept flowing in systems of nutrient recovery.

Applicable Levels of Certification

This requirement applies to the Silver level of certification and above (Silver, Gold, and Platinum) and is one of two options at the Silver level. To reach the Silver level or higher, applicants with product-relevant wastewater must pursue this requirement, with two exceptions: (1) If water is only used to rinse the product, and product residue is not expected in the effluent, or (2) If product-relevant wastewater is produced, but no effluent is discharged from the facility, because any waste is shipped and treated as chemical waste off site. In these two cases, the applicant may choose whether to characterize and assess product-related process effluent chemicals as described here or whether to pursue the supply chain-related water requirements (Sections 6.6 & 6.8) instead. Note that this requirement partially fulfills the Platinum requirement for Material Health.

Intent

The intent of this requirement is not to require analytical testing beyond what is required by a manufacturer's regulatory permit or to identify all chemicals present in the effluent. The intent is for a manufacturer to understand the chemicals used in the manufacturing process and their potential concentrations in effluent. The requirement does not apply to chemicals in the influent to the manufacturing facility.

Methods

1. Determine whether a closed-loop water recycling system is in place and there is therefore no product-relevant effluent leaving the facility. If wastewater would have ordinarily been discharged to water systems without this water recycling system, no further assessment or optimization of process chemicals is necessary. If there is product-relevant effluent leaving the facility, proceed to item 2.

2. Identify the process chemicals used in the final manufacturing stage of the applicant product that are potentially entering effluent leaving the manufacturing facility through the process water, cooling system, input materials, and pipes by chemical name and CAS #. Process chemicals are defined in the Terms and Definitions section. At a minimum, include chemicals that are known or expected to be introduced into water intentionally or unintentionally. If chemical substances that are also part of the finished product are expected to be present in the effluent, these substances also need to be assessed as part of this requirement. It is not expected that analytical testing beyond what is already required for regulatory purposes will be conducted. If the facility has its own wastewater treatment system, the effluent subject to review is the effluent post-treatment, prior to any off-site treatment (e.g., by a municipal wastewater treatment facility). If the final manufacturing stage of a product occurs at more than one facility, chemicals in the effluent must be identified and assessed at each facility.

3. Determine the single chemical risk rating for all chemicals identified in #1 above as described in the C2C *Material Health Assessment Methodology*. The assessment is to be conducted on the primary hydrolyzed or reacted form of the parent chemical that would appear in the effluent.
4. Use the information above to create an effluent optimization plan including measurable goals, timeline, and budget. Detail the actions to be taken to either phase out each x-assessed chemical or keep it sequestered in nutrient recovery systems. The applicant may also wish to include plans to optimize c chemicals to b or a; however, if all chemicals are assessed as c or above, the applicant has already met the effluent optimization requirement for the Gold level (see Section 6.7).

Required Documentation

The following information is required:

1. In the case of a closed-loop water recycling system: A description of the system, confirmation that no product-relevant effluent leaves the facility, and confirmation that wastewater captured by the recycling system would have ordinarily been discharged to water systems. In this case, ignore items 2-6 below.
2. If product-relevant effluent leaves the facility: A list of the chemicals identified in the first step of the Methods section above, including name and CAS #.
3. For each chemical, identify the point in the manufacturing process at which the chemical is likely entering effluent (e.g., used in the process water or cooling system, or are input materials at a particular point in the manufacturing process).
4. Identify the single chemical risk rating (as a, b, c, or x) for each chemical identified. The single chemical risk rating considers the chemical's hazards and exposure to the chemical via the effluent. GREY single chemical risk ratings are permissible if the GREY rating is due to missing toxicity data rather than missing formulation information.
5. A description of the current management strategy, if any, and its effectiveness.
6. An optimization plan including the elements listed in the Methods section above.

6.6 SUPPLY CHAIN WATER ISSUES AND STRATEGY

Standard Requirement

Supply chain-relevant water issues for at least 20% of the total number of Tier 1 suppliers are characterized and a positive impact strategy is developed (required for facilities with no product-relevant effluent).

Applicable Levels of Certification

This requirement applies to the Silver level of certification and above (Silver, Gold, and Platinum) and is one of two options at the Silver level.

Intent

The intent of this requirement is to assist the manufacturer with understanding water-related issues in the supply chain and to challenge them to develop an innovative strategy for positively impacting the issues identified.

Methods

1. To fulfill the water issues characterization part of the requirement, the applicant can perform one or more of the following for at least 20% of the total number of Tier 1 suppliers: (1) characterize the local and business-specific water issues identified in Section 6.2; (2) characterize and quantify water use; and/or (3) determine whether or not a significant violation of their discharge permit has been received within the last two years. This requirement applies regardless of whether or not the Tier 1 suppliers use any process water.

    a. Local and business-specific water issues – follow the methods used in Section 6.2.

    b. Characterize and quantify water use – characterize and quantify water use and/or discharge to water attributable to the product using primary and/or available secondary data. Follow the methods used in Section 6.4.

    c. Determine whether or not a significant violation of their discharge permit has been received within the last two years – follow the methods used in Section 6.1.

2. Develop a positive impact strategy based on the issues identified, including quantitative targets, a timeline, and budget. Example strategies include working with the supply chain to effectively manage water use, particularly for water input and impact intensive materials, consideration of supplier's local water issues as a part of purchasing decisions, and material substitution. A positive impact strategy is required from the applicant regardless of whether any issues are identified during the supply chain water issues characterization. The strategy may include a plan to fulfill more of the investigation options for the same suppliers and/or a plan to increase the percentage of Tier 1 suppliers for which the investigation is conducted over time.

Required Documentation

1. For characterization of local and business-specific water issues, follow the "Required Documentation" in Section 6.2.

2. For characterization of the quantity of water use, provide a report detailing the methods used, the results, and data sources. Follow the "Required Documentation" in Section 6.4. Describe the significance of the results.

3. For determination of whether or not a significant violation of a supplier's discharge permit has been received within the last two years, follow the "Required Documentation" in Section 6.1.

4. Provide a positive impact strategy as follows for each option:

    a. For local and business-specific water issues, follow the "Required Documentation" listed in Section 6.3.

    b. For characterization of the quantity of water use, include a description of the strategy, quantitative targets, a timeline, and budget.

    c. For determination of whether or not a significant violation of a supplier's discharge permit has been received within the last two years, include a description of the strategy, quantitative targets, a timeline, and budget.

6.7 OPTIMIZING PROCESS-RELATED CHEMICALS IN EFFLUENT

Standard Requirement
Process-related chemicals in effluent are optimized. Chemicals identified as problematic are kept flowing in systems of nutrient recovery, and effluents leaving the facility do not contain chemicals assessed as problematic.

Applicable Levels of Certification
This requirement applies to the Gold level of certification and above (Gold and Platinum) and is one of two options at the Gold level. Note that this requirement partially fulfills the Platinum-level requirement for Material Health.

Intent
The intent of this requirement is to ensure that chemicals used in the product manufacturing process do not adversely impact human or environmental health.

Methods
See Section 6.5 for methods. "Optimized" in this case is defined as effluent containing only process-related chemicals that have single chemical risk ratings of a, b, or c (no x or GREY chemicals). See Section 6.5 of this document for more information. The applicable chemicals are those identified in Section 6.5 and any additional process-related chemicals that are currently used in the manufacturing process and are likely to be present in effluent, but that were not previously identified when effluent was initially characterized.

Required Documentation
The documentation required is the same as the documentation required in Section 6.5, with the exception of an optimization plan, which is not required.

6.8 ADDRESSING SUPPLY CHAIN WATER ISSUES

Standard Requirement
Demonstrated progress on the strategy developed for addressing supply chain-relevant water issues at the Silver level (required for facilities with no product-relevant effluent).

Applicable Levels of Certification
This requirement applies to the Gold level of certification and above (Gold and Platinum) and is one of two options at the Gold level.

Intent
The intent of this requirement is to challenge manufacturers to positively impact water issues in their supply chain.

Methods
Demonstrate progress made against the impact strategy/plan developed for the Silver-level requirement (see Section 6.6).

Required Documentation

Provide the original strategy/plan and report progress on each individual action item.

6.9 DRINKING WATER QUALITY

Standard Requirement

All water leaving the manufacturing facility meets drinking water quality standards.

Applicable Levels of Certification

This requirement applies to the Platinum level of certification only.

Intent

The intent of this requirement is to ensure, to the extent possible, that water leaving the manufacturing facility is safe for drinking.

Methods

1. Identify all process-related chemicals potentially entering effluent through the process water, cooling system, input materials, and pipes as a result of the product manufacturing process by chemical name and CAS # (use same method described in Section 6.5).
2. Determine the single chemical risk rating for all chemicals identified in #1 above as described in the *Cradle to Cradle Certified™ Material Health Assessment Methodology*. The assessment is to be conducted on the primary hydrolyzed or reacted form of the parent chemical that would appear in the effluent.
3. All chemicals must have single chemical risk ratings of a, b, or c (no x or GREY) in order to fulfill this requirement.
4. Gather documentation detailing local drinking water standards and conduct analytical testing to demonstrate compliance to those standards. Such standards should be at least as rigorous as the most recent international standard set by the World Health Organization.

Required Documentation

The following information is required:

1. A list of the chemicals identified in the first step of the Methods section above, including name and CAS #.
2. For each chemical, identify the point in the manufacturing process at which the chemical is likely entering effluent (e.g., used in process water or cooling system, or are input materials at a particular point in the manufacturing process).
3. Provide the single chemical risk rating for each chemical identified (must be a, b, or c).
4. Provide documentation on local drinking water standards.
5. Provide a description of the analytical test methods used, test results, and testing laboratory name and contact information.

7 SOCIAL FAIRNESS

Positive Support for Social Systems

Social Fairness ensures that progress is made towards sustaining business operations that protect the value chain and contribute to all stakeholder interests, including employees, customers, community members, and the environment. It is important for business ethics to go beyond the confines of the corporate office and permeate the supply chain, engaging it in responsible manufacturing, enforcing fair treatment of workers, and reinvesting in natural capital.

Table 10 highlights each unique requirement within the Social Fairness category across all levels. In general, to achieve a given level, the requirements at all lower levels are to be met as well. The sections to follow will provide interpretation and suggested methods for achievement.

Table 10 Social Fairness Requirements

LEVEL	ACHIEVEMENT
BASIC	A streamlined self-audit is conducted to assess protection of fundamental human rights. Management procedures aiming to address any identified issues are provided. Demonstration of progress on the management plan is required for re-application.
BRONZE	A full social responsibility self-audit is complete and a positive impact strategy is developed (based on UN Global Compact Tool or B-Corp).
SILVER	COMPLETE ONE OF THE FOLLOWING: Material-specific and/or issue-related audit or certification relevant to a minimum of 25% of the product material by weight is complete (FSC Certified, Fair Trade, etc.). OR Supply chain-relevant social issues are fully investigated and a positive impact strategy is developed. OR The company is actively conducting an innovative social project that positively impacts employees' lives, the local community, global community, social aspects of the product's supply chain, or recycling/reuse.
GOLD	Two of the Silver-level requirements are complete.
PLATINUM	A facility-level audit is completed by a third party against an internationally recognized social responsibility program (e.g., SA8000 standard or B-Corp). All Silver-level requirements are complete.

7.1 STREAMLINED SELF-AUDIT

Standard Requirement
A streamlined self-audit is conducted to assess protection of fundamental human rights.

Applicable Levels of Certification
This requirement applies to the Basic level of certification and above (Basic, Bronze, Silver, Gold, and Platinum).

Intent
The intent of this requirement is to determine if any final manufacturing facilities, contract manufacturing facilities, or tier one supplier facilities are operating in countries and/or industries identified as having high or very high potential for issues with any of the following themes, per the Social Hotspots database (http://socialhotspot.org/):

1. Child labor.
2. Forced labor.
3. Excessive work time.
4. Provision of a living wage.
5. Worker health and safety.
6. Wage Assessment; Issue: Potential of Average wage being < non-poverty guideline.
7. Accidents and death in workplace.
8. Toxicity or chemical exposure in workplace (if data are available).

Methods
1. List final manufacturing and tier one facilities relevant to the product by name, location (i.e., country), and industry sector if available. Note that this has likely already been completed for the Material Health requirements. Commodity-type materials purchased from many and frequently changing locations, such as fasteners or other hardware and post-consumer recycled content paper and pulp, may be excluded.
2. Determine risk or opportunity level (as defined by the Social Hotspots database (SHdb); http://socialhotspot.org) for each location and/or sector. The SHdb is highly recommended for fulfilling this requirement because it contains both country and industry sector-specific information for each issue that needs to be addressed. Once a SHdb account is active, view the themes listed above within the category "Labor Rights & Decent Work" and determine the appropriate risk/opportunity levels. If SHdb provides a risk rating for the applicable industry sector, report that preferentially to the overall country rating. If not, refer to the additional references provided below to explore the applicability of the risk or opportunity level to specific industry sector(s) (although this is not required).

   Alternative references for exploring the applicability of the risk or opportunity level to specific industry sector(s) may be used. Recommendations include UNICEF, U.S. Department of Labor, List of Goods Produced by Child Labor (U.S. Dept. of Labor, 2009), International Labour Organization

(ILO) country reports, World Bank poverty data, UN Human Development reports, U.S. Department of State Human Rights reports, sweatfree.org non-poverty wages, the U.S. Bureau of Labor Statistics, AFL-CIO, International Trade Union Confederation country profiles, and the World Health Organization.

Regardless of the information source used, how the required information was identified for each issue needs to be specified. In the SHDB, the risk themes listed may not correspond directly to the issues listed in the requirement. The applicant must work with their assessor to select the most relevant categories and risk themes for their operations in each region.

A company that has received SA8000 certification or is a certified B Corporation will still need to fulfill the self-audit requirement for the Basic level and may have to do additional work for other social fairness requirements depending on the work conducted to receive the certification. Applicants will need to work with their assessor to determine which additional steps beyond the facility-level, third party audit are required.

Required Documentation

An applicant must work with their accredited assessment body to obtain the appropriate template for conducting the streamlined self-audit.

7.2 MANAGEMENT PROCEDURES TO ADDRESS HIGH RISK ISSUES AND OPPORTUNITIES

Standard Requirement

Management procedures aiming to address any high or very high risk or opportunity issues that were identified in the streamlined self-audit are provided. Demonstration of progress against the management plan is required for re-application.

Applicable Levels of Certification

This requirement applies to the Basic level of certification and above (Basic, Bronze, Silver, Gold, and Platinum).

Intent

The intent of this requirement is to develop a plan for addressing the high or very high risk or opportunity issues that were identified in the streamlined self-audit in an effort to protect basic human rights of workers within the company's supply chain.

Methods

1. Were any final manufacturing or tier one facilities identified as having high or very high risk or opportunity upon conducting the streamlined self-audit? If yes, please continue to the next question. If not, no further action is required (i.e., the requirement to provide or develop management procedures does not apply).
2. Do those facilities identified as having high or very high risk or opportunity provide ≤1% of the value of the product combined? If yes, no further action is required (i.e., the requirement to

provide or develop management procedures does not apply). If no (i.e., facilities provide >1%), please continue as stated below.

3. If required (see #2 above), provide one of the following:

   a. Existing audit, remediation, and management procedures designed to identify and protect basic human rights of workers within the company's supply chain.

      OR

   b. A proposed plan for monitoring and addressing potential issues if the applicant does not have an existing audit and management process.

4. At a minimum, the management procedures must include a draft supply chain code of conduct to be integrated into supplier contracts, that prohibits child and forced labor, requires that a living wage be paid, and allows for unannounced audits. Child labor and living wage are to be defined according to the ILO and UN. Ideally, the plan will include all major points of the UN Declaration of Human Rights, UN Global Compact, and the ILO Core Conventions and Recommendations.

5. In cases where the final manufacturing facility (including contract manufacturing) is of high or very high risk or opportunity, management and self-auditing procedures must also be documented and provided. A third party audit according to SA8000 is a preferred alternative in this case (which would fulfill one Platinum-level requirement).

6. At re-application, a listing of actions taken in carrying out the plan since the initial certification or prior renewal is to be compiled. Examples of the type of information to include are monitoring activities that have been carried out and where they were carried out, identification of new or recurring issues, and results of any self-audits.

Required Documentation

The following information must be provided to the assessor:

1. If applicable, a signed statement indicating that the final manufacturing and tier-one facilities identified as having high or very high risk or opportunity provide ≤1% of the value of the product combined (as described in the Methods section above).
2. A list of facilities included in the plan/procedures, if required.
3. Management plan and procedures, if required. Include self-audit procedure where final manufacturing facility or contract facility is of high or very high risk/opportunity.
4. Example of applicant's supplier contract with integrated code of conduct.
5. Social responsibility report, if available.
6. A list of actions taken and results/findings since initial certification or prior re-application (see Methods).

7.3 FULL SELF-AUDIT

Standard Requirement

A full social responsibility self-audit is complete and a positive impact strategy is developed (based on UN Global Compact Tool or B-Corp).

Applicable Levels of Certification
This requirement applies to the Bronze level of certification and above (Bronze, Silver, Gold, and Platinum).

Intent
The intent of this requirement is for the applicant to continue to gather data about the social impacts of the final manufacturing process.

Methods
1. Conduct a social responsibility self-audit using the UN Global Compact Self-Assessment Tool (http://www.globalcompactselfassessment.org/) or B Impact Assessment. If the final manufacturing or contract manufacturing facility is found to be located in areas with high or very high potential for fundamental human rights issues (as required to be identified at the Basic level), it is recommended that the UN tool be employed.
2. Develop a positive impact strategy based on audit results, including a statement of intent and commitment, measurable goals, and timeline. If using the UN Global Compact Tool, include items in the strategy where answers are NO.

Required Documentation
The following information must be provided to the assessor:

1. The UN Global Compact (Excel spreadsheet) or B Corp survey results.
2. The impact strategy, including those points listed in the Methods section above.

7.4 MATERIAL-SPECIFIC OR ISSUE-SPECIFIC AUDIT

Standard Requirement
Material-specific and/or issue-related audit or certification relevant to a minimum of 25% of the product material by weight is complete (e.g., FSC Certified, Fair Trade, etc.).

Applicable Levels of Certification
This requirement applies to the Silver, Gold, or Platinum levels of certification.

Intent
The intent of this requirement is to encourage the use of materials that are produced and managed to high environmental and social standards.

Methods
1. Material- or supplier-specific certifications must apply to a minimum of 25% of the product material(s) by weight. However, if the certifying body has its own requirements, those will take precedence.
2. Input materials or manufacturers of input materials are certified and/or verified compliant (as appropriate) by an external party according to one or more of the following pre-approved programs:
    - B Corporation

- Blue Angel (when human rights issues are addressed as part of the Standard, such as in RAL-UZ 154 Textile)
- Business Social Compliance Initiative (BSCI) code of conduct
- CarbonNeutral product certification
- Certified Organic (US Department of Agriculture or Quality Assurance International)
- Conflict-free (third-party verified)
- Cotton made in Africa
- Cradle to Cradle Certified
- Electronic Industry Citizenship Coalition (EICC) code of best practice
- Ethical Trading Initiative base code
- Fair for Life
- FairTrade
- Forest Stewardship Council (FSC) Forest Management & Chain of Custody
- Global Organic Textile Standard (GOTS)
- Global Social Compliance Programme Reference Code
- Initiative Clause Sociale (ICS)
- International Council of Toy Industries (ICTI) code of business conduct
- ISCC PLUS
- Leaping Bunny
- Nordic Swan/Nordic Ecolabel for Textiles, hides/skins and leather
- NSF/ANSI 336 Sustainability Assessment for Commercial Furnishings Fabric
- Oeko-Tex Standard 1000 or 100plus
- Responsible Source - Scientific Certification Systems (SCS)
- RSPO Certified Sustainable Palm Oil tracked through the Identity Preserved, Segregated, or Mass Balance supply chain certification systems
- SA8000
- UTZ Certified
- Worldwide Responsible Accredited Production (WRAP)

Pre-approved programs are primarily, with some exceptions, those that are:

1. Focused on fundamental human rights issues, in particular fair labor practices, or on animal rights issues, or
2. Multi-attribute programs that address fair labor practices along with other issues (with social criteria relevant to fundamental human rights, in particular labor practices, required).

Programs that apply only to final consumer products as opposed to potential input materials may fit into the categories above but have not been included because such programs will not likely be relevant to product input materials and/or suppliers as required for this criterion.

The eco-label and verification/auditing environment continues to evolve and additional programs may apply as they become available. Assessors may request an addition to the list by providing C2CPII (certification@c2ccertified.org) with the name of the proposed program and the following details:

a. A summary of the program and how it addresses fundamental human rights and other social fairness issues;
b. A list of any ecolabels/standards (other than C2C) or government programs that reward for use of materials certified under the program; and

c. A summary of any major criticism the program has received from NGOs or governments.

3. Certifications are to be current (unexpired). Audits against programs that do not have expiration dates are eligible if they have been completed within the last three years.
4. Water weight may be excluded from the product weight when calculating the weight fraction of materials with material-specific and/or issue-related certifications/audits.

Required Documentation

The following information must be provided to the assessor:

1. A copy of the certification certificate or similar, signed and dated by the certifying or verifying body.
2. Calculations within the original Bill of Material (used for complying with the Material Health category requirements) showing that at least 25% of the product by weight is covered by the audit or certification.

7.5 SUPPLY CHAIN SOCIAL ISSUES AND IMPACT STRATEGY

Standard Requirement

Supply chain-relevant social issues are fully investigated and a positive impact strategy is developed.

Applicable Levels of Certification

This requirement applies to the Silver, Gold, or Platinum levels of certification.

Intent

The intent of this requirement is to challenge manufacturers to positively impact social issues throughout their supply chain.

Methods

1. Characterize and quantify social issues throughout the supply chain attributable to the product from resource extraction to production (applicant's gate) using primary data wherever possible. At a minimum, applicants must investigate the following:
   a) At least one relevant 'material-specific issue' related to initial resource extraction (palm oil, bauxite mining, etc.).
   b) Tier 1 suppliers' social issues (using primary data collected from their suppliers) or social issues pertaining to all or most of their Tier 2 suppliers at the same level of rigor required at the Basic level for the Tier 1 suppliers.
2. The inventory threshold is left to the applicant to determine and define as part of the boundary and scope decision; however, it is recommended that suppliers of all materials that are 1% or more

of the product's total inputs by weight be investigated. Ideally all inputs will be included to identify as many social issues associated with the product as possible.

3. If primary data are not available or accessible, knowledge of industry type, supplier location data, and available data and information relevant to those locations and industries may be used instead. The SHdb and other references listed in Section 7.1 will be useful. This requirement may be seen as a continuation of the requirements set out in Section 7.1. The methods described there may be applied to the entire supply chain.
4. Social LCA methods should be consulted.
5. Develop a positive impact strategy based on the results. Include a statement of intent and commitment, quantitative targets, timeline, and budget.

Required Documentation

The following information must be included in a report to the assessor:

1. Inventory results.
    a. Description of at least one relevant 'material-specific issue' related to initial resource extraction.
    b. Description of the method used to investigate social issues among Tier 1 or Tier 2 suppliers and a summary of the issues identified.
2. Use of results.
    a. Provide a positive impact strategy that addresses the inventory results in 1a and 1b, including those points listed in the Methods section above.

7.6 INNOVATIVE SOCIAL PROJECT

Standard Requirement

The company is actively conducting an innovative social project that positively impacts employees' lives, the local community, the global community, the social aspects of the product's supply chain, or recycling/reuse.

Applicable Levels of Certification

This requirement applies to the Silver, Gold, or Platinum levels of certification.

Intent

The intent of the innovative social project requirement is to develop and implement a company program that positively impacts social issues and implements the Cradle to Cradle principles. The key aspect of this requirement is that the program or project is an integrated part of company strategy.

Methods

Completion of this requirement involves the development of an innovative company program, as an integrated part of company strategy, that includes communication, education, traineeships, communities of practice, purchasing, and/or political engagement that actively supports (local, national, continental or global) implementation of the Cradle to Cradle principles.

Projects that seek to address all three Cradle to Cradle principles simultaneously are encouraged. Set social responsibility targets and initiatives in a variety of areas, and use these to strategize which innovative social projects to pursue.

The criteria provided for the requirement are broad-based to allow for the development of a wide variety of program types. Because there is a wide range in social fairness policies and practices around the world, the definition of innovative may vary.

The innovative social project can be new to the company, the country, or the world. There may be programs or activities that a company is already engaging in for compliance purposes that would fulfill this requirement; however, basic compliance is not the intent.

The following are examples of applicable goals, targets, and initiatives.

1. Increasing the diversity of the workforce.
2. Creation of programs to engage special needs groups in the local community.
3. Decreasing the wage disparity between upper management and the workforce.
4. Increasing employee involvement in positive community service activities.
5. Actively encouraging staff participation in creative Cradle to Cradle® design and research projects as an integrated part of company strategy.
6. Improvements on the positive impact on all people, places, and things that are indirectly or directly involved in the making or remaking and/or use of the products.
7. Company programs as an integrated part of company strategy that actively support the quality of life of its employees (i.e., health, satisfaction, happiness, enjoyment).
8. Development and implementation of a company-wide Cradle to Cradle "roadmap" including:
    a. Creation of a Cradle to Cradle team with representatives in each operational unit and local markets.
    b. The development of Cradle to Cradle tools and resources.
    c. Company purchasing programs that actively support the purchasing of Cradle to Cradle Certified™ products. This might include a public list of "approved" vendors and venues and a public statement on company purchasing.
9. Taking an active role in organizing workshops, facilitating traineeships, generating public debate, etc. This might include checklists for client-facing teams to create experiences and events that implement the use of exhibits and mobile tours based on the Cradle to Cradle principles, and/or thought leadership blogs, articles, and speakerships on Cradle to Cradle events.
10. Researching successful government or trade association sustainability programs and actively engaging in helping to support those.

Required Documentation

A detailed description of the program or project, including goals and progress made to date, is required.

7.7 FACILITY-LEVEL THIRD PARTY AUDIT OR CERTIFICATION

Standard Requirement

An internationally recognized social responsibility certification (e.g., SA8000 or B-Corp) is obtained, or a facility-level audit is completed by a third party against an internationally recognized social responsibility program.

Applicable Levels of Certification

This requirement applies to the Platinum level of certification only.

Intent

The intent of this requirement is to ensure that manufacturers have adopted policies and procedures that protect the basic human rights of workers.

Methods

1. The applicant must receive certification or be audited at the facility level by a third party against an internationally recognized social responsibility program. The following programs are pre-approved:

   a. B Corp Certification.

   b. Business Social Compliance Initiative (BSCI) audit.

   c. Global Social Compliance Program (GSCP) audit.

   d. SA8000 certified (Social Accountability International).

   e. Worldwide Responsible Apparel Production (WRAP).

   Please contact an assessor or the Cradle to Cradle Products Innovation Institute regarding the applicability and approval of other audits and certifications that fulfill this requirement. At a minimum, other programs are to be internationally accepted and address child labor, forced labor, health and safety, freedom of association and collective bargaining, discrimination, discipline/harassment, working hours, and compensation.

2. Certifications are to be current (unexpired). Audits against programs that do not have expiration dates are eligible if they have been completed within the last three years.

Required Documentation

A copy of the certification certificate or similar, signed and dated by the certifying or verifying body, is required.

8 CONTINUOUS IMPROVEMENT AND OPTIMIZATION

Standard Requirement

Certification holders are required to make a good faith effort toward materials optimization at each recertification period, unless optimization is already complete or is incomplete due to technological constraints. Progress on materials optimization includes both demonstrated progress on eliminating X-assessed materials or x-assessed chemicals in those materials and work toward increasing the percentage of the product assessed as A, B, C, or X at each recertification period.

Applicable Levels of Certification

This requirement applies to the Basic level of certification and above (Basic, Bronze, Silver, Gold, and Platinum).

Intent

The intent of this requirement is to ensure that manufacturers are committed to making a good faith effort toward optimization of their product.

Methods

1. If an applicant has completed their materials optimization work, or if they have reached a point where they cannot go further with materials optimization due to technology constraints, it is required that progress is made in some other program category or categories.
2. In addition to materials optimization, there are several other cases where progress on optimization strategies or plans may be required at re-application (see Table 11 below).
3. An alternative compliance pathway exists for companies that have several certified products and where it is extremely challenging to make progress on each individual product at each recertification. The continuous improvement and optimization requirement can be met by demonstrating significant optimization at the corporate level that impacts many products, but perhaps not all certified products. A clear explanation of the progress that has been made on optimization of other Cradle to Cradle Certified™ products at recertification is required in such cases.

Table 11 Progress on Optimization Strategies or Plans Required Throughout the Program

Strategy/Plan	Levels	Re-application Requirement
Materials Optimization	Bronze and above	Progress required at re-application unless complete or incomplete due to technology constraints.
Nutrient Management	Gold	No specific requirement.
Renewable Energy and Carbon Management (facility level)	Bronze and above	No specific requirement.
Water Stewardship Intentions	Basic and above	Progress may be required at re-application depending on outcome of the local and business-specific water issues investigation.
Supply Chain Water Issues Strategy	Silver and above	No specific requirement.
Social Responsibility Management Procedures	Basic and above	Progress may be required at re-application depending on outcome of the streamlined self-audit.
Positive impact strategy based on Full Social Responsibility Self-Audit	Bronze and above	No specific requirement.
Positive impact strategy based on Supply Chain Social Issues investigation	Silver and above	No specific requirement.

Required Documentation

The original action plan or strategy and a report on the progress against each individual action item are required.

9 SITE VISIT OF PRODUCTION FACILITY

Standard Requirement

A site visit of the final manufacturing facility or facilities is completed.

Applicable Levels of Certification

This requirement applies to the Bronze level of certification and above (Bronze, Silver, Gold, and Platinum).

Intent

The intent of the site visit is to focus on verifying the manufacturing process, the product materials, and the process chemicals used in the final manufacturing step for the finished product that is being assessed for certification. A site visit is also used by the assessment body to verify the product's bill of materials, and, to the extent possible, it serves as quality assurance that the applicant has reported accurate information. It can also be used to increase the percentage of the product that is inventoried and therefore the percentage of the product that is considered assessed (i.e., chemicals identified and evaluated for their material health following the Standard's material health assessment process). The purpose of the site visit is not to verify the specific details regarding the social fairness criteria at the facility or the supplier facilities.

Methods

It is necessary for the assessor assisting with each project to tour the production/assembly process for the applicant product(s) to see how suppliers' components come together to make the finished product and understand some basics on process steps and process chemicals. All parts of the plant involved in the manufacturing of the applicant product(s), including raw material storage, manufacturing processes, and waste streams will need to be shown to the certification assessor. Questions may be asked about process times, process temperatures, pollution controls, and personal protective equipment. Energy use and emissions, water, and social fairness data may also be discussed and reviewed.

The assessor would like to meet with someone who can give them a tour of the manufacturing facility, the contact person at the applicant company that will be responsible for day-to-day data needs for the project, and someone with knowledge of the procurement of purchased materials that go into the product in order to discuss the project's data needs. This may be a group of people or it may be one person, depending on the company. The applicant should be prepared to discuss their manufacturing flow, including inputs and outputs. It is preferred that the applicant also have an outline of the supply chain for the applicant product(s) to review during the site visit meetings. The applicant should also have reviewed the Cradle to Cradle Certified™ application and program documents prior to the arrival of the auditors, so that they can address any questions.

A site visit is required once per product or product group at the time of initial certification. An additional site visit is required if the manufacturing process changes significantly. More than one site

visit may be necessary for the same facility if applicants choose to certify multiple products over time. The product must be on the production line during the site visit in order to be valid.

A site visit is required for the main final manufacturing facility and any other facilities involved in select manufacturing processes for which exposure concerns are considered exceptionally high. These select manufacturing processes are marked with a '*' in the *Final Manufacturing Stage Guidance*. If there is more than one final manufacturing facility, the assessor determines which facility is the "main" facility to be visited based on which one performs the most significant manufacturing processes.

Unless the product's final manufacture involves a process marked with a '*' in the *Final Manufacturing Stage Guidance*, only one site visit is required, regardless of how many individual facilities are included in the final manufacturing stage. For example, if five facilities are involved in the final manufacturing stage, and none of them performs a process marked with a '*,' only one of them needs to be visited.

Required Documentation

A statement confirming that the site visit was conducted by a representative from an accredited assessment body is required. If there is more than one final manufacturing facility, an explanation of how the assessor determined which facility is the "main" facility to be visited is also required.

10 CERTIFICATION DISCLAIMER

The Cradle to Cradle Products Innovation Institute warrants only that any product which has been certified as Basic, Bronze, Silver, Gold or Platinum meets the Institute's Cradle to Cradle Certified™ Product Standard criteria for such certification and except as expressly set forth herein.

(A) The Cradle to Cradle Products Innovation Institute makes no warranty, express or implied as to any product which has been certified under the Institute's Cradle to Cradle Certified Product Standard, including any warranty as to merchantability or fitness for a particular purpose and the Institute hereby expressly disclaims all other warranties;

(B) The Cradle to Cradle Products Innovation Institute shall not be liable for any loss, injury, claim, liability, or damage of any kind resulting in any way from any errors, omissions, content, information, opinions or assessments contained in the Institute's Cradle to Cradle Certified Product Standard; and,

(C) The Cradle to Cradle Products Innovation Institute shall not be liable, in any event, for any incidental, consequential, special, exemplary or punitive damages (including without limitation for lost data, lost profits or loss of goodwill) of any kind or nature arising out of the certification of any product under the Institute's Cradle to Cradle Certified Product Standard, whether such a liability is asserted on the basis of contract, tort, or otherwise, even if the Institute has been made aware of the possibility of such loss or damage in advance.

11 ACRONYMS

ABS	acrylonitrile butadiene styrene
BBP	benzyl butyl phthalate
BOD	Biological oxygen demand
BOF	basic oxygen furnace
BSCI	Business Social Compliance Initiative
CAS	Chemical Abstract Service
CMR	carcinogenic, mutagenic, or reproductively toxic
CO_2	carbon dioxide
COD	chemical oxygen demand
CONEG	Coalition of Northeastern Governors
COTE	Committee on the Environment
CPVC	chlorinated Polyvinyl chloride
DBP	dibutyl phthalate
DEHP	di(2-ethylhexyl)phthalate
EAF	electric arc furnace
EMC	externally managed component
EPEA	Environmental Protection Encouragement Agency
FSC	Forestry Stewardship Council
FTC	Federal Trade Commission
GHG	greenhouse gas
GSCP	Global Social Compliance Program
HDPE	high density polyethylene
IARC	International Agency for Research on Cancer
ICP/AES	inductively coupled plasma/atomic emission spectroscopy
ICP/MS	inductively coupled plasma/mass spectroscopy
ILO	International Labour Organization
IPCC	Intergovernmental Panel on Climate Change
IPS	Intelligent Products System
LCA	life cycle assessment
MBDC	McDonough Braungart Design Chemistry, LLC
MSDA	material safety data sheets
MWh	megawatt hours
PAHs	polycyclic aromatic hydrocarbons
PC	polycarbonate
PCP	pentachlorophenol
PET	polyethylene terephthalate

PFOA	perfluorooctanoic acid
PFOS	perfluorooctanesulfonic acid
POTW	publicly owned treatment works
PP	polypropylene
PTFE	polytetrafluoroethylene
PU	polyurethane
PVC	polyvinyl chloride
PVDC	polyvinylidene chloride
REC	renewable energy credit
RECs	renewable energy certificates
RoHS	restriction of hazardous substances
SCCP	short chain chlorinated paraffin
SHdb	Social Hotspots database
SKU	stock keeping unit
TOC	total organic carbon
UNCED	World Urban Forum of the Rio Earth Summit
U.S. EPA	United States Environmental Protection Agency
WBCSD	World Business Council for Sustainable Development
WRAP	Worldwide Responsible Apparel Production
XRF	X-ray fluorescence

12 TERMS AND DEFINITIONS

TERM	DEFINITION
ACRYLONITRILE BUTADIENE STYRENE	A common thermoplastic.
ASTM D6400-04	Standard specification for compostable plastics.
BIODEGRADABLE	The process by which a substance or material is broken down or decomposed by microorganisms and reduced to organic or inorganic molecules which can be further utilized by living systems. Biodegradation can be aerobic, if oxygen is present, or anaerobic, if oxygen is not present. The OECD defines the appropriate testing methods for ready and inherent biodegradability. If making biodegradability claims for materials that are not commonly known to be biodegradable, testing should be done according to these (or comparable) methods.
BIOLOGICAL METABOLISM	The cycle in which biological nutrients flow. Any material that comes into intentional or likely unintentional contact with the biological metabolism should be designed to safely come into contact with living organisms.
BIOLOGICAL NUTRIENT	A product usable by defined living organisms to carry on life processes such as growth, cell division, synthesis of carbohydrates, energy management, and other complex functions. Any material emanating from product consumption that comes into intentional or likely unintentional and uncontrolled contact with biological systems is assessed for its capacity to support their metabolism. Metabolic pathways consist of catabolism (degradation, decrease in complexity) and anabolism (construction, increase in complexity), both occurring generally in a coupled manner. The status of products as a biological nutrient (or source of nutrients) depends on the biological systems that meet them. They can be more or less complex along the following organizational hierarchy: • Organisms (nutrients for predators) • Organic macromolecules (and combinations thereof) (nutrients for fungi, microorganisms, vegetarian animals; oral, dermal or olfactory nutrients) • Minerals (nutrients for autotrophic plants) Generally, products as biological nutrients fit in with the two last levels.
BIOMASS	Organic, non-fossil material that is available on a renewable basis. Biomass includes all biological organisms, dead or alive, and their metabolic by-products that have not been transformed by geological processes into substances such as coal or petroleum. Examples of biomass are forest and mill residues, agricultural crops and wastes, wood and wood wastes, animal wastes, livestock operation residues, aquatic plants, and some municipal and industrial wastes.
CA PROPOSITION 65	A list of substances known by the state of California to cause cancer or reproductive harm.

TERM	DEFINITION
CARBON DISCLOSURE PROJECT	Organization that helps companies voluntarily disclose greenhouse gas emission accounting.
CARBON OFFSET	Reduction of greenhouse gas emissions to compensate for the release/production of emissions from another source.
CARCINOGEN - KNOWN	A causal relationship has been established between exposure to the agent and human cancer (MAK 1 or TLV A1 or IARC Group 1).
CARCINOGEN - POSSIBLE, OR SUSPECTED	A known animal carcinogen, but evidence of carcinogenicity in humans is non-existent, or there is limited evidence of carcinogenicity in humans and insufficient evidence of carcinogenicity in animals (MAK 3 or TLV A3 or IARC Group 2B).
CARCINOGEN - PROBABLE	A known animal carcinogen, but carcinogenicity in humans has not been definitely proven (MAK 2 or TLV A2 or IARC Group 2A).
CAS NUMBER	Chemical Abstract Service number. This number uniquely identifies each pure chemical compound. This is also designated as Chemical Abstract Service Registry Number (CASRN).
CEN	CEN is a major provider of European Standards and technical specifications. It is the only recognized European organization according to Directive 98/34/EC for the planning, drafting, and adoption of European Standards in all areas of economic activity with the exception of electrotechnology (CENELEC) and telecommunication (ETSI).
CHEMICAL SUBSTANCE	A substance represented by a single Chemical Abstract Service Registry Number (CAS #).
CHEMICAL	AKA chemical substance.
CHEMICAL CLASS	Grouping of elements or compounds according to certain chemical functional or structural properties.
CHEMICAL PROFILE	The process of using human and environmental health endpoints and their associated criteria to determine the inherent hazards of a single chemical.
CHLORINATED POLYVINYL CHLORIDE	A chlorinated version of PVC used for temperature stability.

TERM	DEFINITION
CHILD LABOR	UNICEF definition: work that exceeds a minimum number of hours, depending on the age of a child and on the type of work. Such work is considered harmful to the child and should therefore be eliminated. http://www.unicef.org/protection/index_childlabour.html • Ages 5-11: At least one hour of economic work or 28 hours of domestic work per week. • Ages 12-14: At least 14 hours of economic work or 28 hours of domestic work per week. • Ages 15-17: At least 43 hours of economic or domestic work per week. International Labour Organization (ILO) definition: The minimum age at which children can start work (with some possible exceptions for developing countries): http://www.ilo.org/ipec/facts/ILOconventionsonchildlabour/lang--en/index.htm • Ages 13-15: May perform light work that does not threaten health and safety, or hinder education or vocation orientation and training. • Age 15: The age at which compulsory schooling in generally finished; may begin to work Age 18: May perform hazardous work (that which may jeopardize physical, mental or moral health, safety or morals)
CLEAN DEVELOPMENT MECHANISM	Stimulates sustainable development by allowing emission reduction projects in developing countries while allowing industrialized nations to meet emission reduction targets.
CLEARANCE TIME (CT)	The CT indicates the time needed to eliminate or biodegrade a substance to a certain percentage in an organism. For example, the CT50 indicates the time needed to eliminate 50% of a certain substance, analogous to the half-life time measure t1/2.
CLIMATE ACTION RESERVE	National offset program founded to guarantee transparency, integrity, and financial value of voluntary U.S. carbon market.
CLIMATE, COMMUNITY, AND BIODIVERSITY ALLIANCE, THE	Partnership organization comprised of corporations, international non-government organizations, and research institutions that supports and promotes GHG emission mitigation and removal projects that are "land-based."
CLIMATIC RELEVANCE	This is a measure of the climate-influencing characteristics of the substance. All compounds that contribute to global warming are listed here. Examples include carbon dioxide, methane, CFCs, and sulfur hexafluoride.
CO2 EQUIVALENTS (CO2e)	A quantity that describes the amount of CO2 for a particular greenhouse gas that has the same Global Warming Potential when measured for a specific timescale.
COLORANT	Any chemical or substance used to impart color to matter, such as a pigment or dye.

TERM	DEFINITION
COMPOSTABLE	A material capable of undergoing biological decomposition in a compost site as part of an available program, such that the material is not visually distinguishable and breaks down into carbon dioxide, water, inorganic compounds, and biomass at a rate consistent with known compostable materials. If making claims on the compostable nature of materials that are not commonly known to be compostable, testing should be done according to the appropriate ASTM, ISO, CEN, or DIN standard (for example, ASTM D6400-04 for plastics).
DEGRADATION	Decomposition of a compound by stages, exhibiting well-defined intermediate products.
DIN	The German Institute for Standardization. By agreement with the German Federal Government, DIN is the acknowledged national standards body that represents German interests in European and international standards organizations.
DOWNCYCLING	Consequences of design failures to provide products a status as defined biological nutrients or technical nutrients. It is the name for the practice of recycling a material in such a way that much of its inherent value is degraded (e.g. recycling plastic into park benches), revealing poor design of a lifecycle and the related material flows.
EARTHSTER	A free open-source platform for assessing and reporting a product's social and environmental impact.
EFFECT CONCENTRATION 50 (EC50)	The median exposure concentration (EC50) is the median concentration of a substance that causes some effect in 50 percent of the test animals.
EXCESSIVE WORK TIME	ILO definition: More than 48 hours/week; more than 8 hours/day http://www.ilo.org/global/standards/subjects-covered-by-international-labour-standards/working-time/lang--en/index.htm .
EXTERNALLY MANAGED COMPONENT (EMC)	An Externally Managed Component is a sub-assembly, component, or material within a product that is exempt from the general requirement of full characterization to the 100 ppm level because it is managed in a technical nutrient cycle as part of a supplier or manufacturer commercialized nutrient management program. To be considered an EMC, the sub-assembly, component, or material within a product must meet the following criteria: i. The supplier of the EMC has provided the applicant with a guarantee for take back and appropriate nutrient management. The supplier may designate a third party or parties for implementation. ii. The supplier has signed a declaration that chemicals in the EMC will not negatively impact humans or the natural environment during the intended and unintended but highly likely use of the product for which the EMC is a component. The EMC has undergone testing by an accredited analytical laboratory to ensure that harmful substances are not being emitted from the EMC above the chemicals' analytical detection limits.

TERM	DEFINITION
FACILITY	A facility is termed as the final step of the manufacturing process before distribution to the end-user market.
FINISH (noun)	A surface pretreatment or coating for a variety of materials.
FORCED LABOR	UN Global Compact definition: work or service which is exacted from any person under the menace of a penalty and which the person has not entered into of his or her own free will.
FUNDAMENTAL HUMAN RIGHTS	Please refer to The Universal Declaration of Human Rights, (United Nations, 1948) http://www.un.org/en/documents/udhr/index.shtml .
GHG PROTOCOL CORPORATE ACCOUNTING AND REPORTING STANDARD,THE	International accounting tool to quantify, manage, and report greenhouse gas emissions.
GHG PROTOCOL PRODUCT STANDARD	Standardized methodology for quantifying, managing, and reporting greenhouse gas emissions throughout a product's life-cycle.
GLOBAL WARMING POTENTIAL (GWP)	A scale used to relate a compound to the CO2 equivalents to measure the potential heating effects on the atmosphere. The GWP of a gas is the warming potential caused by the emission of one ton of the gas relative to the warming caused by the emission of one ton of CO2, for the same time period.
GOLD STANDARD, THE	International organization that provides transparency in carbon offset projects and awards projects that are driving sustainable development and local benefits.
HALF-LIFE (T1/2)	The amount of time it takes half of an initial concentration of substance to degrade in the environment.
HALOGENATED ORGANIC COMPOUNDS	The column in the periodic chart of the elements that begins with Fluorine contains the halogens. These elements, when combined with organic compounds, form halogenated organic compounds. Most of these compounds are toxic, carcinogenic, persistent, ozone-depleting, bioaccumulative, or form hazardous substances during production and disposal (e.g., PVC).
HAZARD ENDPOINT	For the purposes of the Cradle to Cradle® Chemical Profiling Methodology, this term refers to the list of human and environmental health endpoints that are reviewed for each chemical in the chemical hazard assessment process.
HAZARD RATING	The traffic light system that assigns a GREEN, YELLOW, RED, or GREY rating to each hazard endpoint based on the hazard criteria. The hazard criteria are based on available toxicity and fate information for each chemical.

TERM	DEFINITION
HOMOGENEOUS MATERIAL	A material of uniform composition throughout that cannot be mechanically disjointed, in principle, into different materials (RoHS definition). A homogenous material is composed of one or more chemical substances.
INPUT	Inputs refer to the chemicals, mixtures, simple and complex materials, assemblies, or sub-assemblies that make up a product.
INSEPARABLE COMPONENT	Smallest unit of an object that is either not designed to or cannot be readily disassembled by the end user into individual materials.
ISO	The International Organization for Standardization is the world's largest developer and publisher of International Standards.
LETHAL CONCENTRATION 50 (LC50)	The inhalative median lethal concentration (LC50) is the median concentration of a substance that causes death in 50 percent of the test animals.
LIVING WAGE	The ILO defines a living wage as that "sufficient to meet the basic living needs of an average-sized family in a particular economy." Living wage is not covered by the ILO conventions.
MATERIAL	AKA homogenous material.
MATERIAL ASSESSMENT	A modified risk assessment process for rating materials based on the intrinsic human and environmental health hazards posed by their ingredients as well as the relevant routes of exposure for those ingredients in the material and in the finished product. This analysis takes into account the intended use of the material/product as well as highly likely unintended uses, throughout the product's lifecycle.
MIXTURE	AKA homogenous material.
PAS 2050	Method designed by Publicly Available Specification (PAS) to assess life-cycle emissions of goods and services.
PART	A vended component or input to a product that is made of only one specific type of material.
PERSISTENCE	This is a measure of a substance's ability to remain as a discrete chemical entity in the environment for a prolonged period of time. A common measuring tool for persistence is "half-life" (t1/2), which is the amount of time required for half of the substance to break down. If half-life is greater than 30 days in the air, or if half-life is greater than 50 days in soil, water, or any other media, the substance is considered to be persistent.
POST-CONSUMER RECYCLED CONTENT	Materials that have been collected for recycling after consumer use.
PRECAUTIONARY PRINCIPLE	The precautionary principle states that if an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is harmful, the burden of proof that it is not harmful falls on those taking the action.

TERM	DEFINITION
PRE-CONSUMER RECYCLED CONTENT	Material collected for recycling prior to consumer use, comes from sources outside of the applicant manufacturer's facility, and has been modified before being suitable for recycling back into a manufacturing process. Waste materials directly incorporated back into the manufacturing process within the applicant facility do not apply.
PRIMARY DATA	Observed process data specific to the given processes owned and operated by the reporting company, such as direct emissions, energy, or physical data.
PROCESS CHEMICAL	A process chemical is defined as any substance that comes into direct contact with the product or any of its material constituents during any of processes that constitute the final manufacturing stage of the product. It is used as an intentional part of any of these processes to fulfill a specific function or achieve a specific effect in the product or any of its material constituents. Within this definition, process chemicals are limited to pure chemical substances and chemical substances present in a mixture at a concentration of 1,000 ppm or above. Mixtures include liquids, sprays, gases, aerosols, solids, etc. The concentration threshold applies to process mixtures directly as received by the supplier and prior to any dilution that may take place at the manufacturing site. This definition does not include maintenance agents for machinery, effluent or wastewater treatment chemicals, chemicals used in steam boilers, or cleaning agents used for the production area, offices, and/or lavatories. Distilled water, tap water, and ambient air in their unaltered state are excluded from the assessment.
PRODUCT	A product is a finished good as sold by one entity to another (can be business-to-business or business-to-consumer). It is composed of parts, assemblies, sub-assemblies, materials, and/or chemicals. In addition, a product is the result of design decisions of its producer. The design encompasses the functional use of the product, the post-use handling, the fate of supplied ingredients used to produce it, and decisions made (or not made) for a contribution to success (or failure) of the product to be beneficial under all these circumstances.
PROGRAM CATEGORY	The term "CATEGORIES" in this context will refer to the five program attributes in which products are rated: material health, material reutilization, renewable energy and carbon management, water stewardship, and social fairness.
RAPIDLY RENEWABLE RESOURCE	A material that is able to grow back in 10 years. See also RENEWABLE RESOURCE.
READILY DISASSEMBLED	Capable of being deconstructed with the use of common hand tools (i.e. wrench, screw driver, pliers, scissors, etc.).

TERM	DEFINITION
RECYCLABLE MATERIAL	A material that can technically be recycled at least once after its initial use phase. At a minimum, the material's physical and mechanical properties allow it to be re-melted or size-reduced and used as filler with similar or dissimilar materials (downcycled). It is preferable to select materials that may be recycled into like or higher-value products when possible. However, it is understood that this is difficult to define, as the collection infrastructure and recycling technologies are still in the early stages of development and the economic value of materials will change in the future. Unless there is an automated process for disassembling and reducing size of materials with adequate identification and sorting technologies to produce the highest quality recyclate possible, then attention must be paid to the design and construction of products so that dissimilar materials can be economically separated for recycling. Ideally, disassembly instructions are provided to the end user and/or recycling facilities, recyclable parts are marked, and disassembly is possible using commonly available tools. If the product is too complex for the consumer or third parties to disassemble and/or is designed as a Managed Nutrient, the consumer should be provided with instructions on where to send the product after use. The Cradle to Cradle definition of "recyclable" is different from the U.S. Federal Trade Commission (FTC) definition. While the intentions of the FTC to protect consumers from deceptive marketing claims is logical and laudable, it may also be unintentionally creating disincentives for manufacturers because it limits their ability to use the diversity of materials whose physical properties are very recyclable, but that are not actually recycled, due to the lack of economically profitable collection and recycling systems.
RECYCLED CONTENT	Proportion, by mass, of recycled material within a product that has been recovered or diverted from the solid waste stream, either during the manufacturing process (pre-consumer/post-industrial) or after consumer use (post-consumer).
RENEWABLE ENERGY CREDIT	Tradable certificates produced by an authorized body that verifies electricity was generated from an eligible renewable energy resource.
RENEWABLE RESOURCE	A material from an agricultural source. See also RAPIDLY RENEWABLE RESOURCE.
SECONDARY DATA	Generic or industry average data from published sources that are representative of a company's operations, activities, or products.
SOLAR INCOME	The ultimate goal of Cradle to Cradle® Design is to have all energy inputs come from "current solar income." Forms of current solar income include geothermal, wind, biomass, hydro (in certain circumstances – to be determined on a case-by-case basis) and photovoltaic.
SUB-ASSEMBLY	A unit assembled separately but designed to fit with other units in a manufactured product. It is composed of different materials and makes up an inseparable component of the product.
SUBSTANCE	AKA chemical substance.

TERM	DEFINITION
TECHNICAL METABOLISM	The cycle that technical nutrients flow in. Materials potentially hazardous to life and health may be used in a technical metabolism, if they are sequestered from uncontrolled contact with life. Note that biological nutrients may flow in technical cycles (e.g., paper and bio-based polymers).
TECHNICAL NUTRIENT	A product capable of "feeding" technical systems. Any material that cannot be processed by biological systems is assessed for its capacity to be processed as a resource in systems of human artifice ("Technical Organisms"). In homology to biological nutrients, technical nutrients are catabolized (deconstruction) and anabolized (construction) according to the following hierarchy: • (Dismantle and) Reuse • (Dismantle and) Physical transformation (e.g. plastic remolding) • (Dismantle and) Chemical transformation (e.g. plastic depolymerization, pyrolysis, gasification) The management of technical nutrients occurs by transferring ownership to the users of only the service, not the materials. It is the service offering side that manages materials as technical nutrients, once the phase of functional use is over.
TERATOGEN	A substance shown to cause damage to the embryo or fetus through exposure by the mother (MAK-list: Pregnancy risk group, category A).
TERATOGEN - SUSPECTED	Currently available information indicates that a risk of damage to the embryo or fetus can be considered probable when the mother is exposed to this substance (MAK-list: Pregnancy risk group, category B).
THIRD PARTY AUDIT	An assessment of an organization's conformance to a standard, regulation, or other set of criteria, by an outside auditor. The auditor is to be independent of the organization being audited.
TOXICOLOGICAL ENDPOINT	Also referred to as "endpoint" or "hazard endpoint."
UPCYCLING	Any measure and activity in the design phase targeting optimal handling of products as nutrients.
UTZ CERTIFIED	UTZ Certified is a label and program for sustainable farming of agricultural products launched in 2002, which claims to be the largest program for coffee in the world.
VERIFIED CARBON STANDARD	Provides a framework for developing a project for quantification, reduction, and removal of GHG emissions.

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15 APPENDIX: BANNED LISTS OF CHEMICALS

The following lists contain the chemicals and substances that are banned for use in Cradle to Cradle Certified™ products as intentional inputs above the applicable threshold in any homogeneous material subject to review in the product (1000ppm in most cases, see below and Section 3.3). These substances were selected for inclusion on the Banned Lists due to their tendency to accumulate in the biosphere and lead to irreversible negative human health effects. In addition, several substances were selected due to hazardous characteristics associated with their manufacture, use, and disposal.

See Section 3.3 for complete details regarding the banned list chemical requirement. The applicable threshold is 1000ppm, with exceptions for metals in biological nutrients. Lead, PTFE, and PAHs are not banned in technological nutrients, except for as noted in Section 3.3.

There are two Banned Lists provided: a banned list of chemicals for technical nutrients (Table A-1) and a banned list of chemicals for biological nutrients (Table A-2). A key component of Cradle to Cradle® design is the recognition of and design for the two nested cycles – biological and technical. Banned Lists were thus created separately for biological and technological nutrients to allow for the use of some substances like lead or cadmium in materials where exposure to humans or the environment is unlikely to occur. Lead, for example, is often used in cast aluminum, from which it does not migrate out of the material and can therefore be managed in safe technical cycles. However, lead should not be used in biological nutrients, which ultimately cycle into the biosphere. On the other hand, mercury is not suitable for either type of nutrient cycles due to its ability to easily migrate out of materials. The overall intention is to inspire and promote innovation in quality products in a way that supports 10 billion people on earth without increasing the natural background level of materials or harming people or the environment.

The intention for the "Banned Lists" is not to simply provide a checklist to eliminate chemicals of concern. Rather, it should be viewed as specific examples that may also be used to guide substitution. There may be chemicals similar in structure that are not on the list but exhibit similar properties to the listed chemical. Thoughtful substitutions using the intentional design approach of Cradle to Cradle would suggest that chemicals with similar properties would not be a good substitution choice.

Table A-1 Banned List of Chemicals for Technical Nutrients

SUBSTANCE	CAS #	COMMENTS
Metals		
Arsenic	7440-38-2	
Cadmium	7440-43-9	Banned only for products with no guaranteed nutrient management.
Chromium VI	18540-29-9	
Mercury	7439-97-6	
Flame Retardants		
Hexabromocyclododecane	3194-55-6; 25637-99-4	
Penta-BDE	32534-81-9	
Octa-BDE	32536-52-0	
Deca-BDE	1163-19-5	
Polybrominated Diphenyl Ethers (PBDEs)	Several	
Tetrabromobisphenol A	79-94-7	
Tris(1,3-dichloro-2-propyl)phosphate	13674-87-8	
Phthalates		
Bis(2-ethylhexyl)phthalate	117-81-7	
Butyl benzyl phthalate	85-68-7	
Dibutyl phthalate	84-74-2	
Halogenated Polymers		
Polyvinyl chloride (PVC)	9002-86-2	
Polyvinylidenechloride (PVDC)	9002-85-1	
Chlorinated polyvinyl chloride (CPVC)	68648-82-8	
Polychloroprene	9010-98-4	
Chlorinated Hydrocarbons		
1,2-Dichlorobenzene	95-50-1	
1,3-Dichlorobenzene	541-73-1	
1,4-Dichlorobenzene	106-46-7	
1,2,4-Trichlorobenzene	120-82-1	
1,2,4,5-Tetrachlorobenzene	95-94-3	
Pentachlorobenzene	608-93-5	
Hexachlorobenzene	118-74-1	
PCB and Ugilec	Several	
Short-chain chlorinated paraffins	Several	
Others		
Pentachlorophenol	87-86-5	
Nonylphenol	104-40-5, 84852-15-3	
Octylphenol	27193-28-8	
Nonylphenol ethoxylates	Several	
Octylphenol ethoxylates	Several	
Tributyltin	688-73-3	
Trioctyltin	869-59-0	

SUBSTANCE	CAS #	COMMENTS
Triphenyltin	892-20-6	
Perfluorooctane sulfonic acid	1763-23-1	
Perfluorooctanoic acid	335-67-1	

Table A-2 Banned List of Chemicals for Biological Nutrients

SUBSTANCE	CAS #	COMMENTS
Metals		
Arsenic	7440-38-2	Restricted to 10 ppm
Chromium	18540-29-9	Restricted to 100 ppm
Mercury	7439-97-6	Restricted to 1 ppm
Cadmium	7440-43-9	Restricted to 2 ppm
Lead*	7439-92-1	Restricted to 90 ppm
Flame Retardants		
Hexabromocyclododecane	3194-55-6; 25637-99-4	
Penta-BDE	32534-81-9	
Octa-BDE	32536-52-0	
Deca-BDE	1163-19-5	
Polybrominated Diphenyl Ethers (PBDEs)	Several	
Tetrabromobisphenol A	79-94-7	
Tris(1,3-dichloro-2-propyl)phosphate	13674-87-8	
Phthalates		
Bis(2-ethylhexyl)phthalate	117-81-7	
Butyl benzyl phthalate	85-68-7	
Dibutyl phthalate	84-74-2	
Halogenated Polymers		
Polyvinyl chloride (PVC)	9002-86-2	
Polyvinylidenechloride (PVDC)	9002-85-1	
Chlorinated polyvinyl chloride (CPVC)	68648-82-8	
Polychloroprene	9010-98-4	
Polytetrafluoroethylene (PTFE)*	9002-84-0	
Chlorinated Hydrocarbons		
1,2-Dichlorobenzene	95-50-1	
1,3-Dichlorobenzene	541-73-1	
1,4-Dichlorobenzene	106-46-7	
1,2,4-Trichlorobenzene	120-82-1	
1,2,4,5-Tetrachlorobenzene	95-94-3	
Pentachlorobenzene	608-93-5	
Hexachlorobenzene	118-74-1	
PCB and Ugilec	Several	
Short-chain chlorinated paraffins	Several	
Other		
Pentachlorophenol	87-86-5	

SUBSTANCE	CAS #	COMMENTS
Nonylphenol	104-40-5, 84852-15-3	
Octylphenol	27193-28-8	
Nonylphenol ethoxylates	Several	
Octylphenol ethoxylates	Several	
Tributyltin	688-73-3	
Trioctyltin	869-59-0	
Triphenyltin	892-20-6	
Perfluorooctane sulfonic acid	1763-23-1	
Perfluorooctanoic acid	335-67-1	
Polycyclic Aromatic Hydrocarbons*		
PAH group (as defined in TRI)	Not applicable	
Benzo(a)pyrene	50-32-8	
5-Methylchrysene	3697-24-3	
Acenaphthene	83-32-9	
Anthracene	120-12-7	
Benz(a)anthracene	56-55-3	
Benz(j)aceanthrylene	202-33-5	
Benzo(b)fluoranthene	205-99-2	
Benzo(c)phenanthrene	195-19-7	
Benzo(g,h,l)perylene	191-24-2	
Benzo(j)fluoranthene	205-82-3	
Benzo(k)fluoranthrene	207-08-9	
Chrysene	218-01-9	
Cyclopenta(c,d)pyrene	27208-37-3	
Dibenzo(a,h)anthracene	53-70-3	
Dibenzo(a,h)pyrene	189-64-0	
Dibenzo(a,i)pyrene	189-55-9	
Dibenzo(a,l)pyrene	191-30-0	
Fluoranthene	206-44-0	
Fluorene	86-73-7	
Indeno(1,2,3,c,d)pyrene	193-39-5	
Naphthalene	91-20-3	
Phenanthrene	85-01-8	
Pyrene	129-00-0	

* *Note these chemicals are on the Banned List for Biological Nutrients only*

Supplemental Guidance for the Cradle to Cradle Certified™ Product Standard, Version 3.1

September 2016

Written in collaboration with MBDC, LLC.

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TABLE OF CONTENTS

SUPPLEMENTAL GUIDANCE FOR THE CRADLE TO CRADLE CERTIFIED™ PRODUCT STANDARD, VERSION 3.1 REVISION HISTORY

REVISION DATE	SECTION	TYPE OF CHANGE	AUTHORIZED BY
September 29, 2016	Initial Release		S. Klosterhaus

1 OVERVIEW OF THE GUIDANCE DOCUMENT

1.1 PURPOSE AND CONTENT

The purpose of this document is to serve as supplemental guidance to the Cradle to Cradle Certified Product Standard, Version 3.1 (the 'standard'). This supplemental guidance provides clarification and further interpretation of the original intent of a number of the requirements in Version 3.1 of the standard document. Information in this document supersedes any conflicting information that may be present in the full standard document.

1.2 SUPPORTING DOCUMENTS

The following documents are to be used in conjunction with this supplemental guidance document:

- Cradle to Cradle Certified™ Product Standard, Version 3.1
- Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.0.
- Supplemental Guidance for the Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.0
- Any additional supporting standard documents and guidance posted on the C2CPII website

Visit the Cradle to Cradle Products Innovation Institute website to download the standard documents and obtain the most current information regarding the product standard (http://www.c2ccertified.org/product_certification/c2ccertified_product_standard).

1.3 DOCUMENT ORGANIZATION

Beginning with Section 2 of this document, supplemental guidance is organized following the sections of the original standard document. Section sub-headings without any additional guidance have been omitted from this document.

2 OVERVIEW OF THE STANDARD

No further clarifications.

3 MATERIAL HEALTH

3.4 COLLECTION OF MATERIAL COMPOSITION DATA

Chemicals Subject to Review at Any Concentration – Textile Auxiliaries and Leather Tanning Agents

Background: The standard states that the chemicals subject to review in each material are those present at a concentration ≥ 0.01% (≥ 100 ppm), and those subject to review at any concentration.

Chemicals subject to review at any concentration are: lead, mercury, hexavalent chromium, cadmium, pigments, dyes and other colorants, phthalates, halogenated organics, scarce elements, metal plating agents, textile auxiliaries, blowing agents, and paper bleaching agents. These chemicals are subject to review even if they do not remain in the final product.

Interpretation: The term 'textile auxiliaries' is to be replaced with 'textile dye auxiliaries' here and in other sections of the standard where this concept is discussed. A textile auxiliary is defined as any process chemical used during the dyeing or finishing of a textile. Textile auxiliaries that are not dye auxiliaries need only be included in the review if they are present at a concentration ≥ 0.01% (≥ 100 ppm) within the textile material. They will also be considered in the Water Stewardship category at the Silver level if they are present in effluent as part of the product's final manufacturing stage.

Interpretation: Leather-tanning agents shall be added to the list of chemicals subject to review at any concentration.

3.6 DETERMINING PERCENTAGE ASSESSED

Percentage Assessed at the Chemical Level

Background: The standard requires that materials in a product be assessed using the ABC-X rating system. In most cases, an increasing percent of homogeneous materials by weight must be assessed as certification level increases. However, an increasing percent of chemicals by weight may be used in some cases as detailed below. Exception #2 below is a new interpretation added to the standard via this guidance document.

Interpretation: The total percentage of the product assessed equals the sum of the individual percentages by weight of each homogeneous material (that meet the requirements detailed in the full standard document), with two exceptions as described below. In both of these cases, the percentages for each chemical by weight may be used in determining the percentage of the product assessed.

1. The product is a single-material product. For this purpose, a product is considered a single-material product if it is composed of:
    a. A single homogeneous material, or
    b. A single homogeneous material that is at least 95% of the final product by weight and 5% or less of other materials that are either a coating, finish, print, paint, ink, other surface treatment, film, or interlayer.
2. The product contains at least one homogeneous material that makes up more than 25% of the product by weight and this material contains one or more GREY substances whose assessment is infeasible due to missing toxicity data or formulation information that the assessor is unable to obtain due to a supplier's refusal to share the information. For a product to qualify for this exception, this homogenous material must itself be at least 95% assessed based on the weight fraction of the individual assessed chemical substances in the material.

Ensuring Absence of CMRs at the Silver Level when Reporting Percentage Assessed at the Chemical Level

Background: If reporting percentage assessed based on the weight of chemicals per one of the exceptions described in the section above and applying at the Silver level, it is necessary to perform additional due diligence to ensure that carcinogens, mutagens, and reproductive toxicants (CMRs) are not present.

Interpretation: In order for a substance to count towards the percentage assessed at the Silver level, it must not be GREY and one of the following is required:

- It is part of a homogenous material in which all of the substances subject to review have been identified (i.e., no GREY ingredients due to lack of formulation data) and none received a single chemical risk score of 'x' as a result of being a CMR (other chemicals may still be GREY due to missing toxicity data and thus not count toward the percentage assessed), OR
- It is part of a homogenous material for which the material supplier or other party with knowledge of the chemical composition of the material has signed a declaration stating that CMRs are not present in the material.

These conditions also apply when the product itself is a single homogenous material. This means that in order for any substances in a single homogenous material product to count towards the percentage assessed at the Silver level, the substance(s) must not be GREY, and either all substances subject to review must be identified, or CMR declarations must be obtained from suppliers of unidentified mixtures.

Percentage Assessed for Biological Nutrients

Background: At the Bronze level and above, complete formulation information needs to have been collected for 100% of BN materials that are released directly into the biosphere as a part of their intended use (e.g., cosmetics, personal care, soaps, detergents, paint, etc.).

Interpretation: Cosmetics, personal care, soaps, detergents, paint, etc., includes all wet applied products and all other liquid products that may be released directly to the biosphere during use.

3.7 MATERIAL OPTIMIZATION STRATEGY

X and GREY Materials Must be Included in the Strategy

Background: The 'Standard Requirement' portion of section 3.7 of the standard states that: 'A phase-out or optimization strategy has been developed for those materials with an X rating.'

Interpretation: The optimization strategy must also include a plan for phase out or complete assessment of any GREY rated materials or chemicals. This is stated in the Methods portion of section 3.7 of the standard: 'All X (problematic) and Grey (data missing) materials are to be included in the optimization plan.'

3.8 DETERMINING ABSENCE OF CMR SUBSTANCES

See Section 3.6 above regarding conditions applying at the Silver level when determining percentage assessed based on the weight of assessed chemicals instead of assessed homogeneous materials.

3.9 VOLATILE ORGANIC CHEMICAL (VOC) EMISSIONS TESTING

7-Day Time Point

Background: The standard states that: 'The time point used is 7 days for VOCs and IVOCs'.

Interpretation: The test duration can be longer than 7 days (up to 14 days) but the testing has to either include a measurement or interpolation to the day 7 concentrations (or earlier), which need to meet the thresholds indicated in the standard.

Testing Requirements for Product Groups

Interpretation: For product groups it is acceptable for the assessor to select and have tested a single representative product (for example the one with the highest number of inputs) if it can reasonably be expected that no other product in the group will perform less well.

4 MATERIAL REUTILIZATION

No further clarifications.

5 RENEWABLE ENERGY AND CARBON MANAGEMENT

5.1 QUANTIFYING ELECTRICITY USE AND EMISSIONS

Reporting Emissions from On-Site Generated Electricity

Background: The standard requires that two mutually exclusive quantities relevant to the final manufacturing stage of the product be reported: electricity use and greenhouse gas emissions.

Interpretation: Greenhouse gas emissions resulting from production of electricity on-site are to be reported in the greenhouse gas emissions category.

5.3 USING RENEWABLE ELECTRICITY AND ADDRESSING GREENHOUSE GAS EMISSIONS

Carry Over of Excess RECs and Offsets

Background: The standard states that "If it is determined that excess offsets or RECs were purchased in the prior year due to use of estimates, the excess may be credited toward the amount to be purchased at the next re-application."

Interpretation: RECs intended for a given certification period may be purchased up to a year prior to the beginning of that certification period. Excess RECs that were originally intended for any given 2-year certification period may be applied to the 2-year certification period following it, but not to any subsequent certification periods.

6 WATER STEWARDSHIP

6.2 LOCAL AND BUSINESS-SPECIFIC WATER ISSUES

Reporting on Scarcity/Stress Level

Interpretation: To address Required Documentation item #4 of the water issues characterization (scarcity/stress level), applicants may report any reasonable water stress metric (e.g. baseline water stress, annual renewable water supply per person, etc.), from any source (Global Water Tool, Aquaduct, etc.). Applicants may also report risk levels for more than one metric if they choose.
Exclusive use of metrics unrelated to water quantity is not permitted, since the intended issue to investigate is scarcity.

6.3 WATER STEWARDSHIP INTENTIONS

High Risk Issues

Background: An action plan to address local and business specific water issues that have been identified per standard section 6.2 is required. Specifically, a plan to address high or very high risk/opportunity categories (Social Hotspot Database) and red ratings (WBCSD Global Water Tool) is required.

Interpretation: Applicants are required to provide a positive impact strategy for any "high" risk issues identified, unless the Global Water Tool is used. In the latter case, a strategy will only be required for "extremely high" risks (since the standard only requires a strategy for "red" ratings outputted by the Global Water Tool). To override a reported high risk from a non-Global Water Tool source, an applicant can report a comparable Global Water Tool result and that result must not be red.

Plan to Address Scarcity

Interpretation: For all identified problems except scarcity, a plausible explanation for why an identified issue is unrelated to the activities of the applicant is acceptable in lieu of an action plan to address the issue. An action plan to address high risk on water quantity (i.e. water scarcity) is required in all cases where water is used at the final manufacturing stage facility. For example, if sanitary water is used but the manufacturing process itself does not require any water, an action plan would still be required.

A list of measures that can be implemented to increase efficient use of water can be found in Appendix A of the U.S. EPA Water Conservation Plan Guidelines.

6.4 WATER AUDIT

Alternative to Facility Wide Water Audit

Background: A facility wide water audit is required. The intent of the requirement is to assist manufacturers with understanding the amount of water used to manufacture the product and identify opportunities for reduction in use. A specific list of metrics to report on is detailed in the standard's Methods section and also within a supporting Water Audit form.

Interpretation: Metrics and supporting documentation other than those listed in the standard and supporting Water Audit form are acceptable as long as the outcome of the data collection and analysis meets the intent of the requirement (i.e., to increase the manufacturer's understanding of the amount of water used to manufacture the product). For example, a cradle to gate water use life cycle assessment (LCA) would be accepted in place of a facility wide water audit.

6.5 CHARACTERIZING AND ASSESSING PRODUCT-RELATED PROCESS CHEMICALS IN EFFLUENT

Water Recovery

Background: At the Silver level and above, "Product-related process chemicals in effluent are characterized and assessed, or product-related process chemicals are not discharged to water systems because wastewater is kept flowing in systems of nutrient recovery."

Interpretation: The term 'nutrient recovery' in the requirement above is referring to water recovery as opposed to chemical recovery. Product-related process chemicals present in any effluent that is discharged are required to be optimized. In other words, even if wastewater is treated prior to leaving the facility as effluent, product-related chemicals remaining in the effluent must still be characterized, assessed, and optimized (per standard section 6.7) due to the presence of low concentrations of these chemicals'.

6.6 SUPPLY CHAIN WATER ISSUES AND STRATEGY

Eligible Tier 1 Suppliers

Background: To fulfill the Silver-level supply chain option, applicants must complete one of the three Basic-level water issues investigation options for at least 20% of the tier 1 suppliers.

Interpretation: Only suppliers for which the given investigation option is applicable are eligible to help fulfill the requirement. In other words, only suppliers that have a facility (and are therefore able to complete a water audit) are eligible to contribute toward fulfillment of the water audit option, and only suppliers that have a discharge permit (and therefore can report on whether there was a violation) are eligible to contribute toward the discharge permit option.

7 SOCIAL FAIRNESS

7.4 MATERIAL-SPECIFIC OR ISSUE-SPECIFIC AUDIT

Additions to List of Approved Programs

Background: A material-specific and/or issue-related audit or certification relevant to a minimum of 25% of the product material by weight is required. A list of pre-approved programs is provided in the standard.

Interpretation: The following have been added to the list of approved programs:

a. Certain statewide professional logger certification programs if it can be shown that the material is supplied directly by a currently certified logger (includes: Pro Logger – North Carolina, Master Logger - Kentucky and Tennessee, and SHARP Logger – Virginia).
b. RSPO Certified Sustainable Palm Oil
c. SustainaWOOL™ under the following conditions:
    a. The wool is sourced only from companies/farmers that are designated as having Ceased Mulesing (CM) or source Non Mulesed (NM) wool. Wool from sheep that have received Pain Relief (PR) treatment may not receive credit as mulesing is still used among these companies/farmers.
    b. A National Wool Declaration (NWD) must be provided. This information will have been collected as part of the SustainaWOOL program.

Requesting Additions to List of Approved Programs

Background: Assessors may request additions to the list of approved programs by providing C2CPII with the name of the proposed program and the following details:

a. A summary of the program and how it addresses fundamental human rights and other social fairness issues;
b. A list of any ecolabels/standards (other than C2C) or government programs that reward for use of materials certified under the program; and
c. A summary of any major criticism the program has received from NGOs or governments.

Interpretation: The following is also required and must be verified by the assessor:

d. Accessibility to the program is open to anyone who qualifies to apply. Programs that are administered/overseen by manufacturers allow competitors to join the initiative.

CRADLE TO CRADLE CERTIFIED™
PRODUCT STANDARD
VERSION 3.0

MATERIAL HEALTH ASSESSMENT METHODOLOGY

PROGRAM ADMINISTERED BY:

CRADLE TO CRADLE PRODUCTS INNOVATION INSTITUTE

DOCUMENTS PREPARED BY:

MBDC

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SUPPORTING DOCUMENTS

The following documents are to be used in conjunction with the Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.0:

- *Supplemental Guidance for the Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.0*
- *Cradle to Cradle Certified™ Product Standard, Version 3.0.*
- *Supplemental Guidance for the Cradle to Cradle Certified™ Product Standard, Version 3.0*
- *Any additional supporting documents and guidance posted on the C2CPII website*

Visit the Cradle to Cradle Products Innovation Institute website to download the standard documents and obtain the most current information regarding the product standard (http://www.c2ccertified.org/product_certification/c2ccertified_product_standard).

TABLE OF CONTENTS

LIST OF TABLES

1 INTENT

The purpose of this resource is to provide guidance on performing chemical hazard assessments and how they are used for material assessments. The overarching goal is to secure access to safe materials for use in products. In this methodology, the following are examined:

- Product Breakdown and Data Collection - Rules and guidelines for obtaining chemical compositions.
- Chemical Profiling Methods – Comprehensive guidance on 24 human and environmental health hazard endpoints and criteria.
- Metabolism Considerations – Considerations beyond the 24 hazard endpoints and how each are applied toward decision-making for material assessments, where applicable.
- Material Assessments – Guidance for evaluation of materials.

2 SCOPE

The boundary of review is when the product leaves the final production facility. The process chemicals associated with the production of certain inputs are included, where applicable, as well as those process chemicals used in the final production of the product.

3 OVERVIEW

Efforts to minimize the use of hazardous chemicals and/or manage their exposure to the general population have clear indications of failure. Numerous studies have demonstrated the presence of hazardous chemicals in the tissues and blood of the general population, including chemicals that have been regulated for decades. With this knowledge, the Cradle to Cradle Certified™ Product Material Health Assessment Methodology will be positioned as a transparency, optimization, and design protocol that gives manufacturers the tools to build products that are safe and healthy for humans and the environment from production to use to reuse. As knowledge advances over time, we will come to a greater understanding of how the manufactured environment interacts with the natural environment, and so it is through the Cradle to Cradle Certified ™ Product Program that we hope to spur the "Next Industrial Revolution."

The aim of the material health assessment methodology is to characterize the hazards of chemicals present in a product, and in turn generate material assessment ratings based on those hazards and their relative routes of exposure during the intended (and highly likely unintended) use and end-of-use product phases. Chemical composition data for materials is needed down to the 100 ppm level (0.01%) to generate full assessment ratings. A rating system has been developed to identify the continuum of risk—from those chemicals that pose the greatest hazard to those that pose little to no hazard. The purpose is to give product designers the opportunity to see those chemicals and materials that contain the greatest hazard in order to pick safer alternatives.

4 PRODUCT COMPOSITION AND DATA COLLECTION

4.1 DETERMINATION OF REVIEW

Products range from simple, homogeneous, formulated mixtures of known chemicals to highly complex constructions using multiple heterogeneous materials, assemblies, and parts. Material assessments can only be conducted with a full understanding of the chemical makeup of those materials, as well as the intrinsic risks those chemicals present in different exposure and use scenarios. In order to make confident decisions about a product's human and environmental health impacts, we must define the process for analyzing the intentional inputs, including chemicals, mixtures, simple and complex materials, assemblies and sub-assemblies.

PVC and any other Banned List Substances present above allowable thresholds (see Section 7.2 for Banned Lists) in the finished product that must be reported and optimized before certification can be granted. Banned List chemicals are those substances that pose the greatest risk to human health due to their ability to accumulate in the biosphere and lead to irreversible negative health impacts.

The spirit of the Cradle to Cradle Certified™ Product Program is to communicate the intention that products will be designed as Technical Nutrients (TN), and/or Biological Nutrients (BN). If the product combines various types of nutrients, they should be clearly marked and reviewed accordingly.

4.2 PROCEDURE FOR BREAKDOWN OF PRODUCT'S PAST CRADLE

The goal for product breakdown is to first identify those homogeneous materials that will be subject to review. The following is a process for breaking a product down to its components, or building blocks, based on the manufacturing/assembly process, or "past cradle," for the specific product under review.

Note that this information is also provided in the Cradle to Cradle Certified™ Product Standard, which is available for download on the Cradle to Cradle Products Innovation Institute website (http://www.c2ccertified.org/).

4.2.1 Determination of Materials Subject to Review

The intent of this exercise is to break a product down to homogeneous inputs used for its production by specific manufacturer trade name and grade and to identify those that contribute to at least 0.01% (100 ppm) of the product's composition by weight.

- For formulated materials/products, this is accomplished by listing all chemical or sub-material inputs by Chemical Abstract Service Registry Number (CASRN or CAS) or Manufacturer Trade name and Grade, where appropriate.
- For more complex products, this is accomplished by separating parts and components of assemblies and sub-assemblies into individual homogeneous materials by manufacturer trade name and grade.

After the product has been broken down into individual homogeneous materials by specific manufacturer trade name and grade and the total product weight has been calculated, the following process will determine what materials are subject to review:

1. Determine the weight of each homogeneous material identified. If the same homogeneous material is used in more than one place in a given product, the weights should be summed to give the overall weight for all uses of that homogeneous material in the product.
2. Divide the weight of each homogeneous material (or the sum of the weights of those homogeneous materials that are used more than once) by the total weight of the product. Multiply this number by 100 to give a percentage.
3. If a homogeneous material is present at ≥0.01%, then it is subject to review.

Some homogeneous materials are subject to review regardless of their concentration in the final product. They are outlined below:

4.2.1.1 Exceptions

The following materials must be assessed regardless of their overall weight percentage in the finished product:

1. All finishes (e.g., coatings, plating, and paints) must be reviewed regardless of their concentration in the final product, and whether or not they are present above the 0.01% threshold in the material onto which they are applied.
2. Blowing agents must be reviewed even if they are not present in the finished product above the 0.01% threshold, and whether or not they are present above the 0.01% threshold in the material into which they are applied.
3. Plating chemistry must be reviewed if a plated part is above the 0.01% threshold in the finished product.

Once these materials have been identified, the next step is to generate a list of chemicals by CASRN present at or above 0.01% by weight of those materials in order to perform chemical hazard assessments, as described in Section 6. In the case of primary materials (i.e., those containing no recycled content), this is achieved by way of chemical composition disclosure from raw material suppliers.

Complete ingredient information for a given homogeneous material must include the following at ANY concentration:

- Toxic heavy metals such as lead, mercury, hexavalent chromium, and cadmium.
- Pigments, dyes, or other colorants.
- Phthalates.

- Halogenated organics**.**
- Scarce elements**,** as defined by the following:
    - Known availability is less than 20 years or,
    - Availability is assumed to be low based on expert opinions.
    - Crucial for high tech industries but not evenly distributed so that parts of mankind could be excluded from access to them.

4.2.1.2 Product Examples

For formulated materials/products, product breakdown is accomplished by listing all chemical or sub-material inputs by CAS or Manufacturer Trade name and Grade, where appropriate. Table 1 provides an example:

Table 1 Example of Formulated Materials/Product Breakdown

NAME	CAS #	%	FUNCTION
Water	7732-18-5	60	Solvent
1-Decanesulfonic acid, sodium salt	13419-61-9	15	Surfactant
Alcohols, C10-14, ethoxylated	66455-15-0	10	Surfactant
Sodium Citrate	6132-04-3	7	Buffer
Citric acid	77-92-9	5	Buffer/chelator
Rose essence fragrance	mixture	2	Fragrance
Antibacterial product	mixture	1	Anti-Microbial

NOTE – since both the fragrance and anti-microbial are mixtures of chemicals, or 'products' themselves, they must be further broken down into their base chemistry and added to this list. This list is considered complete ONLY when there is nothing but individual chemical names and CAS numbers listed.

For more complex products, the product is broken down by virtually separating parts and components of assemblies and sub-assemblies into individual homogeneous materials by manufacturer trade name and grade.

Table 2 provides an example:

Table 2 Example of Complex Product Breakdown

Part Number	Part Description	Parts per Product	Generic Material	Exact Material Specification	Color/ Finish	Part Wt (lbs.)	Total wt. All Parts	Product wt. (lbs.)	% of Total Wt
12345	Chair base	1	Aluminum	380 cast aluminum	none	8	8	50	16
12346	Caster	5	Multiple						
12346.1	Pintle	5	Steel	1010 steel	zinc plate	0.25	1.25	50	2.5
12346.2	Axle	5	Steel	1215 steel	none	0.1	0.5	50	1
12346.3	Wheel	10	Nylon	Acme nylon 123	black	0.075	0.75	50	1.5
12347	Pneumatic Cylinder	1	Multiple						
12347.1	Outer tube	1	Steel	1008 steel	black	3.5	3.5	50	7
12347.2	Inner tube	1	Steel	1010 steel	none	1.5	1.5	50	3
12347.3	Washer	2	Steel	1215 steel	none	0.5	1	50	2
12347.4	Misc pieces	2	Aluminum	6262 aluminum	none	0.2	0.4	50	0.8
12347.5	Seal	2	Rubber	Kraton xyz	none	0.05	0.1	50	0.2
12347.6	End cap	1	Acetal	Delrin xyz	none	0.15	0.15	50	0.3
12347.7	Grease	1	Lubricant	Mobil supber grease	none	0.001	0.001	50	**0.002**

NOTE – The chair base is a single homogeneous material and is listed as such. The Caster, and Pneumatic cylinder, are both heterogeneous parts or sub-assemblies made up of several homogeneous materials and therefore must be broken out further to list all homogeneous materials by official trade name and grade. Since the ultimate threshold for evaluation is 0.01%, the grease, which is present at 0.002% would not be included in the assessment. In this manner, the entire chair must be broken out and ultimately list all homogeneous materials that are present either in assemblies, sub-assemblies, or used directly in the finished chair.

5 MATERIAL ASSESSMENT METHODOLOGY

5.1 INTRODUCTION

The purpose of the comprehensive chemical profiling procedures described later is to use existing toxicological data from peer-reviewed sources on single chemicals and then conservatively extrapolate the human and environmental health risks of complex mixtures, materials and products based on that data. While presenting its particular challenges, decision-making for the human and environmental health risks of complex mixtures must also be coupled with certain exposure, life cycle, and risk-based endpoints and considerations to give a complete picture of "Hazard x Exposure = Risk." This section aims to explain the process of incorporating a broader view of risk in order to make Material Assessment rating decisions.

It is recognized that there are environmental impacts associated with the creation of every material used in commerce at some stage of its lifecycle. It is both impractical and not yet possible to fully identify and assess all of the known and potential impacts at every stage of manufacturing a material; however, Cradle to Cradle® methods apply the Precautionary Principle in most, if not all cases to capture conservative protection standards. Material assessments are generated using chemical profiles, as well as an understanding of the potential routes of exposure to those chemicals once they are combined to make a given material. In addition, the nutrient potential, or ability of these materials to be recaptured/reused as technical or biological nutrients is also evaluated. Therefore, the overall material assessment rating is a combination of human/environmental health impacts and nutrient potential. A summary of the Material Health Assessment process is provided in Section 9.

5.2 MATERIAL ASSESSMENT RATINGS

Table 3 explains the material assessment ratings:

Table 3 Material Assessment Ratings

A	The material is ideal from a Cradle to Cradle perspective for the product in question.
B	The material supports largely Cradle to Cradle objectives for the product.
C	Moderately problematic properties of the material in terms of quality from a Cradle to Cradle perspective are traced back to the ingredient. The material is still acceptable for use.
X	Highly problematic properties of the material in terms of quality from a Cradle to Cradle perspective are traced back to the ingredient. The optimization of the product requires phasing out this ingredient or material.
GREY	This material cannot be fully assessed due to either lack of complete ingredient formulation, or lack of toxicological information for one or more ingredients.
BANNED	BANNED FOR USE IN CERTIFIED PRODUCTS This material contains one or more substances from the Banned list and cannot be used in a certified product.

The following sections discuss considerations that should be taken into account when performing a material assessment.

5.3 CHEMISTRY

5.3.1 Matrix Structure Type

The base material matrix (i.e., base polymer, metal alloy, natural fiber, etc.) is used to judge whether chemical additives are able to freely migrate into external systems. For example, certain plastic additives are considered reactive, i.e., they react with the other monomer(s) and become part of the polymer backbone and therefore are not free to migrate out of the finished resin. Much the same way, it has been shown that lead in cast aluminum is bound in the metal matrix and poses little to no risk. Natural materials in indoor use applications often release volatiles contributing to compromised indoor air quality, so emissions must be verified. Careful consideration is given to the type of matrix when making material assessment decisions.

5.3.2 Reaction Chemistry

Because materials are assessed based on the final state of all inputs to that material, it is important to have an in-depth understanding of the key chemical reactions taking place in a system and whether the chemical is still in its original form after curing or other reactions reach equilibrium. For example, uv inks contain several sensitizing and reactive chemicals in their "raw" state, but after the printing process is complete and the ink has cured, many of those substances are no longer present in their original state but rather have reacted together to form a different molecular structure. Collecting important chemical function data from supply chain technical staff is a good way to gain understanding about the full picture of the complex chemical mixtures present in the

final material or product in order to give the most accurate assessment rating. For example, when evaluating polyurethane foams, it is common to see polyols and isocyanates listed as separate chemicals. However, in the final foam material they do not exist separately, but rather have reacted together to form polyurethane molecules.

5.3.3 Physiochemical Properties

General principles surrounding the physical and performance properties of chemicals impact the material assessment decisions in some cases. Some examples are as follows:

- Solubility – a chemical may be considered less aquatically toxic if it is insoluble in water.
- Volatility – if a chemical is known to volatize completely during manufacture, it is assumed to be present at less than 100 ppm of the final material or product.
- Structure stability – an example where structural stability overrides hazard ratings for ingredients is shown with spinels, which are often used in colorant applications, and are virtually indestructible compounds.

Knowledge of physical properties of substances also aids manufacturers with optimizing chemistry should problematic inputs be found.

5.3.4 Impurities

Unintentional impurities resulting from chemical reactions present in chemical mixtures if below 100 ppm of the material will not contribute to the overall hazard assessment rating of the material. Impurities with known toxicological hazards that are above 100 ppm of the material will, however.

5.4 PROCESSES, SYNTHESIS, AND MANUFACTURING

It is well known that process-related aspects of manufacturing and production can often cause just as much risk to human and environmental health as the products that are produced, by way of water effluent discharges, use of hazardous intermediate chemicals, and worker safety.

Assessment ratings for materials are affected by identifying certain process-related attributes during the data collection process. The following processes will automatically generate an X material assessment rating:

- Metal Plating – if hexavalent chromium is used in any plating processes, the plated material is given an X assessment regardless of the concentration of the hexavalent chromium (Cr(6+)) in the final material.
- Blowing agents used in foams – if a problematic blowing agent is used to manufacture the foam it will be given an X assessment rating regardless of the level of residual blowing agent left in the finished foam.
- Textile process chemistry – Auxiliaries used in the textile manufacturing process are included in the data collection and assessment review regardless of the concentration they are found left on the final product.

- Paper process chemistry – The bleaching process chemicals are identified and factored into the material assessment.

5.5 RELEVANCE OF EXPOSURE ROUTES

Prediction of possible and likely exposure scenarios lends guidance to decision-making for Material Assessment Ratings. Some examples of possible exposure routes are:

- Occupational.
- Inhalation.
- Ingestion.
- Dermal/Membranes.
- Air.
- Water.
- Soil.

5.6 END-OF-USE PHASE CONCERNS

It is imperative to consider the end-of-use phase of products. The purpose of optimization in all five Program Categories is to ensure that any scenario will not lead to unintended risk to humans or the environment at any stage, but most importantly, at the end-of-use. Ideally, the Program promotes safe, perpetual cycling of biological and technical nutrients, but cannot guarantee a consumer will follow through with responsible disposal. Some considerations to keep in mind when assessing the chemical composition of materials are as follows:

- Methods of disposal (i.e., deposits to water or soil by any method).
- Recyclability impacts.
- Incineration products and by-products.
- Societal impacts.
- Ecological impacts.

5.7 FORMALDEHYDE AND INDOOR AIR QUALITY

Assessments of formaldehyde-containing materials often lead to an X assessment for the following reasons:

- Formaldehyde is a highly problematic substance from a human health perspective, and shows moderate to high toxicity to aquatic species in the biosphere.
- The International Agency for Research on Cancer (IARC) has classified formaldehyde as a “confirmed human carcinogen”. In addition, it is a “suspected human carcinogen” according to the American Conference of Governmental Industrial Hygienists (ACGIH) and maximum workplace concentration (MAK) says it has “carcinogenic potential.”

- Formaldehyde is mutagenic in Ames and eukaryotic tests, and is a germ cell mutagen.
- Formaldehyde has high acute toxicity and is an irritant and a sensitizer.

Formaldehyde is hazardous in multiple criteria; therefore, it is not recommended for use in any products at a compositional level above 100 ppm.

There are many formaldehyde-based resins available today, and more are being formulated for future use. The traditional formaldehyde binder resin combinations are Urea-Formaldehyde, Melamine-Formaldehyde and Phenol-Formaldehyde. Each of them has its own set of physical and chemical properties that makes it desirable in various industries and applications. However, all formaldehyde resins emit formaldehyde to a varying degree. For this reason, products containing these binders warrant concern for indoor air quality. The demand is growing for low-formaldehyde-emitting resins, so many combinations of these ingredients, along with other additives, are being tested for possible industry importance by many different companies. This growing number of formulations does not allow us to thoroughly evaluate each one for its chemical properties and emission patterns, so it is best to make a general rule for assessing the human and ecological health impacts of the binder resins in general. This approach is also valid, because the mechanism of formaldehyde emission from all formaldehyde resins is similar.

Formaldehyde is emitted in two ways. First, residual formaldehyde that has not fully reacted into the polymer matrix migrates to the surface and is emitted directly. Second, hydrolysis of the polymer matrix occurs, releasing formaldehyde, which is then emitted from the material. Formaldehyde-based polymers not handled according to manufacturer specifications (i.e., do not over heat above a certain temperature) can become a serious worker safety hazard. Hydrolysis increases with heat and humidity, and continues until it comes to equilibrium with the free formaldehyde in the adjacent air. If the air is vented to provide fresh air to the formaldehyde resin, hydrolysis will continue until the resin is completely depleted. Since the two formaldehyde mechanisms occur simultaneously, as expected, emissions are high when the resin is first formed, due to free formaldehyde release, then tapers off to a lower, more constant level due to hydrolysis. Low-emitting resins often include formaldehyde "scavengers," such as extra urea, therefore their initial emission levels are lower. However, even these scavengers have been shown to undergo hydrolysis, so they will still emit formaldehyde.

Emission of formaldehyde cannot reliably be correlated to free formaldehyde in resin binder matrices; therefore residual formaldehyde cannot be determined by emissions tests and will need to be verified with the supplier. The only acceptable way to determine residual formaldehyde in a resin is to test the material directly.

5.8 VOLATILE ORGANIC COMPOUNDS (VOC) EMISSION TESTING

To demonstrate compliance with emissions standards, a product must comply with the following requirements:

1. One of the following test methods to quantify emissions has been used:
    a. ASTM D5116 for small chamber, or equivalent European Union (EU) standard.

b. ASTM D6670 for large chamber, or equivalent EU standard.

c. BIFMA M7.1 for office furniture, or equivalent EU standard.

2. One of the following loading scenarios to quantify emissions has been used:

   a. BIFMA M7.1 for office furniture.

   b. California Department of Health Services section 01350 for all other products.

3. Emissions results

   a. Individually detected chemicals must not be detectable (detection limits must be < 9.0 $\mu g/m^3$ for formaldehyde and <2$\mu g/m^3$ for all other chemicals).

   b. Total VOC must be < 0.5 mg/m^3.

   c. Individual VOCs < (0.01) x [the lower of the threshold limit value (TLV) or MAK value].

   d. VOCs that are considered known carcinogens, endocrine disruptors, mutagens, reproductive toxins, or teratogens must not be detectable (using same detection limits as above).

   e. The time point used is seven days for VOCs and IVOCs.

   f. The analytical laboratory used must be ISO 17025 certified.

5.8.1 Recycled Content

Recycled content is important to developing products consistent with the Cradle to Cradle® Design Paradigm, and this Program seeks to encourage the use of reclaimed raw materials. However, the use of recycled materials must come into balance with the material chemistry requirements to which virgin materials are subject. There are challenges to achieving this balance because much of the currently available infrastructure in the world used to collect and process post-consumer recycled materials are imperfect and do not adequately protect the inherent intelligent design of the materials that flow through them.

For all materials containing recycled content from post-consumer sources and for which the applicant is NOT able to obtain the exact material formulation or list of ingredients, the applicant must perform analytical testing to determine the presence of certain problematic substances.

The following guidance is provided to highlight the chemical composition review procedure for four common materials that are not typically pure substances:

5.8.1.1 Metals

Metals are some of the most highly recyclable and recycled materials known. Steel mills, aluminum plants, and other facilities that recycle metal alloys perform analytical tests for the purpose of identifying and tightly controlling the elemental composition of the alloys being manufactured using recycled scrap. Therefore, the ingredient composition for metal alloys can usually be found in publicly available sources (e.g., AISI, JIS, Aluminum Association, etc.) or in the mill certificate provided by the metal supplier.[1] Identifying the specific alloy grade being used will give the full

[1] The user must have the specific alloy number for the metal before being able to identify its composition (i.e. AISI 1020 Steel; JIS G 3101 Steel; 6061 Aluminum).

chemical composition of the metal alloy down to 0.01%, or performing approved analytical tests with approved detection limits to obtain the full quantitative composition down to 0.01% can be used to generate a material assessment.

5.8.1.2 Glass

Glass is also one of the most recyclable materials today. Similar to recycled metals, a series of simple and inexpensive analytical tests can be performed to identify the full elemental composition of the inorganic material. Identifying the full elemental composition of the glass material as obtained from the supply chain, if possible, or using approved analytical tests with approved detection limits to obtain the full quantitative composition down to 0.01% can be used to generate a material assessment.

5.8.1.3 Paper and Natural Cellulosic Fibers

Recycled paper and other natural fibers compose one of the largest recycled material pools by weight worldwide. The U.S. Environmental Protection Agency (US EPA) estimated that paper accounted for more than one third of all recyclables (by weight) collected in the United States. In 2009, nearly 43 million metric tons of paper and paperboard were recovered.[2] A number of different process chemicals (e.g., bleaching agents, de-inkers, sizing agents, etc.) may be used in the recycling of paper and natural fiber materials to make them suitable for manufactured products in their second life. To be eligible to earn an A, B, or C material assessment rating in a Cradle to Cradle Certified™ Product, the ingredients remaining on the *finished* paper must be fully identified and assessed. The assessor should then evaluate all ingredients that compose ≥0.01% of the finished paper product using the Cradle to Cradle Certified™ Material Health Assessment Methodology. Pulping chemistry impacts and the importance of addressing them are considered but the scope is limited, as many of those chemicals do not end up in the finished paper. This industry is more appropriately regulated through water stewardship principles and effluent discharge limits. Determining the composition of the paper by weight for all ingredients that remain on the raw finished paper from a paper mill will make it possible to generate a material assessment.[3]

- Untreated Post-Consumer Recycled Paper - If the recycled paper remains in an untreated state (i.e., raw recycled paper), then it might be impossible to determine the full composition by weight for all ingredients. In these cases, a material assessment cannot be performed and the material will earn a GREY assessment and is added to prioritized optimization plan.
- Treated PC Paper - Bleaching agents for pulp are subject to review regardless of concentration. It is required that pulp suppliers disclosed the type of bleaching process used.

5.8.1.4 Plastics

Plastics are an integral part of everyday life and are seen as valuable technical nutrients that need to be kept in closed loop material flows rather than burned for energy or dumped in landfills. In 2008, the US EPA estimated that plastics accounted for 12% of the total tonnage of municipal solid waste in the United States. There are usually significant challenges in obtaining the full composition of a post-consumer recycled plastic due to contamination, varying grades of resin

[2] U.S. EPA http://www.epa.gov/osw/conserve/materials/paper/faqs.htm.

[3] This will require manufacturers to disclose the ingredients used to make the paper after the recycled content has been processed into pulp, bleached, and then pressed into paper.

from different manufacturers, various product labels and content residues. The chart below lays out the material assessment rating hierarchy for post-consumer (PC) and post-industrial (PI) recycled plastics in Cradle to Cradle Certified™ products.

REVIEW PROCEDURE

1. Type 1 – PI from a SINGLE source

Type 1 recycled materials are those coming from a single known source, where the manufacturer name, trade name, and grade of the material is known and it is possible to obtain composition disclosures for the material composition.

- Determine the precise manufacturer trade names, grades, and colors in the recycled stream.
- Obtain full composition disclosures from the manufacturers of those grades to identify all chemical constituents down to 0.01% of each material.
- Perform a material assessment to generate a color rating.

2. Type 2 – PI from MULTIPLE sources

Type 2 recycled materials are those coming from multiple post-industrial sources, but are of a specific type, manufacturer, and/or grade. The universe of materials here is defined, consistent, and pure but may contain two or more different grades of plastic from known raw material manufacturers with the ability to obtain trade names and grades of the resins and additives used.

- Determine the precise manufacturer trade names, grades, and colors in the recycled stream.
- Obtain full composition disclosures from the manufacturers of those grades to identify all chemical constituents down to 0.01% of each material.
- Perform a material assessment to generate a color rating.

3. Type 3 – PC from a DEFINED source

Type 3 recycled materials are those from a post-consumer source, but where segregation has limited the scope to a very consistent and narrow group of plastics. Some examples might include 100% high density polyethylene (HDPE) milk containers, 100% clear polyethylene terephthalate (PET) water bottles, 100% specific laundry detergent bottles, 100% specific food packaging containers, and 100% uncoated car bumpers from a specific car line.

Use of these post-consumer materials in a Cradle to Cradle Certified™ product would be allowed only on a case-by-case basis where emphasis is placed on a very specific defined universe of materials AND there is a high sophistication of collection, separation, identification, and cleaning technologies for the material. Limitations will be placed on the quality of the stream with the requirement that the input stream is highly consistent, there is extremely low variation from batch-to-batch, and the analytical regiment is set up to properly ensure that problematic chemicals are consistently captured.

If the source (i.e., the original manufacturer) can be defined, the assessment will be a combination of the following: [Positively defined, consistent, narrow, characterized material stream] + [Formulation disclosures, if possible] + [Good Recycling Technology] + [Excellent Separation Technology] + [Thorough Cleaning] + [Analytics].

4. Type 4 – PC from UNDEFINED sources

Type 4 recycled materials are those from a post-consumer source where there is low regard for separation, identification, and/or cleaning the materials to a higher level of purity. Examples might include aggregation of various types of plastic and simply molding them into parts with heat.

Type 4 materials will not be allowed for use in Cradle to Cradle Certified™ Products above the SILVER Level due to significant fluctuations in material chemistry and potential toxicity hazards.

5.8.1.5 Recycled Content Assessment Testing and Cutoffs

Table 4 Recycled Content Assessment Scale

Recycled content that cannot be characterized by ingredient formulations must undergo analytical testing, and be free of banned chemicals. The test results determine the color ratings used in the scoring structure, although for some types of recycled content, a color rating cannot be generated based on test results alone.	
RECYCLED CONTENT ASSESSMENT SCALE	
A/B	Recycled content (PCR or PI) is highly defined to exact chemical composition and meets requirements of the A or B assessment rating.
C	Recycled content (PCR or PI) is highly defined to exact chemical composition and meets requirements of the C assessment rating.
GREY	Cannot determine composition enough to generate an assessment rating: Type 4 Post-Consumer Recycled Content Untreated post-consumer recycled paper
X	Post-Consumer Recycled Content shown to contain problematic chemistry **Heavy Metals** Lead, Mercury, Cadmium, and Chromium VI 100-1000 ppm each (all material types). **Organohalogens** Organohalogens > 100 ppm each.
BANNED	PCR containing banned chemicals cannot be included in certified products.

5.9 PROCEDURE FOR PRODUCT BREAKDOWN FOR FUTURE CRADLE(S)

The concept of a product breakdown for a "future cradle" is an important part of Cradle to Cradle® Design and attempts to identify the most likely future scenario(s) for the product and its components once the intended use is over. It is very likely that the product will not be disassembled in the same manner as it was assembled and therefore the product and its components/materials should be evaluated with an eye on the next, or future, cradle.

An externally managed component (EMC) is a sub-assembly, component, or material within a product that is exempt from the general requirement of full characterization to the 100 ppm level because it is managed in a technical nutrient cycle as part of supplier or manufacturer commercialized nutrient management program.

To be considered an EMC, the sub-assembly, component, or material within a product must meet the following criteria:

1. The supplier of the EMC has provided the applicant with a guarantee for take back and appropriate nutrient management. The supplier may designate a third party or parties for implementation.
2. The supplier has signed a declaration that chemicals in the EMC will not negatively impact humans or the natural environment during the intended and unintended but highly likely use of the product for which the EMC is a component. This guarantee may be provided via a Cradle to Cradle certification (Gold level or higher) of the EMC, or other appropriate evidence.
3. The EMC has undergone testing by an accredited analytical laboratory to ensure that harmful substances are not being emitted from the EMC above the chemical's analytical detection limits. Off-gas testing is required for all EMCs (See Section 5.8 for more information on VOCs emission testing). Migration and leaching testing may be required depending on the type of EMC.

See the Cradle to Cradle Certifed™ Product Standard for more information on EMCs.

6 CHEMICAL PROFILING METHODOLOGY

6.1 INTRODUCTION

6.1.1 Purpose

Though new chemicals are produced everyday with the intention of improving the quality of life through new, innovative products, there are also unintended consequences once these chemicals reach the biosphere. Reports of pollution are ever increasing as toxins are being found in the blood serum of citizens in various regions, in the breast milk of mothers, and in our natural habitat including aquatic species, polar bears (Norstrom et al, 1990), and trees (Simonich et al, 1995).

In William McDonough and Michael Braungart's 2002 publication *Cradle to Cradle: Remaking the Way We Make Things*, they proposed that the levels of pollution seen were a result of poor design rather than poor chemical management. In their words, "The decision to create products that are free of obviously harmful substances forms the rudiments of what we call a 'design filter': a filter that is in the designer's head instead of on the ends of pipes." The use of this document in evaluating chemicals for their human and environmental health impacts is anticipated to enhance the quality of products and provide a recognized framework for practitioners of *Cradle to Cradle*® design principles. Its purpose is to give designers a tool to evaluate and profile the hazards presented by a chemical by which they can make educated and informed decisions when creating products.

6.1.2 Scope

The Cradle to Cradle Certified™ Chemical Profiling Methodology includes specified hazard criteria for the basis of a chemical's evaluation. In Table 5 below, the rating scheme used for this methodology is based on a "traffic-light" hierarchy where the hazard is communicated by a GREEN, YELLOW, RED, or GREY rating for a particular endpoint:

Table 5 Hazard rating system for chemicals using the Cradle to Cradle Certified™ Chemical Profiling Methodology

GREEN	No hazard identified for the given endpoint
YELLOW	Borderline hazard identified for the given endpoint
GREY	No data available to determine hazard level for this endpoint
RED	Considered hazardous for this specific endpoint

The "traffic-light" rating scheme is used to describe each individual hazard endpoint based on the criteria discussed below. The Cradle to Cradle Certified™ Chemical Profiling Methodology uses 24 human health, environmental health, and chemical class endpoints whose ratings are used in conjunction with the specific use scenario and related routes of exposure to generate an A, B, C, X rating for each material.

Table 6 lists of the human health hazard endpoints used for the evaluation of chemicals:

Table 6 Human Health Hazard Endpoints Used for the Evaluation of Chemicals

HUMAN HEALTH ENDPOINTS	DESCRIPTION
Carcinogenicity	Potential to cause cancer.
Endocrine Disruption	Potential to negatively affect hormone function and impact organism development.
Mutagenicity	Potential to alter DNA.
Reproductive Toxicity	Potential to negatively impact reproductive system as well as the potential to affect pre and post natal offspring development.
Oral Toxicity	Potential to cause harm via oral exposure. Both short-term (acute) and longer-term (chronic) exposures are considered here.
Dermal Toxicity	Potential to cause harm via dermal exposure. Both short-term (acute) and longer-term (chronic) exposures are considered here.
Inhalative Toxicity	Potential to cause harm via inhalative exposure. Both short-term (acute) and longer-term (chronic) exposures are considered here.
Single Organ Toxicity	Potential to cause organ specific damage upon initial, short-term exposure.
Neurotoxicity	Potential to cause an adverse change in the structure or function of the central and/ or peripheral nervous system.
Sensitization of Skin and Airways	Potential to cause an allergic reaction upon exposure to skin or via inhalation.
Other	Any additional characteristic (e.g. flammability, skin penetration potential, etc.) relevant to the overall evaluation but not included in the previous criteria.

Table 7 lists the environmental health endpoints used for chemical profile evaluation.

Table 7 Environmental Health Endpoints Used for Chemical Profile Evaluation

ENVIRONMENTAL HEALTH ENDPOINTS	DESCRIPTION
Acute Fish Toxicity	Measure of toxicity to fish (both saltwater and freshwater) from single, short-term exposure.
Acute Daphnia Toxicity	Measure of toxicity to Daphnia (or other aquatic invertebrates) from single, short-term exposure.
Acute Algae Toxicity	Measure of toxicity to algae from single, short-term exposure.
Chronic Fish Toxicity	Measure of toxicity to fish (both saltwater and freshwater) from multiple, longer-term exposures.
Chronic Daphnia Toxicity	Measure of toxicity to Daphnia (or other aquatic invertebrates) from multiple, longer-term exposures.
Chronic Algae Toxicity	Measure of toxicity to algae from multiple, longer-term exposures.
Terrestrial Toxicity	Acute toxicity to avian species and soil organisms.
Persistence	Measure of how long a substance will exist in air, soil, or water. Can be biotic or abiotic.
Bioaccumulation	Potential for a substance to accumulate in fatty tissue and magnify as you move up the food chain.
Climatic Relevance	Measure of the impact a substance has on the climate (e.g., ozone depletion, global warming).
Other	Any additional characteristic relevant to the overall evaluation but not included in the previous criteria.

Table 8 lists chemical classes that are always rated RED if shown to be greater than 100 ppm of the material due to the concern that at some point in their life cycle they may have negative impacts on human and environmental health. In the case of organohalogens, they tend to be persistent, bioaccumulative, and toxic, or can form toxic by-products if incinerated.

Table 8 Chemical Classes Rated Red is Greater than 100 ppm

CHEMICAL CLASS ENDPOINTS	DESCRIPTION
Organohalogens	Presence of a non-hydrolysable carbon-halogen (i.e. fluorine, chlorine, bromine, or iodine) bond.
Toxic Metals	Presence of a toxic heavy metal compound (e.g. Antimony, arsenic, cadmium, chromium VI, cobalt, lead, mercury, nickel, tin (organotins only), radioactive elements, and vanadium.

6.1.3 Hazard vs. Risk

It is important to recognize that the Cradle to Cradle Certified™ Chemical Profiling Methodology seeks to capture the intrinsic hazards of each chemical. The likelihood of a chemical causing any of its hazards to human or environmental health depends on the intrinsic hazards present but also depends largely on the exposure potential. Collectively, this is known as risk, which can be defined by the simple formula:

Hazard x Exposure = Risk

Thus, to reduce risk you can either minimize hazard or exposure to minimize the likelihood of adverse health effects. Experience has shown that attempts to only minimize exposure in chemical management systems have ultimately failed, as chemicals with intrinsic hazards are exposed to various populations throughout the globe. Additionally, it is impracticable to postulate the use and exposure of a chemical as one chemical can be used in a myriad of applications, sometimes unintended. For these reasons, the Cradle to Cradle Certified™ Chemical Profiling Methodology captures the intrinsic hazards and related risks presented by a chemical through feasible routes of exposure (e.g., oral, inhalation, or dermal), where applicable.

It should also be noted that there are significant shortcomings to the "single chemical assessment" method, i.e., attempting to determine hazard and risk posed by materials/products based on the potential hazard/risk of the chemicals that make them up as this does not take into account possible synergistic or antagonistic effects of multiple chemical interactions. As such, the Cradle to Cradle Certified™ Chemical Profiling Methodology and Cradle to Cradle Certified™ Material Assessment Methodology are strongly based on the European Union's Precautionary Principle (http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm).

7 SUMMARY OF HAZARD CRITERIA

Table 9 lists the criteria for the 24 human and environmental health hazard endpoints used for chemical evaluation in the Cradle to Cradle Certified™ Product Standard.

Table 9 Summary of Hazard Criteria

HUMAN HEALTH CRITERIA	GREEN	YELLOW	RED	GREY
Carcinogenicity	Not a known or suspected carcinogen given by long-term cancer studies. TLV A5, IARC 4	Not classifiable as to its carcinogenicity given by long-term cancer studies. MAK III 3A, 4, 5	A known or suspected carcinogen given by long-term cancer studies. MAK III 1, 2, 3B IARC Group 1, 2A, 2B TLV A1, A2, A3 GHS Category 1A, 1B, 2 H350: May cause cancer H351: Suspected of causing cancer	No data available for classification. IARC Group 3 TLV A4
Endocrine Disruption	Not known or suspected of endocrine disruption by evidence of no adverse health effects and/ or endocrine activity. EU list category 3C	Insufficient evidence of endocrine disruption.	Sufficient evidence of Endocrine Disruption by data of adverse health effects and endocrine activity. Or Chemical appears on Colborn or EU list (Cat. 1 & 2).	No data available for classification. EU list category 3A, 3B

HUMAN HEALTH CRITERIA	GREEN	YELLOW	RED	GREY
Mutagenicity/ Genotoxicity	Substance induces neither punctual mutations nor aberrations of chromosomes nor aberrations of their segregation at concentrations up to 100 mg/l in *in vitro* systems	Substance doesn't induce punctual mutations at concentrations up to 100 mg/l.	Substance has been tested and induces either punctual mutations or aberrations of chromosomes or of their segregation at concentrations lower than to 100 mg/l in *in vitro* systems or classified as GHS 1A, 1B, 2 MAK IX 1, 2, 3A, 3B, H340: May cause genetic defects H341: Suspected of causing genetic defects	No data available for classification.
Reproductive Toxicity	Exhibits no adverse effects to sexual function and based on human or animal studies; Oral NOAEL > 500 mg/kgBW/day Inhalative NOAEL >2.5 mg/l 6-8 h/day	Equivocal evidence of toxic effects to sexual function and fertility but considered a secondary non-specific consequence of other toxic effects present; Oral NOAEL =50-500 mg/kg BW/day Inhalative NOAEL = 0.25-2.5 mg/l 6-8 h/day	Known or suspected of causing adverse effects to sexual function and fertility based on human or animal studies; classified as GHS 1A, 1B, or 2; Oral NOAEL < 50 mg/kg BW/day Inhalative NOAEL <0.25 mg/l 6-8 h/day H360: May damage fertility or the unborn child H361: Suspected of damaging fertility or the unborn child	No data available for classification.

HUMAN HEALTH CRITERIA	GREEN	YELLOW	RED	GREY
	Exhibits no adverse effects to the development of an embryo or fetus based on human or animal studies;	Equivocal evidence of adverse effects to the development of an embryo or fetus based on human or animal studies;	Known or suspected of causing adverse effects to the development of an embryo or fetus based on human or animal studies; listed as MAK Group A or B, or has been classified as GHS 1, 1A, 1B, or 2; H360: May damage fertility or the unborn child H361: Suspected of damaging fertility or the unborn child H362: May cause harm to breast fed children	No data available for classification. MAK C, D
Oral Toxicity	***Acute:*** LD50 > 2000 mg/kg BW ***Single exposure organ toxicity:*** LOAEL > 2000 mg/kg BW ***Sub – Chronic/Chronic:*** LOAEL > 100 mg/kg BW/day	***Acute:*** 300 < LD50 <= 2000 mg/kg BW classified as GHS 4 H302: Harmful if swallowed ***Single exposure organ toxicity:*** 300 < LOAEL <= 2000 mg/kg BW H371: May cause damage to organs via oral exposure ***Sub – Chronic/Chronic:*** 10 < LOAEL <=100 mg/kg bw/day H373: May cause damage to (organs) through prolonged or repeated dermal exposure	***Acute:*** LD50 <= 300 mg/kg BW classified as GHS 1,2,3 H300a/b: Fatal if swallowed H301 Toxic if swallowed H304: May be fatal if swallowed and enters airways ***Single exposure organ toxicity:*** LOAEL <= 300 mg/kg BW H370: Causes damage to organs via oral exposure ***Sub – Chronic/Chronic:*** LOAEL <= 10 mg/kg bw/day H372: Causes damage to (organs) through prolonged or repeated oral exposure	No relevant data available for classification.

HUMAN HEALTH CRITERIA	GREEN	YELLOW	RED	GREY
Dermal Toxicity	***Acute:*** LD50 > 2000 mg/kg BW ***Single exposure organ toxicity:*** LOAEL > 2000 mg/kg BW ***Sub – Chronic/Chronic:*** LOAEL > 200 mg/kg BW/day	***Acute:*** 1000 < LD50 <= 2000 mg/kg BW H312: Harmful in contact with skin ***Single exposure organ toxicity:*** 1000 < LOAEL <= 2000 mg/kg BW H371: May cause damage to organs via dermal exposure ***Sub – Chronic/Chronic:*** 20 < LOAEL <= 200 mg/kg bw/day H373: May cause damage to (organs) through prolonged or repeated dermal exposure	***Acute:*** LD50 <= 1000 mg/kg BW H310a/b: Fatal in contact with skin H311: Toxic in contact with skin ***Single exposure organ toxicity:*** LOAEL < = 1000 mg/kg BW H370: Causes damage to organs via dermal exposure ***Sub – Chronic/Chronic:*** LOAEL <= 20 mg/kg bw/day H372: Causes damage to (organs) through prolonged or repeated dermal exposure	No relevant data available for classification.

HUMAN HEALTH CRITERIA	GREEN	YELLOW	RED	GREY
Inhalative Toxicity	***Acute:*** Inhalative (gas) LC50 > 20000 ppmV Inhalative (vapor) LC50 > 20 mg/l/4hr Inhalative (dust/mist) LC50 > 5 mg/l/4hr ***Single exposure organ toxicity:*** LOAEL (gasses) > 20000 ppmV/4hr LOAEL (vapor) > 20 mg/L/4hr LOAEL (mists/dusts) > 5.0 mg/L/4hr ***Sub – Chronic/Chronic:*** Inhalation (Gases) LOAEL > 250 ppmV/6h/d Inhalation (Vapors) LOAEL > 1.0 mg/L/6h/d Inhalation (Dusts & Mists) LOAEL > 0.2 mg/L/6h/d	***Acute:*** Inhalative (gas) 2500 < LC50 <= 20000 ppmV Inhalative (vapor) 10 < LC50 <= 20 mg/l/4hr Inhalative (dust/mist) 1.0 < LC50 <= 5 mg/l/4hr H332: Harmful if inhaled ***Single exposure organ toxicity:*** 2500 < LOAEL (gasses) <= 20000 ppmV/4hr 10 < LOAEL (vapor) <= 20 mg/L/4hr 1.0 < LOAEL (mists/dusts) <= 5.0 mg/L/4hr H371: May cause damage to organs via inhalative exposure H335: May cause respiratory tract irritation H336: May cause drowsiness or dizziness ***Sub – Chronic/Chronic:*** Inhalation (Gases) 50 < LOAEL <= 250 ppmV/6h/d Inhalation (Vapors) 0.2 < LOAEL <= 1.0 mg/L/6h/d Inhalation (Dusts & Mists) 0.02 < LOAEL<= 0.2 mg/L/6h/d H373: May cause damage to (organs) through prolonged or repeated inhalation	***Acute:*** Inhalative (gas) LC50 <= 2500 ppmV Inhalative (vapor) LC50 < = 10 mg/l/4hr Inhalative (dust/mist) LC50 <= 1 mg/l/4hr H330a/b: Fatal if inhaled H331: Toxic if inhaled ***Single exposure organ toxicity:*** LOAEL (gasses) <= 2500 ppmV/4hr LOAEL (vapor) <= 10 mg/L/4hr LOAEL (mists/dusts) <= 1.0 mg/L/4hr H370: Causes damage to organs via inhalative exposure ***Sub – Chronic/Chronic:*** Inhalation (Gases) LOAEL < = 50 ppmV/6h/d Inhalation (Vapors) LOAEL <= 0.2 mg/L/6h/d Inhalation (Dusts & Mists) LOAEL <= 0.02 mg/L/6h/d H372: Causes damage to (organs) through prolonged or repeated inhalation	No relevant data available for classification.

HUMAN HEALTH CRITERIA	GREEN	YELLOW	RED	GREY
Neurotoxicity	Single Exposure Organ, Sub-Chronic, and Chronic Toxicity Endpoints for Green Rating.	Single Exposure Organ, Sub-Chronic, and Chronic Toxicity Endpoints for Yellow Rating.	Single Exposure Organ, Sub-Chronic, and Chronic Toxicity Endpoints for Red Rating. *or* Listed in Grandjean et. al. text for neurotoxic effects.	No relevant data available for classification.
Sensitization	No evidence of sensitization in human and/ or animal studies or No evidence of sensitization in use.	Non-adjuvant animal studies elicit a response 15% > population > 0%; Adjuvant animal studies elicit a response of 30% > population > 0%.	Substance has shown medium to strong sensitization effects in human or animal studies or List as a MAK skin or airways sensitizer (MAK Sa or Sh). H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled H317: May cause an allergic skin reaction	No relevant data for classification.
ENVIRONMENTAL HEALTH CRITERIA	**GREEN**	**YELLOW**	**RED**	**GREY**
Vertebrate Toxicity (fish) **Acute and Chronic**	***Acute:*** 96 hour LC50 > 100 mg/L QSAR 96 hour LC50 > 100 mg/L ***Chronic:*** NOEC >10 mg/L	***Acute:*** 96 hour LC50 10 - 100 mg/L QSAR 96 hour LC50 10 - 100 mg/L ***Chronic:*** NOEC = 1-10 mg/L	***Acute:*** 96 hour LC50 < 10 mg/L QSAR 96 hour LC50 < 10 mg/L H400: Very toxic to aquatic life ***Chronic:*** NOEC < 1 mg/L H410: Very toxic to aquatic life with long lasting effects H411: Toxic to aquatic life with long lasting effects H412: Harmful to aquatic life with long lasting effects H413: may cause long lasting harmful effects to aquatic life	No relevant data for classification.

ENVIRONMENTAL HEALTH CRITERIA	GREEN	YELLOW	RED	GREY
Invertebrate Toxicity (daphnia) Acute and Chronic	***Acute:*** 48 hour L(E)C50 > 100 mg/L QSAR 48 hour L(E)C50 > 100 mg/L ***Chronic:*** Same as above	***Acute:*** 48 hour L(E)C50 10 - 100 mg/L QSAR 96 hour L(E)C50 10 - 100 mg/L ***Chronic:*** Same as above	***Acute:*** 48 hour L(E)C50 < 10 mg/L QSAR 48 hour L(E)C50 < 10 mg/L H400: Very toxic to aquatic life ***Chronic:*** Same as above	No relevant data for classification.
Aquatic Plant Toxicity (algae) Acute and Chronic	***Acute:*** 72/ 96 hour L(E)C50 > 100 mg/L QSAR 72/ 96 hour L(E)C50 > 100 mg/L ***Chronic***: Same as above	***Acute:*** 72/ 96 hour L(E)C50 10 - 100 mg/L QSAR 72/ 96 hour L(E)C50 10 - 100 mg/L ***Chronic***: Same as above	***Acute:*** 72/ 96 hour L(E)C50 < 10 mg/L QSAR 96 hour L(E)C50 < 10 mg/L H400: Very toxic to aquatic life ***Chronic***: Same as above	No relevant data for classification.
Birds Sub-acute, sub-chronic and chronic	***Sub-acute:*** Chicken LD50 > 9000 mg/kg fodder (5 days) Duck LD50 > 15000 mg/kg fodder (5 days) ***Sub-chronic/chronic:*** Chicken NOEC > 3000 mg/kg fodder (≥ 20 weeks) Duck NOEC > 5000 mg/kg fodder (≥ 20 weeks)	***Sub-acute:*** Chicken LD50 900 - 9000 mg/kg fodder (5 days) Duck LD50 1500 - 15000 mg/kg fodder (5 days) ***Sub-chronic/chronic:*** Chicken NOEC 300 - 3000 mg/kg fodder (≥ 20 weeks) Duck NOEC 500 - 5000 mg/kg fodder (≥ 20 weeks)	***Sub-acute:*** Chicken LD50 < 900 mg/kg fodder (5 days) Duck LD50 < 1500 mg/kg fodder (5 days) ***Sub-chronic/chronic:*** Chicken NOEC < 300 mg/kg fodder (≥ 20 weeks) Duck NOEC < 500 mg/kg fodder (≥ 20 weeks)	No relevant data for classification.
Toxicity for Soil Organisms (Acute)	EC50 > 1000 mg/kg dry soil	EC50 100 - 1000 mg/kg dry soil	EC50 < 100 mg/kg dry soil	No relevant data for classification.

ENVIRONMENTAL HEALTH CRITERIA	GREEN	YELLOW	RED	GREY
Persistence	$T_{1/2}$ < 30/90 days in water/ soil or sediment; Readily biodegradable (>70% within 28 days) based on OECD guidelines (301); Predicted to be readily biodegradable by QSAR results	30/90 day < $T_{1/2}$ < 60/180 days in water/ soil or sediment; 10% < DOC removal < 70% based on OECD guidelines (301) 10% < ThOD removal < 60% based on OECD guidelines (301) Inherently biodegradable based on OECD guidelines (302, 304A); Predicted to be degradable within weeks to months by QSAR	T1/2 > 60/180 days in water/ soil or sediment DOC and ThOD removal < 10% based on OECD guidelines Predicted to be recalcitrant by QSAR results.	No relevant data for classification *or* substance is considered inorganic and not applicable to this endpoint.
Bioaccumulation	BCF < 100 by experimental or QSAR results if log K_{ow} < 6 *or* log K_{ow} < 2 *or* Molecular weight > 1000	100 < BCF < 500 by experimental or QSAR results if log K_{ow} < 6	BCF > 500 by experimental or QSAR results if log K_{ow} < 6	No relevant data for classification. log Kow>2 and no additional information
Ozone Depletion/climate impacts	Not listed in Annexes to the Montreal Protocol; Does not lead to global warming	Not applicable	Listed in Annexes to the Montreal Protocol; Can lead to global warming	Not applicable
CHEMICAL CLASS CRITERIA	**GREEN**	**YELLOW**	**RED**	**GREY**
Organohalogen Content	Chemical does not contain a non-hydrolysable carbon to halogen (fluorine, chlorine, bromine, or iodine) bond	Not applicable	Chemical contains a non-hydrolysable carbon to halogen (fluorine, chlorine, bromine, or iodine) bond	No relevant data for classification, structure is not understood.
Heavy Metals	Chemical does not contain toxic heavy metal compound (e.g. Antimony, arsenic, cadmium, chromium VI, cobalt, lead, mercury, nickel, tin (organotins only), radioactive elements, and vanadium.	Not applicable	Chemical contains toxic heavy metal compound (e.g. Antimony, arsenic, cadmium, chromium VI, cobalt, lead, mercury, nickel, tin (organotins only), radioactive elements, and vanadium.	No relevant data for classification, structure is not understood.

7.1 HAZARD RATINGS

7.1.1 Carcinogenicity

7.1.1.1 Definitions

Carcinogenicity is the measure of a chemical's potential to cause cancer or a malignant neoplasm. A malignant neoplasm is an autonomous growth of tissue that demonstrates invasive growth characteristics, capable of spreading through the organ of origin and through metastasis to other tissues while showing no physiological attributes (Klaunig et al, 2008).

Although the toxicological endpoint of carcinogenesis is definitive, often the mechanism by which neoplastic development is caused is not readily apparent given its multi-step nature. Carcinogenesis is often broken down into three stages called initiation, promotion, and progression, all of which a given chemical can influence (Boyd, 1990). Initiation is a rapid, irreversible process that results in a carcinogen-induced mutational event. Initiation alone does not result in neoplastic development as the mutated cells can have multiple outcomes including: 1) remaining in a non-dividing state by growth control; 2) cell may become unviable and be deleted through apoptosis; or 3) the cell may undergo division resulting in the proliferation of the initiated cells which is also known as Promotion. Progression is the final stage of carcinogenesis that results in the conversion of benign pre-neoplastic cells into neoplastic cancer. Often progression is another stage where genotoxic events take place due to the increase in DNA synthesis from the proliferation stage. Additional DNA damage including chromosomal aberration and translocations are often characteristic of progression.

7.1.1.2 Ratings

For the purposes of the Cradle to Cradle Certified™ Chemical Profiling Methodology, the endpoint of carcinogenicity is given a GREY, RED, YELLOW, or GREEN rating based on the strength of scientific evidence available from peer-reviewed sources.

In order for a chemical to be rated RED for carcinogenicity, it is either known or suspected to be a carcinogen based on human epidemiologic or animal studies. The YELLOW profile rating for carcinogenicity is reserved for chemical substances that, based on experimental evidence, cannot be classified as a carcinogen or non-carcinogen due to a lack of evidence, equivocal evidence based on experimental structure, or conflicting evidence. In order for carcinogenicity to be rated GREEN the chemical in question is not suspected to be a human carcinogen based on evidence from long-term studies.

There are several existing classification systems that align with this rating scheme including the Threshold Limit Value (TLV), International Agency for Research on Cancer (IARC), maximum workplace concentration (MAK), and the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Based on these classification systems, if a chemical is listed within these publications, a hazard rating can be given for the carcinogenicity endpoint as is summarized in Table 2 below.

Often chemicals are not listed by any of the classification systems adopted in this program, and the practitioner must determine the carcinogenicity rating of a chemical with available studies. As

defined by GHS, the carcinogen classification of a chemical considers both the strength of evidence and the weight of evidence (UNECE, 2009). GHS differentiates these interrelated criteria with the following definitions:

Strength of evidence – the enumeration of tumors in human and animal studies. Sufficient evidence in both human and animal studies demonstrates causality between exposure and development of cancer or an increased incidence of tumors. Limited evidence can demonstrate a positive association between exposure and incidence but cannot determine a causal relationship.

Weight of Evidence – other factors that influence the overall likelihood that an agent may pose a carcinogenic hazard in humans. These factors include but are not limited to the following:

1. Tumor type and background incidence.
2. Multi-site responses.
3. Progression of lesions to malignancy.
4. Reduced tumor latency.
5. Whether responses are in single or both sexes.
6. Whether responses are in a single species.
7. Structural similarity or not to a chemical(s) for which there is good evidence of carcinogenicity.
8. Routes of exposure.
9. Comparison of absorption, distribution, metabolism, and excretion, between test animals and humans.
10. The possibility of a confounding effect of excessive toxicity as test doses.
11. Mode of action and its relevance for humans, such as mutagenicity, cytotoxicity with growth stimulation, mitogenesis, immunosuppression (UNECE, 2009).

The strength and weight of evidence must be considered when determining whether a chemical is classifiable as a carcinogen by the definitions given above. Table 10 provides an overview on how a GREEN, YELLOW, RED, or GREY classification is reached for this criterion:

Table 10 Summary of the Rating Scheme for Carcinogenicity in the Cradle to Cradle Certified™ Chemical Profiling Methodology.

GREEN	YELLOW	RED	GREY
Not a known or suspected carcinogen given by long-term cancer studies. TLV A5, IARC 4	Not classifiable as to its carcinogenicity given by long-term cancer studies. MAK III 3A, 4, 5	A known or suspected carcinogen given by long-term cancer studies. MAK III 1, 2, 3B IARC Group 1, 2A, 2B TLV A1, A2, A3 GHS Category 1A, 1B, 2 H350: May cause cancer H351: Suspected of causing cancer	No data available for classification. IARC Group 3 TLV A4

7.1.2 Endocrine Disruption

7.1.2.1 Definitions

For the purposes of this profiling methodology, it is important to recognize that endocrine disruption is considered a mode of action, not a hazard itself, but it could potentially give rise to toxic results. Mode of action refers to the specific biochemical interaction of a drug or chemical through which an adverse health effect is produced. A mode of action includes specific molecular targets to which a chemical will bind, in this case the endocrine system. Concurrent with this caveat the definition developed by Weybridge is adopted in this methodology:

"An endocrine disruptor is an exogenous substance that causes adverse health effects in an intact organism, or its progeny, secondary (consequent) to changes in endocrine function. A potential endocrine disruptor is a substance that possesses properties that might be expected to lead to endocrine disruption in an intact organism." (Weybridge, 1996).

The endocrine system consists of glands and hormones that guide the development, growth, reproduction, and behavior of human beings and animals.

7.1.2.2 Rating

Following the definition given by Weybridge, the evidence needed to support rating a chemical as a known or suspected endocrine disruptor is two-fold. Primarily, evidence of adverse effects to sex organs, reproductive systems, accessory tissue, and development of offspring meets one criteria of the Weybridge definition. Secondly, *in vitro* or *in vivo* data identifying chemicals that bind to endocrine receptors, alter gene transcription, affects synthesis of sex hormones, possess androgenic activity, or anti-androgenic activity, for example, identify the ancillary operation of changes in endocrine function. Where both of these measures are met there is sufficient evidence of endocrine disruption and rating of a chemical as RED for this criterion. Although endocrine disruption is listed under human health evidence of this adverse health effect in animals including avian, amphibians, and fish will give rise to a RED rating.

Tantamount to the evidence required above are definitive lists including the Colborn list and the EU list Categories 1 and 2. Appearance on these lists also affords a RED rating for a given chemical.

Exposure concentrations have not been set for this endpoint given the complex and controversial nature of this topic. Studies have shown the endocrine disruptors can act at extremely low levels, in the parts per billion or trillion, especially at critical points in the development of a fetus (Colborn, 1996). Moreover, in some cases, high doses will actually reduce adverse health effects and disruption of the endocrine system while low doses show greater potency. The relationship of dose to response clearly doesn't exist in a straightforward manner for endocrine disruption as in other endpoints, and consequently potency and exposure concentrations have not been set for this endpoint.

Table 11 lists the hazard rating levels for endocrine disruption. In cases where there have been adverse health effects linked to reproductive toxicity, teratogenicity, and other relevant endpoints but there is no evidence for endocrine activity, a rating of YELLOW is given where there is insufficient evidence of endocrine disruption. This rating is assigned due to endocrine disruption being a mode of action. In other words, conclusive evidence of endocrine disruption cannot be determined where mechanistic studies do not link changes in endocrine function to adverse health effects.

In instances where no adverse health effects are seen in *in vivo* studies, absence of toxic effects can be taken as definitive evidence of no endocrine disrupting properties (ECETOC, 2009). Additionally, if no endocrine activity has been identified through appropriate studies then there is conclusive evidence that endocrine disruption is of low concern and a GREEN rating is given. Where no empirical data are available and a chemical does not appear on the aforementioned Colborn or EU list a rating of GREY is given.

Table 11 Summary of the Rating Scheme for Endocrine Disruption in the Cradle to Cradle Certified™ Profiling Methodology.

GREEN	YELLOW	RED	GREY
Not known or suspected of endocrine disruption by evidence of no adverse health effects and/ or endocrine activity. *Or* EU list category 3C	Insufficient evidence of endocrine disruption.	Sufficient evidence of Endocrine Disruption by data of adverse health effects and endocrine activity. Or Chemical appears on Colborn or EU list (Cat. 1 & 2).	No data available for classification. EU list category 3A, 3B

7.1.3 Mutagenicity

7.1.3.1 Definitions

This endpoint is primarily concerned with chemicals that cause mutations in both germ and somatic cells in humans and other organisms that can either be passed along to progeny or cause

initiation of neoplasms. Although the latter overlaps with the endpoint of carcinogenicity (see Section 1) this testing is not always available and mutagenicity testing gives insight into the potential hazard within this category.
Mutagenicity is defined as a chemical's ability to alter genetic material in cells, both germ and somatic, resulting in the transmission of changes during cell division. Genotoxicity is also commonly used in this category and is termed to agents or processes which alter the structure, information content, or segregation of DNA (UNECE, 2009). Genotoxic studies are often taken as indicators for mutagenic effects.

When multiple studies are available for the determination of a chemical's mutagenic/ genotoxic character, a hierarchy of relevance is applied based on the varying characteristics of the studies available. Studies that carry the most weight in terms of supplying confidence in how a chemical will affect the health of humans are *in vivo* eukaryotic studies. Examples of such studies include rodent dominant lethal mutation test (OECD 478), mouse heritable translocation assay (OECD 485), mammalian bone marrow chromosome aberration test (OECD 475), mouse spot test (OECD 484), and mammalian erythrocyte micronucleus test (OECD 474) (UNECE, 2009). Such tests complement *in vitro* tests well since they account for the whole animal processes such as absorption, tissue distribution, metabolites, and excretion of chemical and their metabolites (Klaunig et al, 2008). When *in vivo* tests are not available, *in vitro* tests performed in eukaryotic cells are the next preferred type of study. Included within this categorization of studies is unscheduled DNA synthesis, sister chromatid exchange, chromosome aberrations, and mouse lymphoma assays. Lastly, given the rapid results and low cost, prokaryotic mutagenicity tests are considered both in Ames and E. Coli tests. For these studies to be sufficient they must include both assays where metabolic activation was used as well as those where it wasn't used. Since prokaryotic assays are performed in single celled organisms, don't account for whole animal processes, and have a low concordance with carcinogenic effects, these studies are given the least weight when considering the final rating for mutagenicity.

Below is a definitive list of tests developed by OECD that are applicable for this endpoint:

<u>*In vivo* heritable germ cell mutagenicity tests:</u>
OECD 477: Genetic Toxicology: Sex-Linked Recessive Lethal Test in Drosophila melanogaster.
OECD 478: Genetic Toxicology: Rodent Dominant Lethal Test.
OECD 485: Genetic toxicology, Mouse Heritable Translocation Assay.

<u>*In vivo* somatic cell mutagenicity tests:</u>
OECD 474: Mammalian Erythrocyte Micronucleus Test.
OECD 475: Mammalian Bone Marrow Chromosome Aberration Test.
OECD 484: Genetic Toxicology: Mouse Spot Test.

<u>Mutagenicity/ genotoxicity tests in germ cells:</u>
OECD 483: Mammalian Spermatogonial Chromosome Aberration Test.

<u>Genotoxicity tests in somatic cells:</u>
OECD 479: Genetic Toxicology: *In vitro* Sister Chromatid Exchange Assay in Mammalian Cells.
OECD 481: Genetic Toxicology: Saacharomyces cerevisiae, Miotic Recombination Assay.
OECD 482: Genetic Toxicology: DNA Damage and Repair, Unscheduled DNA Synthesis in Mammalian Cells *in vitro*.

OECD 486: Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells *in vivo*

In vitro mutagenicity tests:
OECD 471: Bacterial Reverse Mutation Test
OECD 473: *In vitro* Mammalian Chromosome Aberration Test
OECD 476: *In vitro* Mammalian Cell Gene Mutation Test
OECD 480: Genetic Toxicology: Saccharomyces cerevisiae, Gene Mutation Assay

7.1.3.2 Rating

Within the context of the Cradle to Cradle Certified™ Chemical Profiling Methodology, mutagenicity is an endpoint that is solely based on empirical evidence and neither quantitative structure-activity relationship (QSAR) results nor definitive global regulatory lists are relied upon for decision-making. Without any relevant studies for mutagenicity, the rating for this endpoint is GREY. Table 12 provides a summary of the rating scheme.

For the mutagenicity endpoint, a rating of GREEN is defined as a substance that has been tested and shown to induce neither punctual mutations nor aberrations of chromosomes nor aberrations of their segregation in *in vitro* systems.

A YELLOW hazard rating has been defined as a substance that has been tested and shown not to induce punctual mutations.

A RED rating is assigned to this endpoint if the chemical shows statistically significant positive results in eukaryotic or prokaryotic mutagenic assays.

Table 12 Summary of the Rating Scheme for Mutagenicity in the Cradle to Cradle Certified™ Profiling Methodology

GREEN	YELLOW	RED	GREY
Substance induces neither punctual mutations nor aberrations of chromosomes nor aberrations of their segregation at concentrations up to 100 mg/l in *in vitro* systems	Substance doesn't induce punctual mutations at concentrations up to 100 mg/l.	Substance has been tested and induces either punctual mutations or aberrations of chromosomes or of their segregation at concentrations lower than to 100 mg/l in *in vitro* systems or classified as GHS 1A, 1B, 2 MAK IX 1, 2, 3A, 3B, H340: May cause genetic defects H341: Suspected of causing genetic defects	No data available for classification.

7.1.4 Reproductive Toxicity

7.1.4.1 Definitions

The Globally Harmonized System offers the following definition of reproductive toxicity:

"Reproductive toxicity includes adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring." (UNECE, 2009).

Appropriate experimental design for reproductive toxicity studies includes internationally accepted test methods such as OECD Guidelines 421 – Reproduction/ Developmental Toxicity Screening Test, 422 – Combined Repeated Dose Toxicity Study with Reproduction/ Developmental Toxicity Screening Test, and methods for two-generation toxicity testing (e.g., OECD Test Guidelines 415 and 416). Studies must also use appropriate routes of administration that apply to potential human exposure. For reproductive toxicity studies, administration is often given by the oral route, which is suitable for evaluating a chemical's relevancy to human health. However, if there is evidence that this route of administration is not relevant to humans by clearly identifying mechanistic and mode of actions considerations then a positive study for reproductive toxicity should not be considered.

A limit dose is not applied to the Cradle to Cradle Certified™ Profiling Methodology since different chemicals will have varying levels of exposure and difference in species toxicokinetics. However, adverse effects on reproduction seen only at very high dose levels in animal studies would not lead to a Red rating (for example does that induce prostration, severe inappetence, excessive morality) (UNECE, 2009).

7.1.4.2 Rating

For the purpose of rating reproductive toxicity, chemicals are given a GREY, RED, YELLOW, or GREEN rating based on evidence of effects on sexual function, fertility, and development of offspring. Table 13 lists the rating scheme.

A RED rating is applied to those chemicals that have shown adverse effects to the male or female reproductive system based on either evidence from humans or evidence from animal studies. Data from animal studies should provide clear evidence of adverse effects on human reproduction and fertility in the absence of other toxic effects. In the case of simultaneous toxic effects, the adverse effect on reproduction is not considered to be a secondary non-specific consequence of other toxic effects (UNECE, 2009). Collectively, this classification is for chemicals that are either suspected, presumed, or known to be a reproductive toxin. Other classifications that are harmonized with this system include California's Proposition 65 list of reproductive and carcinogenic substances and GHS's 1A, 1B, and 2 classifications.

A YELLOW rating is applied to studies that yield an equivocal result for reproductive toxicity. This includes where other toxic effects are present and reproductive toxicity is considered a secondary toxic effect.

A GREEN rating is applied to chemicals that have shown no adverse toxic effects to sexual function or fertility. This evidence can be based on either human or animal studies. Additionally, where no studies are available for the reproductive toxicity of a chemical and does not appear on either the MAK or California Proposition 65 list, a GREY rating is applied.

The hazard rating for reproductive toxicity is based on all appropriate available evidence. This includes epidemiological studies, case reports in humans, reproduction studies, and sub-chronic/chronic study results that provide relevant data to fertility and sexual function. The significance of studies upon the final categorization are determined by such factors as the quality of the studies, consistency of results, nature and severity of effects, level of statistical significance for intergroup differences, number of endpoint affects, relevance of route of administration to humans, and freedom from bias (UNECE, 2009). All relevant data are considered, negative and positive results alike, to reach a final rating; however, a single positive result from a study showing statistically significant results and performed with sound scientific principles affords a RED rating.

Table 13 Summary of Classification System for Reproductive Toxicity

GREEN	YELLOW	RED	GREY
Exhibits no adverse effects to sexual function and fertility and to the development of an embryo or fetus based on human or animal studies. Oral NOAEL 500 mg/kgBW/day. Inhalative NOAEL >2,5 mg/l 6-8 h/day.	Equivocal evidence of toxic effects to sexual function and fertility but considered a secondary non-specific consequence of other toxic effects present. Oral NOAEL =50-500 mg/kg BW/day. Inhalative NOAEL =0,25-2,5 mg/l 6-8 h/day.	Known or suspected of causing adverse effects to sexual function and fertility based on human or animal studies. classified as GHS 1A, 1B, or 2. Oral NOAEL < 50 mg/kg BW/day. Inhalative NOAEL <0,25 mg/l 6-8 h/day. H360: May damage fertility or the unborn child. H361: Suspected of damaging fertility or the unborn child.	No data available for classification.

7.1.5 Developmental Toxicity

7.1.5.1 Definitions

The Globally Harmonized System has included developmental toxicity under the wider category of "reproductive toxicity" and therefore, although called out separately here for purposes of description, will also be included in the category above titled "Reproductive Toxicity."

"Taken in its widest sense, developmental toxicity includes any effect which interferes with normal development of the conceptus, either before or after birth, and resulting from exposure of either parent prior to conception, or exposure of the developing offspring during prenatal development, or postnatally, to the time of sexual maturation. However, it is considered that classification under the heading of developmental toxicity is primarily intended to provide a hazard warning for pregnant women and men and women of reproductive capacity. Therefore, for pragmatic purposes of classification, developmental toxicity essentially means adverse effects induced during pregnancy, or as a result of parental exposure. These effects can be manifested at any point in the life span of the organisms. The major manifestations of developmental toxicity include death of the developing organism, structural abnormality, altered growth, and functional deficiency." (UNECE, 2009).

The Cradle to Cradle Certified™ Chemical Profiling Methodology also takes a pragmatic approach to teratogenicity where the scope of adverse effects is drawn from exposure of either parent prior to conception and prenatal exposure.

Primarily, studies that are difficult to interpret are those in which maternal toxicity is also seen that can affect the development of offspring throughout gestation and the early postnatal stage (UNECE, 2009). Generally, developmental effects seen in the presence of maternal toxicity are still

rated RED unless it can be unequivocally demonstrated that the developmental effects are secondary to maternal toxicity. However, where minor developmental changes are seen (e.g., small changes in fetal/pup body weight, retardation of ossification) in association with maternal toxicity as YELLOW rating is appropriate. Additionally, maternal mortality greater than 10% is considered excessive and the data for that does level should not normally be considered for further consideration (UNECE, 2009).

Acceptable tests for developmental toxicity include:

- OECD Test Guideline 414, 415, and 416.
- OECD Test Guidelines 421 and 422.
- ICH Guideline S5A.
- ICH S5B.

This list is not exhaustive and studies structured similarly and within the guidelines of Good Laboratory Practices should be considered as well.

7.1.5.2 Rating

For the purpose of characterizing reproductive toxicity, chemicals are allocated to one of four categories of GREY, RED, YELLOW, or GREEN based on evidence of effects on sexual function and fertility. Table 14 outlines the rating scheme.

A RED rating is applied to those chemicals that have shown adverse toxic effects on the development of an embryo or fetus based on either evidence from humans or evidence from animal studies. Within this classification, data from animal studies should provide clear evidence of teratogenic effects in the absence of other toxic effects. In the case of simultaneous toxic effects, including maternal toxicity, the adverse effect on development is considered not to be a secondary non-specific consequence of other toxic effects (UNECE, 2009). Collectively, this classification is for chemicals that are suspected, presumed, or known to be a teratogen. Other classifications that are harmonized with this system include MAK Group A or B (damage to embryo or fetus in humans has been unequivocally demonstrated, or according to currently available information damage to embryo or fetus must be expected), California's Proposition 65 list of reproductive and carcinogenic substances, and GHS's 1A, 1B, and 2 classifications.

A YELLOW rating is applied to studies that yield equivocal results for teratogenicity in human or animal studies. If a chemical is listed as a MAK Group C (there is no reason to fear damage to the embryo or fetus when MAK and BAT values are observed) this also warrants a YELLOW rating.

A GREEN rating is applied to chemicals that have shown no adverse toxic effects to the development of the fetus or embryo in human or animal studies. Additionally, where no studies are available for the reproductive toxicity of a chemical and does not appear on either the MAK or California Proposition 65 list a GREY rating is applied.

Table 14 Summary of Classification Scheme for Developmental Toxicity

GREEN	YELLOW	RED	GREY
Exhibits no adverse effects to the development of an embryo or fetus based on human or animal studies.	Equivocal evidence of adverse effects to the development of an embryo or fetus based on human or animal studies.	Known or suspected of causing adverse effects to the development of an embryo or fetus based on human or animal studies. Listed as MAK Group A or B, or has been classified as GHS 1, 1A, 1B, or 2. H360: May damage fertility or the unborn child. H361: Suspected of damaging fertility or the unborn child. H362: May cause harm to breast fed children.	No data available for classification. MAK C, D,

7.1.6 Oral Toxicity

7.1.6.1 Definitions

Oral toxicity refers to adverse effects following oral administration of a single dose (acute) or longer-term repeated exposures (sub-chronic/chronic).

The definition given by the Globally Harmonized System (GHS) for Acute Oral Toxicity states that, "Acute toxicity refers to those adverse effects occurring following oral administration of a single dose of a substance, or multiple doses given within 24 hours." (UNECE, 2009). This definition has been adopted for the purposes of the Cradle to Cradle Certified™ Chemical Profiling Methodology.

Acute toxicity values are expressed as LD_{50} values of mg of substance per kg of organism body weight (mg/kg). LD_{50} values represent the statistically derived median dose of a substance that can be expected to cause death in 50% of the test population. However, specific organ toxicity not resulting in death can also occur from acute exposure. This is captured here as well.

The sub-chronic (90 day - 1 year) and chronic (1-2 years) hazard endpoints are intended to capture specific target organ toxicity that may present potential adverse health effects in humans when the target organ toxicity hasn't been classified in other endpoints of the Cradle to Cradle Certified™ Chemical Profiling Methodology that are subject to repeated exposure (e.g., reproductive toxicity, carcinogenicity, etc). Often, these types of studies do not end in morbidity, thus LD_{50} values are not appropriate and the measured endpoint used for the purposes of this classification system is the lowest observable adverse effect level (LOAEL).

7.1.6.2 Rating

Chemicals are allocated to one of three toxicity categories based on the acute and/or sub-chronic/chronic toxicity by the oral route of exposure as measure by the LD_{50}, and LOAEL, as summarized in Table 15.

Table 15 Summary of Oral Toxicity Classification Scheme Based on LD_{50}, and LOAEL Endpoints

GREEN	YELLOW	RED	GREY
Acute: LD50 > 2000 mg/kg BW	**Acute:** 300 < LD50 <= 2000 mg/kg BW classified as GHS 4 H302: Harmful if swallowed	**Acute:** LD50 <= 300 mg/kg BW classified as GHS 1,2,3 H300a/b: Fatal if swallowed H301 Toxic if swallowed H304: May be fatal if swallowed and enters airways	No relevant data available for classification.
Single exposure organ toxicity: LOAEL > 2000 mg/kg BW	**Single exposure organ toxicity:** 300 < LOAEL <= 2000 mg/kg BW H371: May cause damage to organs via oral exposure	**Single exposure organ toxicity:** LOAEL <= 300 mg/kg BW H370: Causes damage to organs via oral exposure	
Sub –Chronic/Chronic: LOAEL > 100 mg/kg bw/day	**Sub –Chronic/Chronic:** 10 < LOAEL <=100 mg/kg bw/day H373: May cause damage to (organs) through prolonged or repeated dermal exposure	**Sub –Chronic/Chronic**: LOAEL <= 10 mg/kg bw/day H372: Causes damage to (organs) through prolonged or repeated oral exposure	

7.1.7 Dermal Toxicity

7.1.7.1 Definitions

Dermal toxicity refers to adverse effects following dermal administration of a single dose (acute) or longer-term repeated exposures (sub-chronic/chronic).

The definition given by the Globally Harmonized System (GHS) for Acute Dermal Toxicity states that, "Acute toxicity refers to those adverse effects occurring following dermal administration of a single dose of a substance, or multiple doses given within 24 hours." (UNECE, 2009). This definition has been adopted for the purposes of the Cradle to Cradle Certified™ Chemical Profiling Methodology.

Acute toxicity values are expressed as LD_{50} values of mg of substance per kg of organism body weight (mg/kg). LD_{50} values represent the statistically derived median dose of a substance that can be expected to cause death in 50% of the test population. However, specific organ toxicity not resulting in death can also occur from acute exposure. This is captured here as well.

The sub-chronic (90 day - 1 year) and chronic (1-2 years) hazard endpoints are intended to capture specific target organ toxicity which may present potential adverse health effects in humans when the target organ toxicity hasn't been classified in other criteria of the Cradle to Cradle Certified™ Chemical Profiling Methodology that are subject to repeated exposure (e.g., reproductive toxicity, carcinogenicity, developmental toxicity). Often, these types of studies do not end in morbidity, thus LD_{50} values are not appropriate and the measured endpoint used for the purposes of this classification system is the LOAEL.

7.1.7.2 Rating

Chemicals are allocated to one of three toxicity categories based on the acute and/or sub-chronic/chronic toxicity by the dermal route of exposure as measure by the LD_{50} and LOAEL as summarized in Table 16.

Table 16 Summary of Dermal Toxicity Classification Scheme Based on LD_{50} and LOAEL Endpoints

GREEN	YELLOW	RED	GREY
Acute: LD50 > 2000 mg/kg BW	**Acute:** 1000 < LD50 <= 2000 mg/kg BW H312: Harmful in contact with skin	**Acute:** LD50 <= 1000 mg/kg BW H310a/b: Fatal in contact with skin H311: Toxic in contact with skin	No relevant data available for classification.
Single exposure organ toxicity: LOAEL > 2000 mg/kg BW	**Single exposure organ toxicity:** 1000 < LOAEL <= 2000 mg/kg BW H371: May cause damage to organs via dermal exposure	**Single exposure organ toxicity:** LOAEL < = 1000 mg/kg BW H370: Causes damage to organs via dermal exposure	
Sub –Chronic/Chronic: LOAEL > 200 mg/kg bw/day	**Sub –Chronic/Chronic:** 20 < LOAEL <= 200 mg/kg bw/day H373: May cause damage to (organs) through prolonged or repeated dermal exposure	**Sub –Chronic/Chronic:** LOAEL <= 20 mg/kg bw/day H372: Causes damage to (organs) through prolonged or repeated dermal exposure	

7.1.8 Inhalative Toxicity

7.1.8.1 Definitions

Inhalative toxicity refers to adverse effects following inhalative administration of a single dose (acute) or longer-term repeated exposures (sub-chronic/chronic).

The definition given by the Globally Harmonized System (GHS) for Acute Inhalative Toxicity states that, "Acute toxicity refers to those adverse effects occurring following an inhalation exposure of 4 hours." (UNECE, 2009). This definition has been adopted for the purposes of the Cradle to Cradle Certified™ Chemical Profiling Methodology.

Acute toxicity values are expressed as LC_{50} (inhalation) values of mg of substance per volume (mg/m^3). LC_{50} values represent the statistically derived median dose of a substance that can be expected to cause death in 50% of the test population. However, specific organ toxicity not resulting in death can also occur from acute exposure. This is captured here as well.

The sub-chronic (90 day - 1 year) and chronic (1-2 years) hazard endpoints are intended to capture specific target organ toxicity that may present potential adverse health effects in humans when the target organ toxicity hasn't been classified in other endpoints of the Cradle to Cradle Certified™ Chemical Profiling Methodology that are subject to repeated exposure (e.g., reproductive toxicity, carcinogenicity, developmental toxicity). Often, these types of studies do not end in morbidity, thus LD_{50} values are not appropriate and the measured endpoint used for the purposes of this classification system is the LOAEL.
For inhalative toxicity, multiple forms of a substance must be considered. Inhalation of vapor/gas is considered separately from inhalation of dust/mist.

7.1.8.2 Rating

Chemicals are allocated to one of three toxicity categories based on the acute and/or sub-chronic/chronic toxicity by the inhalative route of exposure as measure by the LD_{50} and LOAEL as summarized in Table 17.

Table 17 Summary of Inhalative Toxicity Classification Scheme Based on LD_{50} and LOAEL Endpoints

GREEN	YELLOW	RED	GREY
Acute: Inhalative (gas) LC50 > 20000 ppmV Inhalative (vapor) LC50 > 20 mg/l/4hr Inhalative (dust/mist) LC50 > 5 mg/l/4hr	**Acute:** Inhalative (gas) 2500 < LC50 <= 20000 ppmV Inhalative (vapor) 10 < LC50 <= 20 mg/l/4hr Inhalative (dust/mist) 1.0 < LC50 <= 5 mg/l/4hr H332: Harmful if inhaled	**Acute:** Inhalative (gas) LC50 <= 2500 ppmV Inhalative (vapor) LC50 < = 10 mg/l/4hr Inhalative (dust/mist) LC50 <= 1 mg/l/4hr H330a/b: Fatal if inhaled H331: Toxic if inhaled	No relevant data available for classification.

GREEN	YELLOW	RED	GREY
Single exposure organ toxicity: LOAEL (gasses) > 20000 ppmV/4hr LOAEL (vapor) > 20 mg/L/4hr LOAEL (mists/dusts) > 5.0 mg/L/4hr	**Single exposure organ toxicity:** 2500 < LOAEL (gasses) <= 20000 ppmV/4hr 10 < LOAEL (vapor) <= 20 mg/L/4hr 1.0 < LOAEL (mists/dusts) <= 5.0 mg/L/4hr H371: May cause damage to organs via inhalative exposure H335: May cause respiratory tract irritation H336: May cause drowsiness or dizziness	**Single exposure organ toxicity:** LOAEL (gasses) <= 2500 ppmV/4hr LOAEL (vapor) <= 10 mg/L/4hr LOAEL (mists/dusts) <= 1.0 mg/L/4hr H370: Causes damage to organs via inhalative exposure	
Sub –Chronic/Chronic: Inhalation (Gases) LOAEL > 250 ppmV/6h/d Inhalation (Vapors) LOAEL > 1.0 mg/L/6h/d Inhalation (Dusts & Mists) LOAEL > 0.2 mg/L/6h/d	**Sub –Chronic/Chronic:** Inhalation (Gases) 50 < LOAEL <= 250 ppmV/6h/d Inhalation (Vapors) 0.2 < LOAEL <= 1.0 mg/L/6h/d Inhalation (Dusts & Mists) 0.02 < LOAEL<= 0.2 mg/L/6h/d H373: May cause damage to (organs) through prolonged or repeated inhalation	**Sub –Chronic/Chronic:** Inhalation (Gases) LOAEL < = 50 ppmV/6h/d Inhalation (Vapors) LOAEL <= 0.2 mg/L/6h/d Inhalation (Dusts & Mists) LOAEL <= 0.02 mg/L/6h/d H372: Causes damage to (organs) through prolonged or repeated inhalation	

7.1.9 Neurotoxicity

7.1.9.1 Definitions

Neurotoxicity is an adverse change in the structure or function of the central and/ or peripheral nervous system following exposure to a chemical, physical, or biological agent (Tilson, 1990). Structural neurotoxic effects are defined as neuroanatomical changes occurring at any level of nervous system organization. While functional neurotoxic effects include adverse changes in somatic/autonomic, sensory, motor, and/ or cognitive function, structural neurotoxic effects are defined as neuroanatomical changes occurring at any level of nervous system organization (U.S. EPA, 1998).

Neurotoxins can elicit cellular, anatomical, physiological, or behavioral effects. Cellular effects can include inhibition of macromolecule transmitter synthesis, alteration of ion flow, or prevention of

the release of neurotransmitters. Anatomical effects include alterations of the cell body, axon, or the myelin sheath. Physiological effects may include change in neural activation or reduction of neurotransmission speed. Lastly, behavioral effects include significant changes in sensations of sight, hearing, touch, reflexes, motor functions, and cognitive functions (U.S. EPA, 1998).

For the purposes of the Cradle to Cradle Certified™ Profiling Methodology the alterations to the central nervous system listed above are included as evidence of neurotoxic effects. Knowledge of exact mechanisms of action for adverse effects is not necessary to conclude that a chemical is a neurotoxin.

7.1.9.2 Rating

As defined above, neurotoxic effects can be seen over a number of timelines including acute/ single, sub-chronic, and chronic exposures. There are several accepted testing methods acceptable for this endpoint, including OECD 418, 419, and 424, not all of which require specific exposure periods. Since neurotoxic effects can be seen over a range of exposure periods, the criteria for single exposure organ toxicity, sub-chronic, and chronic toxicity are applied for neurotoxicity and summarized in Table 18.

Several types of data points can be used to rate a chemical's potential for neurotoxicity based on the definitions above. Human studies can be used, including clinical evaluations, case reports, epidemiologic studies, and human laboratory exposure studies if an OAEL or NO(A)EL have been determined. Animal studies, which provide more precise exposure information and control environmental factors, can be used as well for the purposes of rating a chemical's neurotoxic effects. Within animal studies, structural, neurochemical, neurophysiological, behavioral, and neurological endpoints are considered for this endpoint. Endpoints for these types of adverse health effects are provided below and are considered in this methodology:

Structural or neuropathological endpoints

- Gross changes in morphology, including brain weight.
- Histologic changes in neurons or glia (neuronopathy, axonopathy, myelinopathy).

Neurochemical endpoints

- Alterations in synthesis, release, uptake, degradation of neurotransmitters.
- Alterations in second-messenger-associated signal transduction.
- Alterations in membrane-bound enzymes regulating neuronal activity.
- Inhibition and aging of neuropathy enzyme.
- Increases in glial fibrillary acidic protein in adults.

Neurophysiological endpoints

- Change in velocity, amplitude, or refractory period of nerve conduction.
- Change in latency or amplitude of sensory-evoked potential.
- Change in electroencephalographic pattern.

Behavioral and neurological endpoints

- Increases or decreases in motor activity.
- Changes in touch, sight, sound, taste, or smell sensations.

- Changes in motor coordination, weakness, paralysis, abnormal movement or posture, tremor, ongoing performance.
- Absence or decreased occurrence, magnitude, or latency of sensorimotor reflex.
- Altered magnitude of neurological measurement, including grip strength, hind limb splay.
- Seizures.
- Changes in rate or temporal patterning of schedule-controlled behavior.
- Changes in learning, memory, and attention.

Developmental endpoints

- Chemically induced changes in the time of appearance of behaviors during development.
- Chemically induced changes in the growth or organization of structural or neurochemical elements (USEPA, 1998).

In addition to experimental data, a survey of industrial chemicals by Grandjean et al. provides a succinct summary of chemicals which have displayed neurotoxic effects (Grandjean, 2006). If a chemical, identified by their CAS number, appears on the Mundy list a RED rating is given as sufficient evidence is available for adverse neurotoxic effects.

Table 18 Summarization of Hazard ratings for Neurotoxicity

GREEN	YELLOW	RED	GREY
Single Exposure Organ, Sub-Chronic, and Chronic Toxicity Endpoints for Green Rating.	Single Exposure Organ, Sub-Chronic, and Chronic Toxicity Endpoints for Yellow Rating.	Single Exposure Organ, Sub-Chronic, and Chronic Toxicity Endpoints for Red Rating. *or* Listed in Grandjean et al. text for neurotoxic effects.	No relevant data available for classification.

7.1.10 Skin, Eye, and Respiratory Corrosion/Irritation

The following describes skin, eye, and respiratory corrosion/irritation, but this endpoint is included in the dermal and inhalative toxicities mentioned above.

7.1.10.1 Definitions

Corrosion is the production of irreversible damage to the skin, eyes, or respiratory system. In skin, corrosion is typified by ulcer, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin (UNECE, 2009). For eyes, irreversible damage is observed by grade four cornea lesions observed during the test, as well as persistent corneal opacity, adhesion, pannus, and interference with the function of the iris or other effects that impair sight (UNECE, 2009). The respiratory tract is considered to comprise the nose, nasal cavity, larynx, trachea, bronchi, and alveoli. Irreversible effects on these organs include fibrosis, dyspneoea, bronchitis, and histomorphology.

Irritation is defined as the production of reversible damage to the skin, eyes, or respiratory tract in the appropriate time frames. For skin, an application of 4 hours is expected followed by 14 days of observation while for eyes a 21-day observation period is expected for reversible effects. Reversible effects on the respiratory tract include coughing, conjunctivitis, rhinitis, and scratchy throat.

7.1.10.2 Rating

Table 19 summarizes the rating scheme for corrosion/irritation. For practitioners to determine the appropriate hazard rating within this endpoint, review of human or animal *in vivo* studies are primary resources for consultation. Suitable studies for skin will have application periods of up to 4 hours and observation periods of 14 days. If within this time frame, one of three animals illicits signs of corrosion as described above, a rating of RED is given. In animal studies, if a mean score between 1.5 and 4.0 is generated for two of three animals, the chemical tested may be labeled as an irritant and classified YELLOW. Inflammation that occurs throughout the observation period but no signs of corrosion are present, a YELLOW rating is also warranted. If no irritating or corrosive effects are seen on the skin in animals or from human experience, the chemical may be classified GREEN.

For damage to the eye, irreversible effects in animal studies can be defined by several endpoints. Evidence that effects on the cornea, iris, or conjunctiva have not reversed or are expected to reverse within an observation period of 21 days can be classified as RED. In addition, if 2 of 3 animals have received mean scores of ≥ 3 and/or >1.5 following grading at 24, 48, and 72 hours a RED rating is warranted. A mild to severe irritant, a YELLOW rating, can be defined by 2 of 3 test animals receiving mean scores in the following gradings:

a. corneal opacity ≥ 1.
b. iritis ≥ 1.
c. conjunctival redness ≥ 2.
d. conjunctival oedema ≥ 2.

In cases where the means scores are less than those listed above or no effects of irritation or corrosion are seen, a GREEN classification is given.

When no human or animal studies are available, pH extremes of ≤ 2 or ≥ 11.5 are the basis for classifying a chemical as RED. Such agents are expected to cause serious damage to eyes, skin, and the respiratory tract.

Additional criteria that can be used and are often presented for regulatory purposes are European Hazard Statements (H-phrases). This convention aligns with the definitions given above for irritation and corrosion and can thus be used for hazard ratings. H-phrases of 314 and 318 can be used for classifying a substance as RED while H-phrases of 315 and 319 afford a classification of YELLOW.

Table 19 Summarization of Classification for Corrosion/ irritation of Skin, Eyes, and Respiratory Tract

GREEN	YELLOW	RED	GREY
No irritation to skin, eyes, or respiratory tract in relevant human or animal studies;	Mild to severe irritation to skin, eyes, or respiratory tract in relevant human or animal studies; H315: Causes skin irritation H319: Causes serious eye irritation	Causes burns, corrosion, or serious damage to skin, eyes, or the respiratory tract in relevant human or animals studies; pH < 2 or pH > 11.5 H314: Causes severe skin burns and eye damage H318: Causes serious eye damage	No relevant data available for classification.

7.1.11 Skin and Respiratory Sensitization

7.1.11.1 Definitions

The clinical definition of sensitization is an eczematous skin reaction resulting from hypersensitivity upon secondary skin or inhalation contact by an allergen (Smith et al, 2001). This adverse health effect is considered to have two phases, known as induction or sensitization and elicitation. Upon exposure to a sensitizing dose, the immune system develops a memory to the allergen and a second exposure to the same allergen elicits production of a cell-mediated or anti-body, allergic response. Accordingly, appropriate tests incorporate both of these phases in order to identify clinical responses.

For the purposes of this classification system, a skin sensitizer is a substance that will lead to an allergic response following skin contact and a respiratory sensitizer is a substance that will lead to hypersensitivity of the airways following inhalation (UNECE, 2009).

7.1.11.2 Rating

If there is either evidence in humans or positive results from an appropriate animal test that a substance can lead to sensitization by skin contact or respiratory inhalation, then the substance will be profiled RED for this endpoint. In the case of sensitization, results from animal studies are generally more reliable than studies from human exposure. Human studies are normally not conducted in controlled experiments for the purpose of hazard classification but rather as part of risk assessment (UNECE, 2009). For skin contact sensitization, human studies can include patch testing, epidemiological studies, well-documented episodes of allergic contact dermatitis (e.g., dermatitis from epoxy resins on watch wristbands) (UNECE, 2009). In airways sensitization, human evidence can include *in vivo* immunological tests, *in vitro* immunological tests, bronchial challenge tests, or studies that indicate specific hypersensitivity reactions. It is important to note that negative human data should not normally be used to disprove positive results from animal studies (UNECE, 2009).

Animal studies can either be classified as adjuvant, where an additional agent is used to modify the effects of a substance of interest, or non-adjuvant where the substance in question is tested alone. For an adjuvant animal study to be considered positive, a response must be elicited in 30% of the population whereas in a non-adjuvant study, 15% of the population must show sensitizing effects (UNECE, 2009). Acceptable studies include Guinea Pig Maximization, Buehler guinea pig, mouse ear swelling test (MEST), and other methods that are scientifically validated. If these tests give an elicitation between 0-15% for non-adjuvant and 0-30% for adjuvant studies this hazard criterion will be classified as YELLOW.

If the data indicates no sensitization effects were seen in any populations, then this endpoint is assigned a GREEN hazard rating. However, experimental data are not always available and in these cases MAK designations are used for reference. If a substance is not listed as a MAK sensitizer of airways (MAK Sa) or sensitizer of skin (MAK Sh), a GREY rating is afforded. Where a chemical is listed according to MAK definition as a medium to strong airway or skin sensitizer, a RED profile is given. Table 20 provides a quick reference for the hazard rating scheme for sensitization.

Table 20 Summary of Classification for Sensitizing Effects

GREEN	YELLOW	RED	GREY
No evidence of sensitization in human and/ or animal studies. *or* No evidence of sensitization in use.	Non-adjuvant animal studies elicit a response 15% > population > 0%. Adjuvant animal studies elicit a response of 30% > population > 0%.	Substance has shown medium to strong sensitization effects in human or animal studies. *or* List as a MAK skin or airways sensitizer (MAK Sa or Sh). H334: May cause allergy or asthma symptoms or breathing difficulties in inhaled. H317: May cause an allergic skin reaction.	No relevant data for classification.

7.1.12 Aquatic Toxicity (Acute and Chronic)

7.1.12.1 Definitions

Acute aquatic toxicity is the ability of a chemical to cause adverse or injurious health effects to an organism in a short-term aquatic exposure scenario. For the purposes of the Cradle to Cradle Certified™ Chemical Profiling Methodology, fish (vertebrate), daphnia (invertebrate), and algae are chosen since they cover a range of trophic levels and taxa in the aquatic environment and are generally representative of aquatic fauna and flora. In addition, data on these taxa are more likely to be available as they are accepted or required in many regulatory schemes.

Chronic aquatic toxicity is the intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposure that is determined in relation to the life-cycle of the organism

(UNECE, 2009). Similar to acute toxicity, for the purposes of the Cradle to Cradle Certified™ Chemical Profiling Methodology, fish (vertebrate), daphnia (invertebrate), and algae are chosen since they cover a range of trophic levels and taxa in the aquatic environment and are generally representative of aquatic fauna and flora.

7.1.12.2 Rating

Required tests for this endpoint include 96-hour LC_{50} for vertebrate species, 48-hour EC_{50} for invertebrate species, and 72- to 96-hour EC_{50} for algal species. Data quality and interpretation of results that are dependent on a chemical's properties are also important for these endpoints. Criteria for RED, YELLOW, and GREEN ratings are provided in Table 21.

The toxicological thresholds for aquatic toxicity should preferably be drawn from data required for regulatory purposes, recognized databases, and relevant literature. As a general rule, data generated by recognized international standards (OECD guidelines EPA, ASTM, or ISO EU) or conforming with Good Laboratory Practices is preferred. In cases where this is not available, less rigorous types of data can be used, such as MSDS data, or Quantitative Structure-Activity Relationships (QSAR) software can be used for appropriate chemicals.

For this rating scheme, freshwater and marine species toxicity are considered equivalent. No preference is given to exposure regimes that typically are employed in four types: static, static-renewal, recirculation, and flow-through. Depending on the characteristics of a chemical, different methods are used and as long as a valid test is performed all exposure scenarios are equivalent.

Occasionally there are multiple acceptable tests for a taxonomic group. In this case, the most sensitive test (i.e., study with the lowest $L(E)C_{50}$) is used for rating purposes. This is applied on a case-by-case basis and where large data sets are available (four or more), a mean average of the results can be used for classification (UNECE, 2009). However, this should only be applied in cases where the tests are performed on the same species.

Difficult to Test Substances

Although this classification system is intended to apply to all chemicals and substances, it is recognized that there are some substances (i.e., metals, poorly soluble chemicals, volatile chemicals) that need special consideration when interpreting test results. Testing for aquatic toxicity requires the dissolution of the substance in the test water media and continuation of a constant exposure concentration over the duration of the test period (UNECE, 2009). However, some substances make this requirement difficult and professional judgment must be applied for these chemicals that generally cause difficulties in testing.

Chemical properties that can contribute to losses of concentration in testing conditions include poorly water soluble, volatile, photo-degradable, hydrolytically unstable, oxidizable, biodegradable, adsorbing, chelating, colored, hydrophobic, ionized, or complex mixtures (UNECE, 2009). In all of these difficult testing conditions, the actual test concentration is likely to be below the nominal test concentration provided by the guideline (UNECE, 2009). If acute toxicities are reported to be < 10 mg/L, the practitioner can be fairly confident in a RED rating. However, it is more difficult in cases where the $L(E)C_{50}$ is reported to be > 10 mg/L where expert judgment is needed on the validity of the study and appropriate rating for a chemical.

Unstable Substances
Unstable substances include those that are quickly hydrolyzed in water, photo-degrade, oxidize, and are volatile or biodegrade. In these cases, not only is there concentration loss in the study, but secondary, degradation products arise that can have unique toxicity hazards. In cases where chemicals exhibit these properties it is essential to have data on the measured exposure concentrations at suitable time points in the study. Without this prerequisite, a study should be deemed invalid for hazard ratings. Where these data are available, the mean average of the start and end concentrations of the test can be used to calculate the $L(E)C_{50}$ (UNECE, 2009).

Where the identification of the breakdown products is known, classification of these chemicals for acute aquatic toxicity hazards should also be determined by the normal protocol. The resulting rating for acute aquatic toxicity of the breakdown products will affect the overall aquatic toxicity rating for the parent compound (i.e., a byproduct RED for acute aquatic toxicity will result in a RED rating for aquatic toxicity of the parent chemical).

Poorly Soluble Substances
Typically these chemicals are considered to be < 1 mg/L, but there are additional scenarios where the guidance for these substances may be applicable. In older studies it is normal to find toxicity levels in excess of the water solubility, or where dissolved levels are below the detection limit of a method used (UNECE, 2009). Where studies of this kind are the only available data, some practical rules may be applied.

In studies that report acute toxic effects in the aquatic environment at levels in excess of the water solubility, the $L(E)C_{50}$ may be assumed to be equal to the measured water solubility. The assumption in this case is that the excess, undissolved substance did not contribute to toxicity through physical effects and should be carefully considered. Similarly, where no acute toxicity effects are seen in excess of water solubility, the $L(E)C_{50}$ may be considered to be greater than the measured water solubility (UNECE, 2009). This value still may not give clarity on the final rating a chemical should receive and it is therefore assumed that if a chemical does not show toxic effects with its range of solubility then it may be rated GREEN.

Some studies fail to report the concentration since the detection limit of the method used may not be sensitive enough and be able to capture poorly soluble chemicals. In such instances, where acute toxic effects are observed, the $L(E)C_{50}$ may be considered to be less than the analytical detection limit. Where no toxicity is observed, the $L(E)C_{50}$ may be considered to be greater than the water solubility. As indicated above, in this latter case, a rating of GREEN may be given to this endpoint.

Other Factors
Several other factors can contribute to concentration loss in studies, including sedimentation, adsorption, and bioaccumulation. For sedimentation and bioaccumulation, determination of the $L(E)C_{50}$ is analogous to chemicals that exhibit instability. Adsorption tends to occur with chemicals that have high log Kow values and loss of concentration tends to be rapid. In these instances, end of test concentrations may be used to determine exposure thresholds.

Quantitative Structure Activity Relationships (QSAR)
When no other data are available through studies, Quantitative Structure Activity Relationships (QSARs) are used to predict the toxicity of chemicals. In particular, Ecosar v.1.00h, developed as part of EPA's Episuite, is used for these purposes.

Chronic effects include a range of sub-lethal endpoints and are generally expressed in terms of a No Observable Effect Concentration (NOEC). Observable endpoints from acceptable tests (OECD 210 – Fish Early Life Stage, 211 – Daphnia Reproduction, and 201 Algal Growth) include survival, growth, morphological abnormalities, and behavioral effects. Other validated and internationally accepted test methods may be used in these classification schemes that are comparable to the OECD tests listed above. The NOEC's determined in the appropriate tests are used in the Cradle to Cradle Certified™ Chemical Profiling Methodology in order to rate a chemical for its intrinsic chronic aquatic toxicity. The criteria for each rating are provided in Table 22.

Typically, acute toxicity is more widely available than chronic toxicity data for aquatic species and subsequently is relied upon in many classification schemes with the appropriate combination of biodegradation and bioaccumulation data. Where both data points are available, preference shall be given to chronic toxicity rather than a combination of acute toxicity with degradability and bioaccumulation data. If chronic toxicity is only available for one or two trophic levels a comparison to acute toxicity should be made. Whichever endpoint gives the most stringent rating should be used.

Table 21 Criteria Values for Classification of Aquatic Acute Toxicity in Vertebrate, Invertebrate, and Aquatic Plants

	GREEN	YELLOW	RED	GREY
Vertebrate Toxicity (fish)	96 hour LC50 > 100 mg/L QSAR 96 hour LC50 > 100 mg/L	96 hour LC50 10 - 100 mg/L QSAR 96 hour LC50 10 - 100 mg/L	96 hour LC50 < 10 mg/L QSAR 96 hour LC50 < 10 mg/L H400: Very toxic to aquatic life	No relevant data for classification.
Invertebrate Toxicity (daphnia)	48 hour L(E)C50 > 100 mg/L QSAR 48 hour L(E)C50 > 100 mg/L	48 hour L(E)C50 10 - 100 mg/L QSAR 96 hour L(E)C50 10 - 100 mg/L	48 hour L(E)C50 < 10 mg/L QSAR 48 hour L(E)C50 < 10 mg/L H400: Very toxic to aquatic life	No relevant data for classification.
Aquatic Plant Toxicity (algae)	72/ 96 hour L(E)C50 > 100 mg/L QSAR 72/ 96 hour L(E)C50 > 100 mg/L	72/ 96 hour L(E)C50 10 - 100 mg/L QSAR 72/ 96 hour L(E)C50 10 - 100 mg/L	72/ 96 hour L(E)C50 < 10 mg/L QSAR 96 hour L(E)C50 < 10 mg/L H400: Very toxic to aquatic life	No relevant data for classification.

Table 22 Criteria for Classification of Aquatic Chronic Toxicity in Vertebrate, Invertebrate, and Aquatic Plants

GREEN	YELLOW	RED	GREY
Fish, Daphnia, and/or Algae NOEC >10 mg/L	Fish, Daphnia, and/or Algae NOEC =1 – 10 mg/L	Fish, Daphnia, and/or Algae NOEC < 1 mg/L H410: Very toxic to aquatic life with long lasting effects H411: Toxic to aquatic life with long lasting effects H412: Harmful to aquatic life with long lasting effects H413: may cause long lasting harmful effects to aquatic life	No relevant data for classification.

7.1.13 Terrestrial Toxicity

7.1.13.1 Definitions

Terrestrial toxicity is the ability of a chemical to pose an adverse health effect to a species that lives on land. For the purposes of the Cradle to Cradle Certified™ Profiling Methodology, toxicity to avian species and soil organisms is considered within this endpoint as they are not represented in other endpoints in this methodology. Adverse health effects can include morbidity and reproduction/ developmental endpoints.

7.1.13.2 Rating

To determine the hazard rating for terrestrial toxicity, several tests may be considered for a variety of avian species and soil organisms that are considered beneficial to soil by being able to increase its productivity. Toxicity studies for birds follow the same principles described above for acute toxicity and reproductive/ developmental toxicity and are measured by LD50s and NOECs, respectively. Table 23 provides a summary of the criteria using these measures for each hazard rating used in this methodology. Acceptable experimental designs for rating include:

- OECD 205: Avian Dietary Toxicity Tests.
- OECD 206: Avian Reproduction Test.

Observable endpoints for these tests include mortality, body weights of adults and of the young at 14 days, food consumption of adults and young, gross pathological examination of adult birds, egg product, cracked eggs, egg shell thickness, viability, hatchability, and effects on young birds. If significant adverse health effects are found in these studies the appropriate rating should be applied according the criteria displayed in Table 23 (e.g., small changes in body weight would not be considered a significant adverse health effect).

The importance of soil as a key component of ecosystems is now widely recognized and understanding how organisms that contribute to soil health are affected by chemicals is important. For invertebrate species, earthworms are the most commonly tested given their predominance in soil and their importance to ecological health. There are several established tests for earthworms including:

- OECD 207: Earthworm Acute Toxicity Tests.
- OECD 220: Enchrtraeid Reproduction Test.
- OECD 222: Earthworm Reproduction Test.

In addition to earthworms there are several other invertebrates and insects that are considered crucial to the health of soil, including honeybees, mites, beetles, and springtails. Several standardized tests exist for these species including:

- OECD 213: Honeybees, Acute Oral Toxicity Test.
- OECD 214: Honeybees, Acute Contact Toxicity Test.
- OECD 226: Predatory mite reproduction test in soil.
- OECD 228: Determination of Developmental Toxicity of a Test Chemical to Dipteran Dung Flies.

- OECD 232: Collembolan Reproduction Test in Soil.

All of these species are considered to be organisms important to the health of soils and are included in this vertebra for rating purposes. Table 23 summarizes the criteria for rating a chemical's effect on these species.

Table 23 Guidelines for Determining the Hazard Ratings of Terrestrial Toxicity

	GREEN	YELLOW	RED	GREY
Birds (Sub-acute)	Chicken LD50 > 9000 mg/kg fodder (5 days) Duck LD50 > 15000 mg/kg fodder (5 days)	Chicken LD50 900 - 9000 mg/kg fodder (5 days) Duck LD50 1500 - 15000 mg/kg fodder (5 days)	Chicken LD50 < 900 mg/kg fodder (5 days) Duck LD50 < 1500 mg/kg fodder (5 days)	No relevant data for classification.
Birds (Sub-chronic/ Chronic)	Chicken NOEC > 3000 mg/kg fodder (≥ 20 weeks) Duck NOEC > 5000 mg/kg fodder (≥ 20 weeks)	Chicken NOEC 300 - 3000 mg/kg fodder (≥ 20 weeks) Duck NOEC 500 - 5000 mg/kg fodder (≥ 20 weeks)	Chicken NOEC < 300 mg/kg fodder (≥ 20 weeks) Duck NOEC < 500 mg/kg fodder (≥ 20 weeks)	No relevant data for classification.
Toxicity for Soil Organisms (Acute)	EC50 > 1000 mg/kg dry soil	EC50 100 - 1000 mg/kg dry soil	EC50 < 100 mg/kg dry soil	No relevant data for classification.
Toxicity for Soil Organisms (Sub-chronic/ Chronic)	NOEC > 100 mg/kg dry soil	NOEC 10 - 100 mg/kg dry soil	NOEC < 10 mg/kg dry soil	No relevant data for classification.

7.1.14 Persistence

7.1.14.1 Definitions

Persistence is a measure of a substance's ability to remain as a discrete chemical entity in the environment for a prolonged period of time. Biodegradation is one process by which a substance or material is broken down by microorganisms and reduced to organic and inorganic molecules, ultimately taking the form of carbon dioxide, water, and salts. It is important to note that biodegradation applies solely to organic or organometallic chemicals. The concept of biodegradability as applied to organic compounds has limited to no meaning for inorganic compounds (UNECE, 2009). Inorganic chemicals react differently in the environment through changing speciation or dissociation and don't have measurable endpoints such as oxygen depletion or carbon dioxide generation as organic compounds do.

7.1.14.2 Rating

To determine the hazard rating for this endpoint, several endpoints may be considered with biodegradability tests being preferred and estimation of biodegradability by QSAR results representing the least accurate. A number of OECD guidelines have been developed for biodegradation and they are used for classification purposes. Results from OECD guidelines 301: "Ready Biodegradability" may be used for ratings as GREEN, YELLOW, or RED depending upon the

removal of Dissolved Organic Carbon (DOC) or Theoretical Oxygen Demand (ThOD). For a GREEN classification, either 70% removal of DOC or 60% removal of ThOD must be reached in a 10-day window within the 28-day timeframe. The 10-day window begins once 10% biodegradation has been reached by DOC, ThOD, or $ThCO_2$. If the 10% biodegradation is reached but the chemical in question does not reach the required degradation within 10 days, a YELLOW rating is given. In cases where 10% biodegradation does not trigger the 10-day window, a hazard of RED is given.

Inherent biodegradability (OECD Test Guidelines 302, 304A) may be used to determine hazard ratings; however, these tests may not be used to give a GREEN rating. The optimum conditions for biodegradation set within these guidelines, primarily the adaptation of microorganisms, cannot allow a practitioner to assume ready biodegradability of inherently biodegradable substances (UNECE, 2009). Substances that have been degraded more than 70% for inherent biodegradability may be rated as YELLOW. When inherent biodegradability studies are the only available data and less than 70% removal has been seen, a rating of RED is applied. However, if half-life or QSAR results (discussed below) conflict with this rating, reevaluation of the endpoints is considered. If inherent biodegradability tests are employed without pre-exposure and adaptation of microorganisms, these results may be used for a GREEN rating.

When empirical evidence is not available for readily or inherent biodegradability studies, estimation of degradation by QSAR results are used for classification. BIOWIN is the QSAR model used for this methodology, as it is publicly available and updated regularly. When identifying chemicals by their CAS number, if BIOWIN gives a result of readily biodegradable, then a rating of GREEN is given. Where BIOWIN indicates a chemical can be degraded within weeks to months a classification of YELLOW is given. If BIOWIN labels a substance as recalcitrant, this results in a rating of RED.

Table 24 provides a quick reference for generating hazard ratings for persistence and biodegradation.

Table 24 Guidelines for Determining Hazard Ratings for Persistence and Biodegradation

GREEN	YELLOW	RED	GREY
$T_{1/2}$ < 30/90 days in water/ soil or sediment; Readily biodegradable (>70 % within 28 days) based on OECD guidelines (301); Predicted to be readily biodegradable by QSAR results	30/90 day < $T_{1/2}$ < 60/180 days in water/ soil or sediment; 10% < DOC removal < 70% based on OECD guidelines (301) 10% < ThOD removal < 60% based on OECD guidelines (301) Inherently biodegradable based on OECD guidelines (302, 304A); Predicted to be degradable within weeks to months by QSAR	T1/2 > 60/180 days in water/ soil or sediment DOC and ThOD removal < 10% based on OECD guidelines Predicted to be recalcitrant by QSAR results.	No relevant data for classification or substance is considered inorganic and not applicable to this endpoint.

7.1.15 Bioaccumulation

7.1.15.1 Definitions

Bioaccumulation is a measure of the tendency for a chemical to accumulate in an organism and is the net result of uptake, transformation, and elimination of a substance due to all routes of exposure. This is often measured by a bioaccumulation factor (BAF), which is the ratio of the concentration of a substance in a living organism (mg/kg) to the concentration of that substance in the surrounding environment (mg/L for aquatic systems). An additional endpoint that can be used to predict the bioaccumulation of a chemical in the environment is the n-octanol-water partition coefficient (K_{ow}). The K_{ow} is a measure of a chemical's lipophilicity and has been empirically shown that an increasing K_{ow} correlates with an increasing BAF. These endpoints, BAF and $K_{ow,}$ have been utilized for reference in determining the hazard rating of a chemical's potential to bioaccumulate in organisms. Note bioconcentration factors (BCF) are a type of BAF and pertain to bioaccumulation from water in laboratory tests.

7.1.15.2 Rating

Based on BCF or BAF and K_{ow} values, the rating of a chemical as GREY, RED, YELLOW or GREEN for bioaccumulation potential is shown in Table 25.

Preference is given to high-quality studies that determine the BCF or BAF according to internationally accepted guidelines. The degree of bioconcentration/bioaccumulation depends on numerous intrinsic factors of the chemical but also experimental factors such as bioavailability, size of the organism, maintenance of exposure concentration, or exposure duration. GHS provides guidance on the determination of high-quality BCF studies in Annex 9 of the 3rd edition. These guidelines are used for reference in this methodology. When test data for fish species is not available, high-quality tests involving other species such as oysters, mussels, or scallops are also usable.

Experiments deriving the BCF value of low or uncertain quality can underestimate the potential for bioaccumulation. In such cases, consideration for the use of an experimentally determined K_{ow} value should be used instead. The determination of the K_{ow} value will also have to be considered as high-quality experiments are preferred or values assigned as "recommended values." GHS provides guidelines for review of experiments in determining the K_{ow} and their overall quality in Annex 9 of the 3rd edition. These guidelines are followed for the purposes of rating a chemical for bioaccumulation.

Although the relationship between increasing K_{ow} and BCF has been empirically established, this linear relationship becomes equivocal for highly lipophilic substances ($K_{ow} > 6$). At K_{ow} values above 6, the relationship with BCF begins to decrease. This relationship has been postulated to be due to reduced membrane permeation and kinetic or reduce biotic lipid solubility for large molecules (UNECE, 2009). Based on the curvilinear relationship between K_{ow} and BCF, an upper limit of the K_{ow} is appropriate given the decreasing relationship. From the literature, the best upper limit for the K_{ow} is estimated at 8 (Bintein, 1993). When the experimental determination of K_{ow} is not always possible (e.g., very water-soluble substances, very lipophilic substances, and surfactants), a QSAR-derived K_{ow} may be used. For the purposes of this classification, the BioWin application is used (Syracuse Research Corporation).

For some chemicals, the determination of a BCF value becomes difficult as chemical properties can limit the ability of a chemical to be soluble in lipids present in water, or available for transfer across fish gills. These substances include poorly soluble substances and high molecular weight substances. Poorly soluble substances for which the solubility is less than the detection limit create problems in interpreting the BCF. For such substances, the bioconcentration potential should be based on the experimental determination of log K_{ow} or QSAR estimations (UNECE, 2009). For chemicals with a high molecular weight the tendency to bioaccumulate decreases. This result is possibly due to the steric hindrance of a chemical preventing passage across the gill membranes. For chemicals that have a molecular weight above 1000, it has been proposed that these chemicals do not have the potential to bioaccumulate and is employed for the purposes of this rating system (CSTEE, 1999).

Cases may arise where there are multiple endpoints available that give conflicting classifications. In general, a "weight of evidence" approach should be used where the highest quality study for BCF

or BAF is used. If this approach does not give parity to various endpoints then the highest value should be used to determine the hazard rating.

Table 25 Cut-off Values for Classification of a Chemical's Bioaccumulation Potential

GREEN	YELLOW	RED	GREY
BCF < 100 by experimental or QSAR results if log K_{ow} < 6 *or* log K_{ow} < 2 *or* Molecular weight > 1000.	100 < BCF < 500 by experimental or QSAR results if log K_{ow} < 6.	BCF > 500 by experimental or QSAR results if log K_{ow} < 6.	No relevant data for classification. log Kow>2 and no additional information.

7.1.16 Organohalogens

7.1.16.1 Definitions

Organohalogens, defined as chemicals with a carbon to halogen bond (i.e., contains a carbon-to-fluorine, -chlorine, -bromine, or –iodine bond), are flagged for their trends in increased toxicity, bioaccumulation, and persistence. The chemicals falling into this category are now ubiquitous in our environment and are being used in a variety of applications— from colorants and adhesives to plastic molding, piping, coatings, and pesticides. They are also major components of commercial formulations in furniture foam (pentaBDE), plastics for TV cabinets, consumer electronics, wire insulation, back coatings for draperies and upholstery (decaBDE), and plastics for personal computers and small appliances (octaBDE). Toxicological testing indicates these chemicals cause a variety of concerns, from liver toxicity and thyroid toxicity, to neurodevelopmental abnormalities. In addition, polytetrafluoroethylene (PTFE), a popular material for non-stick applications, is a heavily fluorinated polymer manufactured with perfluorooctanoic acid (PFOA). PFOA and the congeners of PTFE degradants have been found in polar bears, marine life, fetal umbilical cord blood, and even in human breast milk.

Dietrich Henschler, an eminent German toxicologist, studied the human health impacts and potency of organohalogens and compared them to their non-halogenated analogues (Henschler, 1994). Henschler used a large data set of organic compounds that included organochlorines - chlorinated alkanes, alkenes, butadienes, benzenes, phenols, paraffins, dioxins, furan, biphenyls, and insecticides. Four major conclusions were reached in this study:

1. The introduction of chlorine into organic compounds is almost always associated with an increase in toxic potential for a variety of toxic effects.
2. Chlorination usually produces entirely new toxic effects.
3. With introduction of chlorine most organic compounds exhibit mutagenic and carcinogenic properties not present in the non-halogenated analogue.
4. Chlorination often increases the potency of toxic effects. With little empirical data on the toxic effects of all organochlorines and the limited knowledge of chlorinated by-products in the synthesis of this chemical class, the trend identified by Henschler demonstrates that there is something inherently dangerous in chlorinating organic molecules.

Chlorination radically affects the chemical stability of organic chemicals—usually increasing it. Because many organochlorines resist natural degradation processes, even very dilute discharges tend to build up in the environment over time. Some organochlorines, such as 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), do not break down to any appreciable degree; virtually all the TCDD released into the environment will remain in one place or another almost indefinitely. Many other organochlorines are persistent, but will degrade very slowly, with environmental half-lives in the years or decades.

Another effect of chlorination is that chlorine atoms invariably increase the ability of organic chemicals to dissolve in oils. Once oil-soluble organochlorines are released into the environment, they accumulate in the fatty tissues of living things—a process called bioaccumulation. Bioaccummulative compounds gravitate from the ambient environment into the food web, magnifying in concentration as they move upward from tiny organisms to large predators. By the time they get to the top of the food web (i.e., humans, eagles, polar bears, and other species), some organochlorines reach concentrations many millions of times greater than their levels in the ambient environment. Finally, chlorination of organic compounds virtually always increases toxicity. This effect occurs because modulating the persistence, reactivity, and oil solubility of a chemical changes its interactions with proteins and fats inside living systems in a way that can disrupt the natural processes of physiology and development.

Chlorination of organic molecules also increases the solubility within fats and oils while also radically affecting an organic chemical's stability, usually increasing it. This allows for the gradual build-up of organochlorinated compounds in sediments, waterways, and in the tissue of living organisms. The insidious nature of organochlorine bioaccumulation and persistence is starting to be recognized globally as there is evidence of contamination in the upper atmosphere contributing to ozone depletion. Organochlorines such as DDT, hexachlorobenzene, chlordane, heptachlor epoxide, and lindane have been found in tree bark all over the world (IJCSAB, 1989). Dioxins have been found throughout the food chain as evidenced by EPA's estimate that 90% of the average American's dioxin exposure is from their diet (Yang, 1994). PCBs and a number of organochlorine pesticides have been identified in the bodies of seals, walruses, beluga whales, porpoises, and polar bears (Robins et al, 1982). Organochlorine pollutants even fall from the skies, having been found in falling snow throughout the arctic (Willes et al, 1993). The ubiquitous presence of organochlorine pollutants throughout the globe as well as in the fat tissue of humans, infants, and animals demonstrates an additional danger of this chemical class.

7.1.16.2 Rating

Certain halogenated materials, such as PVC, polychloroprene, chlorinated polyethylene, and other chlorinated polymers, are prohibited for use in Cradle to Cradle Certified™ products and will be found on the Banned Lists.

The trends discussed above are cause for concern for the organohalogen family as a whole, and subsequently any chemical with a carbon to halogen bond has been classified as RED. Those chemicals that lack this functionality are given a classification of GREEN, as shown in Table 26

Rating Scheme for Halogenated Organic Compounds

Green	YELLOW	RED

Chemical does not contain a carbon to halogen (fluorine, chlorine, bromine, or iodine) bond.	Not applicable.	Chemical contains a carbon to halogen (fluorine, chlorine, bromine, or iodine) bond.

Table 26 Rating Scheme for Halogenated Organic Compounds

GREEN	YELLOW	RED
Chemical does not contain a carbon to halogen (fluorine, chlorine, bromine, or iodine) bond.	Not applicable.	Chemical contains a carbon to halogen (fluorine, chlorine, bromine, or iodine) bond.

7.1.17 Toxic Metals

7.1.17.1 Definitions

Antimony, arsenic, cadmium, chromium VI, cobalt, lead, mercury, nickel, thallium, tin (organotins only), radioactive elements, and vanadium are considered toxic heavy metals for the Cradle to Cradle Certified™ Chemical Profiling Methodology. In general, these metals have shown toxic effects no matter the speciation of the metal, even if incorporated in an organo-metal structure.

7.1.17.2 Rating

The presence of any toxic heavy metal derived from either the chemical structure or analytical testing of mixtures (e.g., petroleum distillates) results in a RED rating for this endpoint. The absence of toxic heavy metals in the chemical structure or if it is below 0.01% (100 ppm) for a mixture then a GREEN rating is given, as shown in the rating scheme in Table 27.

Table 27 Classification Scheme for Toxic Heavy Metals

GREEN	YELLOW	RED
Chemical does not contain toxic heavy metal compound (e.g. antimony, arsenic, cadmium, chromium VI, cobalt, lead, mercury, nickel, tin (organotins only), radioactive elements, and vanadium.	Not applicable.	Chemical contains toxic heavy metal compound (e.g. antimony, arsenic, cadmium, chromium VI, cobalt, lead, mercury, nickel, tin (organotins only), radioactive elements, and vanadium.

7.1.18 Ozone Depleting Potential

7.1.18.1 Definitions

The Globally Harmonized System for Classification offers a definition of Ozone Depleting Potential:

"*Ozone Depleting Potential (ODP) is an integrative quality, distinct for each halocarbon source species, that represents the extent of ozone depletion in the stratosphere expected from the halocarbon on a mass-for-mass basis relative to CFC-11. The formal definition of ODP is the ration of integrated perturbations to total ozone, for differential mass emission of a particular compound relative to an equal emission of CFC-11.*" (UNECE, 2009).

7.1.18.2 Rating

For the purposes of the Cradle to Cradle Certified™ Chemical Profiling Methodology, this hazard endpoint is completely list driven and no criteria are given for ODP, as shown in Table 28. If a substance is listed as either a Class I or II Ozone Depleting Substance (ODS) by the Montreal Protocol then a rating of RED is given. If a chemical is not present within this documentation then a GREEN rating is given.

Table 28 Classification Scheme for Ozone Depleting Potential

GREEN	YELLOW	RED
Not listed in Annexes to the Montreal Protocol.	Not applicable.	Listed in Annexes to the Montreal Protocol.

7.2 BANNED CHEMICALS

The following lists contain those chemicals and substances that are banned for use in Cradle to Cradle Certified™ products as **intentional inputs above 1000 ppm**. These substances were selected for inclusion on the Banned Lists due to their tendency to accumulate in the biosphere and lead to irreversible negative human health effects. In addition, several substances were selected due to hazardous characteristics associated with their manufacture, use, and disposal.

The intention for the "Banned Lists" is not to simply provide a checklist to eliminate chemicals of concern. Rather, it should be viewed as providing specific examples that may also be used to guide substitution. There may be chemicals similar in structure that are not on the list but exhibit similar properties to the listed chemical. Thoughtful substitutions using the intentional design approach of Cradle to Cradle would suggest that chemicals with similar properties would not be a good substitution choice.

There are two lists provided: a banned list of chemicals for chemical nutrients (Table 29) and a banned list of chemicals for biological nutrients (Table 30). A key component of Cradle to Cradle® design is the recognition of and design for the two nested cycles – Biological and Technical. Banned Lists were thus created separately for biological and technological nutrients to allow for the use of some substances like lead or cadmium in materials where exposure to humans or the environment is highly unlikely to occur. Lead, for example, is often used in cast aluminum, from which it does not migrate out of the material and can therefore be managed in safe technical cycles. However, lead should not be used in biological nutrients, which ultimately cycle into the biosphere. On the other hand, mercury is not suitable for either type of nutrient cycles due its ability to easily migrate out of materials. The overall intention is to inspire and promote innovation in quality products in a way that supports 10 billion people on earth without increasing the natural background level of materials or harming people or the environment.

Note that lead, PTFE, and polycyclic aromatic hydrocarbons (PAHs) are substances that are on the Biological Nutrients Banned List but not the Technical Nutrients Banned List. While these substances can be used in some materials as technical nutrients, where exposure is not expected to occur (e.g., lead in aluminum, PAHs in carbon black), they are harmful chemicals and should not be present in materials that may result in exposure to humans and the environment. Therefore, despite not being present on the Technical Nutrient Banned List (with the exception of cadmium),

lead, cadmium, PTFE, and PAHs are banned for use in materials where exposure to humans or the environment is highly likely to occur. Examples of these materials include paints, coatings, and finishes that are used on the surface of products such as toys or other children's products and jewelry. Relevant material use scenarios will be determined and evaluated by the assessor. Note also that PTFE is banned in Technical Nutrients if it is the primary component of the product or material.

Table 29 Banned List of Chemicals for Technical Nutrients

SUBSTANCE	CAS #	COMMENTS
Metals		
Arsenic	7440-38-2	
Cadmium	7440-43-9	Banned only for products with no guaranteed nutrient management
Chromium VI	18540-29-9	
Mercury	7439-97-6	
Flame Retardants		
Hexabromocyclododecane	3194-55-6; 25637-99-4	
Penta-BDE	32534-81-9	
Octa-BDE	32536-52-0	
Deca-BDE	1163-19-5	
Polybrominated Diphenyl Ethers (PBDEs)	Several	
Tetrabromobisphenol A	79-94-7	
Tris(1,3-dichloro-2-propyl)phosphate	13674-87-8	
Phthalates		
Bis(2-ethylhexyl)phthalate	117-81-7	
Butyl benzyl phthalate	85-68-7	
Dibutyl phthalate	84-74-2	
Halogenated Polymers		
Polyvinyl chloride (PVC)	9002-86-2	
Polyvinylidenechloride (PVDC)	9002-85-1	
Chlorinated polyvinyl chloride (CPVC)	68648-82-8	
Polychloroprene	9010-98-4	
Chlorinated Hydrocarbons		
1,2-Dichlorobenzene	95-50-1	
1,3-Dichlorobenzene	541-73-1	
1,4-Dichlorobenzene	106-46-7	
1,2,4-Trichlorobenzene	120-82-1	
1,2,4,5-Tetrachlorobenzene	95-94-3	
Pentachlorobenzene	608-93-5	
Hexachlorobenzene	118-74-1	
PCB and Ugilec	Several	
Short-chain chlorinated paraffins	Several	

Others		
Pentachlorophenol	87-86-5	
Nonylphenol	104-40-5, 84852-15-3	
Octylphenol	27193-28-8	
Nonylphenol ethoxylates	Several	
Octylphenol ethoxylates	Several	
Tributyltin	688-73-3	
Trioctyltin	869-59-0	
Triphenyltin	892-20-6	
Perfluorooctane sulfonic acid	1763-23-1	
Perfluorooctanoic acid	335-67-1	

Table 30 Banned List of Chemicals for Biological Nutrients

SUBSTANCE	CAS #	COMMENTS
Metals		
Arsenic	7440-38-2	Restricted to maximum background concentration in soils
Chromium VI	18540-29-9	
Mercury	7439-97-6	
Cadmium	7440-43-9	
Lead*	7439-92-1	
Flame Retardants		
Hexabromocyclododecane	3194-55-6; 25637-99-4	
Penta BDE	32534-81-9	
Octa BDE	32536-52-0	
Deca BDE	1163-19-5	
Polybrominated Diphenyl Ethers (PBDEs)	Several	
Tetrabromobisphenol A	79-94-7	
Tris(1,3-dichloro-2-propyl)phosphate	13674-87-8	
Phthalates		
Bis(2-ethylhexyl)phthalate	117-81-7	
Butyl benzyl phthalate	85-68-7	
Dibutyl phthalate	84-74-2	
Halogenated Polymers		
Polyvinyl chloride (PVC)	9002-86-2	
Polyvinylidenechloride (PVDC)	9002-85-1	
Chlorinated polyvinyl chloride (CPVC)	68648-82-8	
Polychloroprene	9010-98-4	
Polytetrafluoroethylene (PTFE)*	9002-84-0	

SUBSTANCE	CAS #	COMMENTS
Chlorinated Hydrocarbons		
1,2-Dichlorobenzene	95-50-1	
1,3-Dichlorobenzene	541-73-1	
1,4-Dichlorobenzene	106-46-7	
1,2,4-Trichlorobenzene	120-82-1	
1,2,4,5-Tetrachlorobenzene	95-94-3	
Pentachlorobenzene	608-93-5	
Hexachlorobenzene	118-74-1	
PCB and Ugilec	Several	
Short-chain chlorinated paraffins	Several	
Other		
Pentachlorophenol	87-86-5	
Nonylphenol	104-40-5, 84852-15-3	
Octylphenol	27193-28-8	
Nonylphenol ethoxylates	Several	
Octylphenol ethoxylates	Several	
Tributyltin	688-73-3	
Trioctyltin	869-59-0	
Triphenyltin	892-20-6	
Perfluorooctane sulfonic acid	1763-23-1	
Perfluorooctanoic acid	335-67-1	
Polycyclic Aromatic Hydrocarbons*		
PAH group (as defined in TRI)	Not Applicable	
Benzo(a)pyrene	50-32-8	
5-Methylchrysene	3697-24-3	
Acenaphthene	83-32-9	
Anthracene	120-12-7	
Benz(a)anthracene	56-55-3	
Benz(j)aceanthrylene	202-33-5	
Benzo(b)fluoranthene	205-99-2	
Benzo(c)phenanthrene	195-19-7	
Benzo(g,h,l)perylene	191-24-2	
Benzo(j)fluoranthene	205-82-3	
Benzo(k)fluoranthrene	207-08-9	
Chrysene	218-01-9	
Cyclopenta(c,d)pyrene	27208-37-3	
Dibenzo(a,h)anthracene	53-70-3	
Dibenzo(a,h)pyrene	189-64-0	
Dibenzo(a,i)pyrene	189-55-9	
Dibenzo(a,l)pyrene	191-30-0	
Fluoranthene	206-44-0	
Fluorene	86-73-7	
Indeno(1,2,3,c,d)pyrene	193-39-5	
Naphthalene	91-20-3	
Phenanthrene	85-01-8	
Pyrene	129-00-0	

Note these chemicals are on the Banned List for Biological Nutrients only

8 QSAR MODELING

In the absence of available toxicological information for product inputs, decision-making for Cradle to Cradle Certified™ Chemical Profiles must rely on structural modeling comparisons. Modeling can be effective when quality toxicological and physiochemical data are available on known substances. Assessors routinely consult the EPA's EPIWIN software system to predict chemical toxicity to aquatic organisms, as well as biodegradation and bioaccumulation rates when data are unavailable. In addition a variety of other peer-reviewed sources for research on the 24 human and environmental health endpoints such as the OECD List of High Production Volume (HPV) Chemicals are used. Occasionally, chemical structures unavailable in existing models must be manually validated against similar substances with known properties.

8.1 DEFINITIONS

Quantitative Structure-Activity Relationship analysis (QSAR) – Technique for comparing molecular structure and physicochemical properties of a chemical having unknown hazards with molecular structures and physiochemical properties of other similar chemicals having known toxic or carcinogenic effects.

Precautionary Principle – The precautionary principle states that if an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is harmful, the burden of proof that it is not harmful falls on those taking the action.

8.2 QSAR AND OECD METHODS

Comparisons are made in at least three ways:

1. Using structural elements that cause known effects. Not exhaustively:
    a. Steric hindrance of side chains.
    b. Alkylation/arylation reactivity.
    c. Uncoupler of oxidative phosphorylation.
    d. Carbonyl reactivity
2. Using whole structure similarities (i.e., read-across).
    a. When possible, the relationship between the structure features or physiochemical properties that cause the adverse effects is known.
    b. Necessary elements of read-across comparisons include each structure having the same functional groups and the structures being 90% similar by molecular weight.
3. Using hazard profiles for groups of chemicals by general categorization (i.e., homologous series.)

a. Identification of consistent patterns of effects within a category increases confidence in the reliability of the results for all the individual substances in the category, compared to evaluation of data purely on a substance-by-substance basis.

b. A chemical group may have one or more of the following features:

    i. A common functional group.

    ii. Similar breakdown or metabolic products.

    iii. Incremental change across a group, such as carbon chain length.

8.3 DECISION-MAKING IN THE ABSENCE OF MODELS

Models are limited and only provide clues on how a chemical *might* behave with respect to human and environmental health, so it is important to articulate which assumptions have been used for profile decisions. When modeling is not available for an unknown structure, the decision level of confidence for manual comparisons takes into account the following:

- Is it a chemical of regulatory concern? If the chemical in question is suspected of being a chemical of concern, the most conservative use of the Precautionary Principle is applied.

- Is the chemical structure correct? Purity/impurity profiles are obtained, when possible, as small amounts of impurities can lead to large differences in toxicology[1].

- Are you actually measuring the parent chemical or a metabolite? Analysis of metabolic pathways is considered in assessment decision-making.

- What do we understand about the kinetics of the system? Is there any loss to hydrolysis that affects concentrations?

9 SUMMARY OF THE MATERIAL HEALTH ASSESSMENT PROCESS

A summary of the material health assessment process is provided below. This information can also be found in the *Cradle to Cradle Certified™ Product Standard* document.

Material assessments combine chemical hazard ratings, potential exposure information, and material cyclability information into a single ABC-X assessment for each material in the product. Material assessments must be completed for each homogeneous material subject to review with the exception of products that are themselves homogeneous materials. In this case, each chemical ingredient in the product receives an individual assessment.

9.1 CHEMICAL HAZARD PROFILING

Hazard rating profiles must be completed for each chemical in each homogeneous material subject to review (as determined in Section 4). The Cradle to Cradle® chemical hazard profiling methodology uses 24 human health, environmental health, and chemical class endpoints for the basis of a chemical's evaluation. The rating scheme used for this methodology follows a "traffic-light" hierarchy where the chemical's hazard is communicated by a GREEN, YELLOW, RED, or GREY rating for each endpoint (Table 5 and Table 31). The "traffic-light" rating for each chemical is based on the criteria for each hazard endpoint (Section 7).

Table 31 Hazard rating system for chemicals using the Cradle to Cradle Certified™ Chemical Profiling Methodology

GREEN	No hazard identified for the given endpoint
YELLOW	Borderline hazard identified for the given endpoint
GREY	No data available to determine hazard level for this endpoint
RED	Considered hazardous for this specific endpoint

9.2 EXPOSURE ASSESSMENT

Exposure assessment includes definition of product interaction scenarios and characterization of environmental fate.

1. Define product interaction scenarios: The following questions related to different possible exposure scenarios are to be answered about the product overall. Consider all possible relevant routes of exposure including inhalation, oral, and dermal/membranes. In general, upstream exposure issues (i.e., those occurring before the final manufacturing facility) are not considered.
    a. Production scenario: How are workers exposed to production inputs?

b. Use scenario: How does the product interact with the user and what is the user exposed to?

c. "Highly likely unintended use scenarios": Are there any highly likely unintended uses of the product that would expose the user to product inputs?

d. Standard post-consumer scenario: What is the most likely end-of-use scenario(s) for the product?

e. Additional disposal scenario: Usually incineration or landfill.

Information regarding probable routes of human exposure and occupational exposure concerns may be found in several of the resources listed in Sections 11 and 12.

2. Characterize Environmental Fate: The base material matrix (i.e., base polymer, metal alloy, natural fiber, etc.) is used to judge whether chemical additives and/or components are able to freely migrate into external systems. For example, it has been shown that lead in cast aluminum is bound in the metal matrix and poses little to no risk. Also, natural materials in indoor use application often release volatiles contributing to compromised indoor air quality.

9.3 HAZARD X EXPOSURE = SINGLE RISK ASSESSMENT

Chemical hazard information is combined with exposure information for those scenarios in which exposure is determined to be of concern to complete a risk assessment rating for each homogenous material and/or first tier input (note that if the input is a homogenous material, risk assessments are conducted for each chemical ingredient in the material). For example, the following may be considered (note this is an incomplete list):

1. Acute toxicity risk during current production.
2. Acute toxicity risk during future production.
3. Acute toxicity risk during current use.
4. Sensitization risk during current use.
5. Cancer risk during production.
6. Cancer risk during use.
7. Cancer risk during incineration.
8. Aquatic risk after accidental release.

Unless there is good reason to expect that exposure will not occur during the product interaction scenarios, the single risk assessment ratings are not altered from those based only on hazard identification. If sufficient information exists to determine that exposure is highly unlikely to occur, risk assessment ratings may reflect that. Note that if a chemical is of regulatory concern, the assessment will not be altered regardless of the exposure assessment. The risk assessment rating system is shown in Table 32. Note that a designation of “a” is considered to be ideal and is highly unlikely to occur at present.

Table 32 Risk Assessment Rating System

A	This material is ideal from a human and environmental health perspective for the defined product scenarios in which it exists.
B	No moderate or significant risks identified for the given use scenarios.
C	One or more moderate risks identified for the material and/or one or more process chemicals where evaluated.
X	One or more significant risks identified for the material and/or one or more process chemicals subject to review at any level.

9.4 CYCLABILITY ASSESSMENT

The fate of each homogenous material and/or first tier input (as required) in the product use scenario context for the future standard post-consumer scenario (Cradle to Cradle® scenario) is described using the definitions below and rated as listed in Table 33.

Table 33 Cyclability Rating System

B	Biological cycle: rapidly degradable. Technical cycle: recyclable.
C	Biological cycle: slowly degradable. Technical cycle: partially recyclable.
X	Biological cycle: not degradable. Technical cycle: not recyclable.

Recyclable: A material that may be recycled into a material of similar quality and/or value. In the case of coatings, their effect on the recyclability of the substrate material is of primary concern as these generally would not be recyclable themselves.

Partially Recyclable: A material that is only downcyclable. Resulting material is of lower quality and/or value; resulting material will most likely be landfilled at the end of use. For example, the options for recycling of thermosets are very limited.

Not Recyclable: Material is not downcyclable. Materials that cannot be separated may not be recyclable. For example, in the case of foam glued to a fabric, each may be recyclable on their own, but because they cannot be separated, neither is recyclable.

Rapidly degradable: Readily biodegradable based on OECD guidelines (301). In cases where materials are not generally known to be inherently biodegradable, testing may be required to receive this designation.

Slowly degradable: Inherently biodegradable based on OECD guidelines (302, 304A). In cases where materials are not generally known to be inherently biodegradable, testing may be required to receive this designation. Materials that come from the earth and may be returned to the earth but are not biodegradable may receive this designation (e.g., clay, natural stone, etc.).

Not degradable: Material is not rapidly or inherently biodegradable and cannot be returned safely to the biosphere.

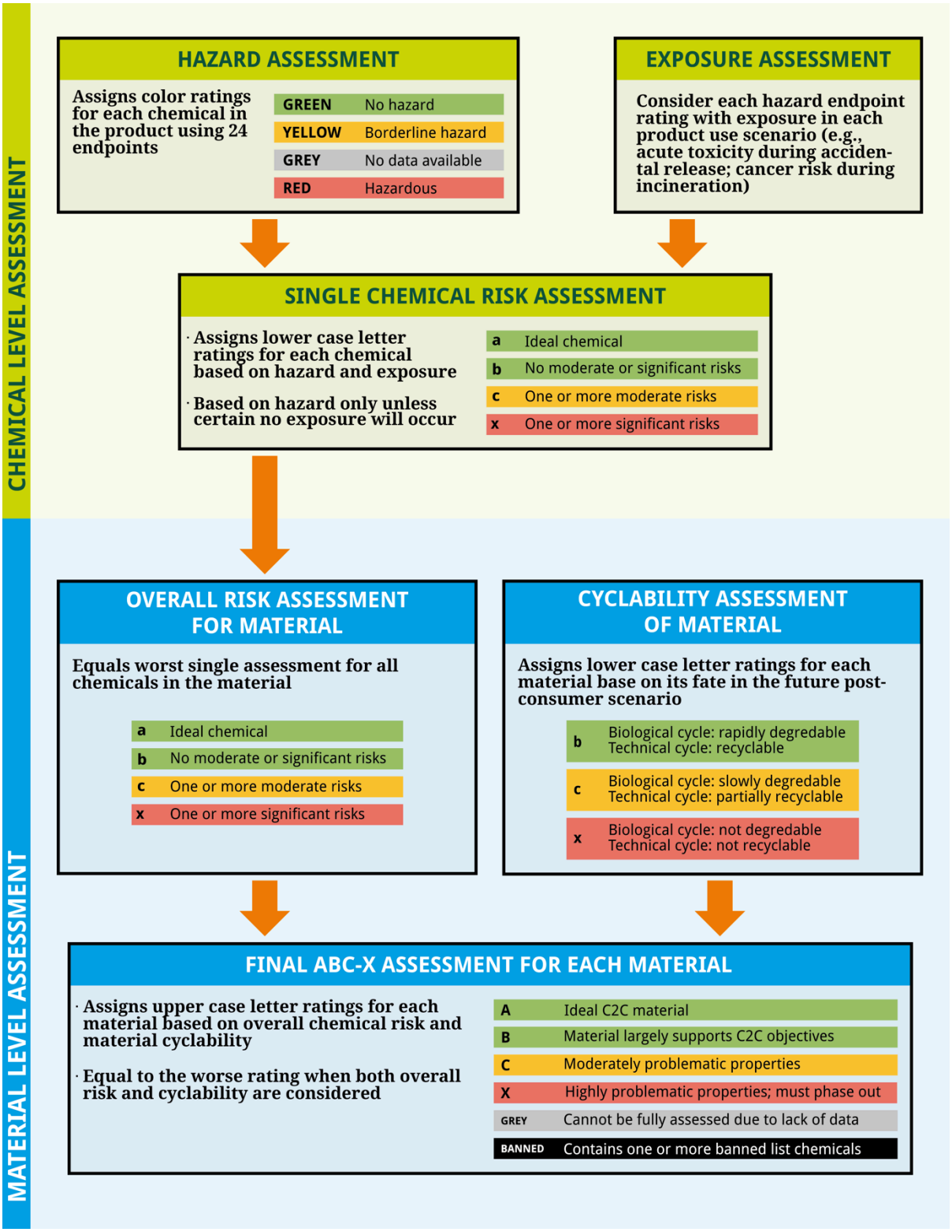
9.5 THE FINAL ABC-X MATERIAL ASSESSMENT

The final ABC-X Assessment for each material is a combination of the Single Risk Assessments and Cyclability Assessments, equaling the worse category of both. In other words, if the worst case Single Risk Assessment is x, and the cyclability assessment is b, then the final ABC-X assessment = X (note use of capital letters here and lower case letters above) (Table 3 and Table 34). Note that the A designation is unlikely to occur at present. A summary of the material assessment process is shown in Figure 1.

Table 34 Final ABC-X Material Assessment Rating System

A	The material is ideal from a Cradle to Cradle perspective for the product in question.
B	The material supports largely Cradle to Cradle objectives for the product.
C	Moderately problematic properties of the material in terms of quality from a Cradle to Cradle perspective are traced back to the ingredient. The material is still acceptable for use.
X	Highly problematic properties of the material in terms of quality from a Cradle to Cradle perspective are traced back to the ingredient. The optimization of the product requires phasing out this ingredient or material.
GREY	This material cannot be fully assessed due to either lack of complete ingredient formulation, or lack of toxicological information for one or more ingredients.
BANNED	BANNED FOR USE IN CERTIFIED PRODUCTS This material contains one or more substances from the Banned list and cannot be used in a certified product.

Figure 1 **Summary of the Material Health Assessment Process**



10 MATERIAL HEALTH CERTIFICATION LEVELS

The list of material assessments generated for a product is used to determine which certification level is obtained for the product. To achieve a given level, the requirements at all lower levels are to be met as well.

Externally Managed Components (EMCs) are considered to be optimized materials for the purposes of determining the overall level of achievement in the Material Health Category.

Table 35 Material Health Certification Levels

LEVEL	ACHIEVEMENT
BASIC	The product is 100% characterized by its generic materials (e.g., aluminum, polyethylene, steel, etc.) and/or product categories and names (e.g., coatings). The appropriate metabolism (i.e., technical nutrient (TN) or biological nutrient (BN)) is identified for the product and its materials and/or chemicals. The product does not contain any Banned List chemicals based on supplier declarations.
BRONZE	The product is at least 75% assessed (by weight) using ABC-X ratings. Externally Managed Components (EMCs) are considered assessed and contribute to the overall percentage of the product that has been assessed. Products that are entirely BN in nature (e.g., cosmetics, personal care, soaps, detergents, etc.) are 100% assessed. A phase out or optimization strategy has been developed for those materials with an X rating.
SILVER	The product has been at least 95% assessed (by weight) using ABC-X ratings. Externally Managed Components (EMCs) are considered assessed and contribute to the overall percentage of the product that has been assessed. Products that are entirely BN in nature (e.g., cosmetics, personal care, soaps, detergents, etc.) are 100% assessed. The product contains no substances known or suspected to cause cancer, birth defects, genetic damage, or reproductive harm (CMRs) after the A, B, C, X assessment has been carried out.
GOLD	The product has been 100% assessed (by weight) using ABC ratings. All EMCs are considered assessed as non-X. The product contains no X assessed materials (optimization strategy is not required). Product meets C2C emissions standards.
PLATINUM	All process chemicals have been assessed and none have been assessed as X.

11 ACRONYMS

ACGIH	American Conference of Governmental Industrial Hygienists
BAF	bioaccumulation factor
BCF	bioconcentration factors
BIFMA	Business and Institutional Furniture Manufacturer's Association
BN	biological nutrients
CASRN	Chemical Abstracts Service registry number
Cr(6+)	hexavalent chromium
DOC	dissolved organic carbon
EMC	externally managed component
GHS	Globally Harmonized System
HDPE	high density polyethylene
IARC	International Agency for Research on Cancer
K_{ow}	n-octanol-water partition coefficient
LOAEL	lowest observable adverse effect level
MAK	"maximale Arbeitsplatz-Konzentration" or maximum workplace concentration
MEST	mouse ear swelling test
NOEC	no observable effect concentration
ODP	ozone depleting potential
OECD	Organisation for Economic Co-operation and Development
PAHs	polycyclic aromatic hydrocarbons
PC	post-consumer
PET	polyethylene terephthalate
PFOA	perfluorooctanoic acid
PI	post-industrial
PTFE	polytetrafluoroethylene
PVC	polyvinyl chloride
QSAR	quantitative structure-activity relationship
TCDD	2,3,7,8-tetrachlorodibenzo-p-dioxin
ThOD	theoretical oxygen demand
TLV	threshold limit value
TN	technical nutrients
US EPA	U.S. Environmental Protection Agency
VOC	volatile organic compounds

12 TERMS AND DEFINITIONS

TERM	DEFINITION
ALGAE TOXICITY	Several Genera and Species of Green Algae found in lakes, ponds, and streams that are responsible for aquatic oxygen balance and food sources for fish are tested for their reaction to chemical exposure. Chemicals that kill algae are considered dangerous to aquatic eco-systems due to the possible food chain effects and food source depletion. Algae Toxicity is a measure of a substance's toxicity when consumed by these various types of Algae. A common measuring tool is LC50 ("lethal concentration"), which is the concentration of a substance in the water required to kill fifty (50) percent of the algae test population. If LC50 < 10 mg/L, the substance is considered algae toxic.
ANDROGEN	Any natural or synthetic compound, usually a steroid hormone that stimulates or controls the development and maintenance of male characteristics in Vertebrates by binding to androgen receptors.
BIOACCUMULATION	The process by which substances are stored and accumulated in the tissue or organs of humans or animals.
BIOCONCENTRATION FACTOR (BCF)	A measure of the tendency for a chemical to accumulate. The ratio of the concentration of a substance in a living organism (mg/kg) to the concentration of that substance in the surrounding environment (mg/l for aquatic systems).
BIODEGRADABLE	The process by which a substance or material is broken down or decomposed by microorganisms and reduced to organic or inorganic molecules which can be further utilized by living systems. Biodegradation can be aerobic, if oxygen is present, or anaerobic, if not oxygen is present. The OECD defines the appropriate testing methods for ready and inherent biodegradability. If making biodegradability claims for materials that are not commonly known to be biodegradable, testing should be done according to these methods.
BIOLOGICAL METABOLISM	The cycle that biological nutrients flow in. Any material that comes into intentional or likely unintentional contact with the biological metabolism, should be designed to safely come into contact with living organisms.
BIOLOGICAL NUTRIENT	A product usable by defined living organisms to carry on life processes such as growth, cell division, synthesis of carbohydrates, energy management and other complex functions. Any material emanating from product consumption that comes into intentional or likely unintentional and uncontrolled contact with biological systems is assessed for its capacity to support their metabolism. Metabolic pathways consist of catabolism (degradation, decrease in complexity) and anabolism (construction, increase in complexity), both occurring generally in a coupled manner. The status of products as a biological nutrient (or source of nutrients) depends on the biological systems that meet them. They can be more or less complex along the following organizational hierarchy Organisms (nutrients for predators)

TERM	DEFINITION
	Organic macromolecules (and combinations thereof) (nutrients for fungi, microorganisms, vegetarian animals; oral, dermal or olfactory nutrients) Minerals (nutrients for autotrophic plants) Generally, products as biological nutrients fit in with the two last levels.
BIOMASS	Organic, non-fossil material that is available on a renewable basis. Biomass includes all biological organisms, dead or alive, and their metabolic by-products that have not been transformed by geological processes into substances such as coal or petroleum. Examples of biomass are forest and mill residues, agricultural crops and wastes, wood and wood wastes, animal wastes, livestock operation residues, aquatic plants, and some municipal and industrial wastes.
CARCINOGEN - KNOWN	A causal relationship has been established between exposure to the agent and human cancer (MAK 1 or TLV A1 or IARC Group 1).
CARCINOGEN - POSSIBLE, OR SUSPECTED	A known animal carcinogen, but evidence of carcinogenicity in humans is non-existent, or there is limited evidence of carcinogenicity in humans and insufficient evidence of carcinogenicity in animals (MAK 3 or TLV A3 or IARC Group 2B).
CARCINOGEN - PROBABLE	A known animal carcinogen, but carcinogenicity in humans has not been definitely proven (MAK 2 or TLV A2 or IARC Group 2A).
CAS NUMBER	Chemical Abstract Service number. This number uniquely identifies each pure chemical compound. This is also designated as Chemical Abstract Service Registry Number (CASRN) as well.
CHEMICAL	A substance represented by a single Chemical Abstract Service Registry Number (CAS#)
CHEMICAL CLASS	Grouping of elements or compounds according to certain chemical functional or structural properties.
CHEMICAL PROFILE	The process of using the 24 Human and Environmental Health criteria to determine inherent hazards of a single chemical.
CHEMICAL PROFILES DATABASE	A database set up to house the color-coded rating of chemicals based on their hazards to human and environmental health.
CLEARANCE TIME (CT)	The CT indicates the time needed to eliminate or biodegrade a substance to a certain percentage in an organism. For example, the CT50 indicates the time needed to eliminate 50% of a certain substance, analogous to the half-life time measure t1/2.
CLIMATIC RELEVANCE	This is a measure of the climate-influencing characteristics of the substance. All compounds that contribute to global warming are listed here. Examples include carbon dioxide, methane, CFCs, and sulfur hexafluoride.
COLORANT	Any chemical or substance used to impart color to matter, such as a

TERM	DEFINITION
	pigment or dye.
COMPOSTABLE	A material capable of undergoing biological decomposition in a compost site as part of an available program, such that the material is not visually distinguishable and breaks down into carbon dioxide, water, inorganic compounds, and biomass at a rate consistent with known compostable materials. If making claims on the compostable nature of materials that are not commonly known to be compostable, testing should be done according to the appropriate ASTM, ISO, CEN, or DIN standard. For example, ASTM D6400-04 for plastics.
DAPHNIA TOXICITY	Water fleas of the genus Daphnia can be found in most ponds and streams. They feed upon microscopic particles of organic matter and are in turn food for fish and other aquatic organisms. Daphnia Toxicity is a measure of a substance's toxicity when consumed by these water fleas. A common measuring tool for daphnia toxicity is EC50 ("effective concentration"), which is the concentration of a substance in the water required to immobilize 50 percent of the test animals. If EC50<10 mg/liter, the substance is named daphnia toxic.
DEGRADATION	Decomposition of a compound by stages, exhibiting well-defined intermediate products.
EFFECT CONCENTRATION 50 (EC50)	The median exposure concentration (EC50) is the median concentration of a substance that causes some effect in 50 percent of the test animals.
ENDOCRINE DISRUPTOR	A substance that mimics, blocks, or interferes with hormones and their production, metabolism, and excretion causing malfunction of the endocrine system which can lead to malfunction of the reproductive, nervous, and immune systems.
FINISH (noun)	A surface pretreatment or coating for a variety of materials.
FISH TOXICITY	Several Genera and Species of fish found in lakes, ponds, and streams that are part of the food chain are tested for their reaction to chemical exposure. Chemicals that kill fish are considered dangerous to aquatic eco-systems due to the possible food chain effects and food source depletion. Fish Toxicity is a measure of a substance's toxicity when consumed by these various types of fish. A common measuring tool is LC50 ("lethal concentration"), which is the concentration of a substance in the water required to kill fifty (50) percent of the fish test population. If LC50 < 10 mg/L, the substance is considered fish toxic.
FULLY DEFINED	A product is considered “fully defined” when all homogeneous materials have been identified by generic material type, and specific grade/trade name.
GLOBAL WARMING POTENTIAL (GWP)	A scale used to relate a compound to the CO2 equivalents to measure the potential heating effects on the atmosphere. The GWP of a gas is the warming potential caused by the emission of one ton of the gas relative to the warming caused by the emission of one ton of CO2, for the same time period.

TERM	DEFINITION
HALF-LIFE (T1/2)	The amount of time it takes half of an initial concentration of substance to degrade in the environment.
HALOGENATED ORGANIC COMPOUNDS	The column in the periodic chart of the elements that begins with Fluorine contains the halogens. These elements, when combined with organic compounds, form halogenated organic compounds. Most of these compounds are toxic, carcinogenic, persistent, ozone depleting or bioaccumulative, or form hazardous substances during production and disposal (e.g., PVC).
HAZARD ENDPOINT	For the purposes of the Cradle to Cradle Chemical Profiling Methodology, this term refers to the list of 24 human and environmental health endpoints that are reviewed for each chemical in the chemical hazard assessment process.
HAZARD RATING	The traffic light system that assigns a GREEN, YELLOW, RED, or GREY rating to each hazard endpoint based on the hazard criteria. The hazard criteria are based on available toxicity and fate information for each chemical.
HEAVY METAL	The term "Heavy Metals" is generally interpreted to include those metals from periodic table groups IIA through VIA. The semi-metallic elements: boron, arsenic, selenium, and tellurium are often included in this classification.
HETEROGENOUS MATERIAL	Any material that does not fit within the definition of a homogeneous material.
HOMOGENEOUS MATERIAL	A material of uniform composition throughout.
HYBRID PRODUCTS	Goods that are composed of both biological nutrients and technical nutrients. Certain components are designed to biodegrade, and therefore return to natural systems, while others can remain in a closed loop system of manufacture, use and recovery.
INPUT	Inputs refer to the chemicals, mixtures, simple and complex materials, assemblies or sub-assemblies that make up a product.
INSEPARABLE COMPONENT	Smallest unit of an object that is either not designed to or cannot be readily disassembled by the end user into individual materials.
IRRITATION OF SKIN/MUCOUS MEMBRANES	For the testing of skin irritation with the standard Draize test, rabbits are used. The chemical is applied to the rabbit skin and usually kept in contact for 4 h. The degree of skin irritation is scored for erythema, eschar and edema formation and corrosive action. These dermal irritation observations are repeated at various intervals after the chemical has been removed. Mucous membrane irritation is measured in a similar manner. Site-specific mechanical responses within the respiratory tract and eyes are measured, and a chemical is classified as an irritant based on the conclusions of these tests.
LETHAL CONCENTRATION 50 (LC50)	The inhalative median lethal concentration (LC50) is the median concentration of a substance that causes death in 50 percent of the test

TERM	DEFINITION
	animals.
LETHAL DOSE 50 (LD50)	The median lethal dose (LD50) is the statistically derived median dose of a substance that can be expected to cause death in 50 percent of the test animals.
LOAEL	The lowest-observed-adverse-effect level is the lowest concentration or amount of a substance found by experiment or observation which causes an adverse alteration of morphology, function, capacity, growth, development or life span of a target organism distinguished from normal organisms of the same species under defined conditions of exposure.
MATERIAL	A group of one or more chemicals that together comprise a component or input to a finished product.
MATERIAL ASSESSMENT	The process of using combinations of chemical profiles to determine inherent risks of complex materials.
MATERIAL ASSESSMENT METHODOLOGY	A modified risk assessment process for rating materials based on the intrinsic human and environmental health hazards posed by their ingredients as well as the relevant routes of exposure for those ingredients in the material and in the finished product. The nutrient potential of the material is included here as well.
MIXTURE	Two or more substances, which have been combined such that each substance retains its own chemical identity.
MODE OF ACTION	Mode of action refers to the specific biochemical interaction of a drug or chemical through which an adverse health effect is produced. A mode of action includes specific molecular targets to which a chemical will bind.
MUTAGEN	This is a substance that may cause hereditary disorders in the offspring due to mutations in the chromosomes of the male or female reproductive cells. These mutations can be alterations in the structure or number of chromosomes, or nucleotide substitutions known as point mutations.
NOAEL	(No observed adverse effect level) denotes the level of exposure of an organism, found by experiment or observation, at which there is no biologically or statistically significant (e.g. alteration of morphology, functional capacity, growth, development or life span) increase in the frequency or severity of any adverse effects in the exposed population when compared to its appropriate control.
OCTANOL-WATER PARTITIONING COEFFICIENT (Pow)	A measure of the tendency of a chemical to partition between an aliphatic hydrocarbon system and an aqueous system. Often used as a predictor for bioaccumulation potential.
OZONE DEPLETION POTENTIAL	This is the measure of the ozone depleting characteristics of the substance. Ozone depletion in the upper atmosphere leads to an increase of UV-radiation on the earth and as a result, an increase in skin cancer. CFCs are included here.

TERM	DEFINITION
PART	A vended component or input to a product that is made of only one specific type of material.
PARTIALLY RECYCLABLE	A material that is only downcyclable. Resulting material is of lower quality and/or value; resulting material will most likely be landfilled at the end-of-use. For example, the options for recycling of thermosets are very limited.
PERSISTENCE	This is a measure of a substance's ability to remain as a discrete chemical entity in the environment for a prolonged period of time. A common measuring tool for persistence is "half-life" (t1/2), which is the amount of time required for half of the substance to breakdown. If half-life is greater than 30 days in the air, or if half-life is greater than 50 days in soil, water, or any other media the substance is considered to be persistent.
PHYSICO-CHEMICAL CLASSIFICATION	Chemical classification by properties such as molecular weight, electrical charge: uncharged, positively, negatively, partially charged, formal charge, oxidation state, solubility, and pH value
POST-CONSUMER RECYCLED CONTENT	Materials that have been collected for recycling after consumer use.
PRECAUTIONARY PRINCIPLE	The precautionary principle states that if an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is harmful, the burden of proof that it is not harmful falls on those taking the action.
PRE-CONSUMER RECYCLED CONTENT	Materials collected for recycling prior to consumer use; comes from sources outside of the applicant manufacturer's facility, and has been modified before being suitable for recycling back into a manufacturing process. Waste materials directly incorporated back into the manufacturing process within the applicant facility do not apply.
PROCESS CHEMICAL	Chemicals used during the manufacturing stages of product development
PRODUCT	A product is a finished good, under review for Cradle to Cradle certification, composed of parts, assemblies, sub-assemblies, materials, or chemicals. In addition, a product is the result of design decisions of its producer. The design encompasses the functional use of the product, the post-use handling, the fate of supplied ingredients used to produce it and decisions made (or not made) for a contribution to success (or failure) of the product to be beneficial under all these circumstances.
PROGRAM CATEGORY	The term "CATEGORIES" in this context will refer to the 5 program attributes which products are reviewed against. These include material health, material reutilization, renewable energy and carbon management, water stewardship, and social responsibility.
QUANTITATIVE STRUCTURE-ACTIVITY RELATIONSHIP ANALYSIS (QSAR)	Technique for comparing molecular structure and physicochemical properties of a chemical having unknown hazards with molecular structures and physiochemical properties of other similar chemicals having known toxic or carcinogenic effects.

TERM	DEFINITION
RATING	Chemical Profiles and Material Assessments are given a GREEN, YELLOW, RED, or GREY rating based on inherent hazards.
READILY DISASSEMBLED	Capable of being deconstructed with the use of common hand tools (i.e. wrench, screw driver, pliers, scissors, etc.).
RECYCLABLE	Material can technically be recycled at least once after its initial use phase. At a minimum, the material's physical and mechanical properties allow it to be re-melted or size reduced and used as filler with similar or dissimilar materials (downcycled). It is preferable to select materials that may be recycled into like or higher value products when possible. However it is understood that this is difficult to define as the collection infrastructure and recycling technologies are still in the early stages of development and the economic value of materials will change in the future. Unless there is an automated process for disassembling and reducing size of materials with adequate identification and sorting technologies to produce the highest quality recyclate possible, then attention must be paid to the design and construction of products so that dissimilar materials can be economically separated for recycling. Ideally, disassembly instructions are provided to the end user and/or recycling facilities, recyclable parts are marked, and disassembly is possible using commonly available tools. If the product is too complex for the consumer or third parties to disassemble and/or is designed as a Managed Nutrient, the consumer should be provided with instructions on where to send the product after use. The Cradle to Cradle® definition of "recyclable" is different from the U.S. Federal Trade Commission (FTC) definition. While the intentions of the FTC to protect consumers from deceptive marketing claims is logical and laudable, it may also be unintentionally creating disincentives for manufacturers because it limits their ability to use the diversity of materials whose physical properties are very recyclable, but that are not actually recycled, due to the lack of economically profitable collection and recycling systems.
RECYCLED CONTENT	Proportion, by mass, of recycled material within a product that has been recovered or diverted from the solid waste stream, either during the manufacturing process (pre-consumer/post-industrial) or after consumer use (post-consumer).
SENSITIZATION	The ability of a substance to induce an immunologically-mediated (allergic) response. An eczematous skin reaction that resulting from hypersensitivity upon secondary skin or inhalation contact by an allergen. A skin sensitizer is a substance that will lead to an allergic response following skin contact, and a respiratory sensitizer is a substance that will lead to hypersensitivity of the airways following inhalation
SKIN PENETRATION POTENTIAL	A measure of the ability of a compound to assist in the absorption of chemicals into the skin.
SUB-ASSEMBLY	A unit assembled separately but designed to fit with other units in a manufactured product. It is composed of different materials and makes

TERM	DEFINITION
	up an inseparable component of the product.
TECHNICAL METABOLISM	The cycle that technical nutrients flow in. Materials potentially hazardous to life and health may be used in a technical metabolism, if they are sequestered from uncontrolled contact with life. Note that biological nutrients may flow in technical cycles (for example, paper and bio-based polymers).
TECHNICAL NUTRIENT	A product capable to "feed" technical systems. Any material that cannot be processed by biological systems is assessed for its capacity to be processed as a resource in systems of human artifice ("Technical Organisms"). In homology to biological nutrients, technical nutrients are catabolized (deconstruction) and anabolized (construction) according to the following hierarchy: (Dismantle and) Reuse. (Dismantle and) Physical transformation (e.g. plastic remolding). (Dismantle and) Chemical transformation (e.g. plastic depolymerization, pyrolysis, gasification). The management of technical nutrients occurs by transferring ownership to the users of only the service, not of materials. It is the service offering side that manages materials as technical nutrients, once the phase of functional use is over.
TERATOGEN	A substance shown to cause damage to the embryo or fetus through exposure by the mother (MAK-list: Pregnancy risk group, vertebra A).
TERATOGEN - SUSPECTED	Currently available information indicates that a risk of damage to the embryo or fetus can be considered probable when the mother is exposed to this substance (MAK-list: Pregnancy risk group, vertebra B).
TOXICITY - ACUTE	A measure of how poisonous or "deadly" a substance is during initial exposure. A common measuring tool for acute toxicity is LD50 ("lethal dose"), which is the dose required to kill 50 percent of the test animals. If LD50<200 mg/kg, the substance is named acutely toxic.
TOXICITY - CHRONIC	This is a measure of how poisonous a substance can become over time with repeated exposure. A substance may have low acute toxicity (i.e., little harmful effects from the initial exposure) but may become poisonous over time with repeated exposure. This may be due to accumulation of the substance or due to repeated minor damaging of target organs.
TOXICOLOGICAL ENDPOINT	Also referred to as "endpoint"

13 GENERAL DATA AND INFORMATION SOURCES

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14 HAZARD DATA RESOURCES

Resources Referenced in Chemical Hazard Criteria Tables

The following resources are specifically referenced within the chemical hazard criteria tables:

1. International Agency for the Research on Cancer (IARC) – provides a list of classifications by CAS Registry Number order http://monographs.iarc.fr/ENG/Classification/index.php.
2. United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) Revision 4, 2011 http://www.unece.org/trans/danger/publi/ghs/ghs_rev04/04files_e.html. Hazard categories and statements that have been developed based on the GHS are available on some MSDS and through other sources listed below.
3. Maximum Workplace Concentrations (MAK) -- available for purchase from Wiley-VCH.
4. American Conference of Governmental & Industrial Hygienists (ACGIH) -- Total Limit Values (TLVs) for carcinogenicity may be available though the Hazardous Substances Databank http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB or for purchase from ACGIH.
5. Colborn List (of endocrine disruptors): http://www.ourstolenfuture.com/Basics/chemlist.htm.
6. EU Priority list of endocrine disruptors (download available here): http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#priority_list
7. California Proposition 65 List, Chemicals Known to the State to Cause Cancer or Reproductive Toxicity: http://oehha.ca.gov/prop65/prop65_list/newlist.html.
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10. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), Safety Guidelines http://www.ich.org/products/guidelines/safety/article/safety-guidelines.html.
11. Organisation for Economic Co-operation and Development (OECD), Guidelines for the Testing of Chemicals, http://www.oecd-ilibrary.org/content/package/chem_guide_pkg-en.
12. BIOWIN™ (and other QSAR models): available through the U.S. Environmental Protection Agency, Estimation Program Interface (EPI) Suite, http://www.epa.gov/oppt/exposure/pubs/episuite.htm.
13. Montreal Protocol, Ozone Depleting Substances; available through U.S. EPA http://www.epa.gov/ozone/science/ods/index.html.

Additional Chemical Hazard Profiling Resources

Additional useful chemical hazard profiling references for finding TLVs, LD50s, LC50s, LOAELs, NOAELs, half-lives, ready and inherent biodegradability test results, BCF and K_{ow} values, and other relevant data and information include:

1. European Chemical Substances Information System (ESIS) http://ecb.jrc.ec.europa.eu/esis/.

2. Australian Inventory of Chemical Substances (AICS): http://www.nicnas.gov.au/Industry/AICS/Search.asp.
3. National Toxicology Program (NTP) http://ntp-apps.niehs.nih.gov/ntp_tox/index.cfm.
4. U.S. Environmental Protection Agency (EPA), Ecotox (aquatic and terrestrial toxicity) http://cfpub.epa.gov/ecotox/.
5. U.S. Environmental Protection Agency, High Production Volume Information System (HPVIS) http://www.epa.gov/hpvis/.
6. U.S. Environmental Protection Agency, ACToR: http://actor.epa.gov/actor/faces/ACToRHome.jsp
7. Safe Work Australia, Hazardous Substance Information System http://hsis.ascc.gov.au/SearchHS.aspx.
8. Human and Environmental Risk Assessment on ingredients of household cleaning products (HERA project) http://www.heraproject.com/RiskAssessment.cfm.
9. International Programme on Chemical Safety (INCHEM) http://www.inchem.org/
10. MSDS online: http://www.msdsonline.com/ (available through purchase)
11. United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) Revision 3, 2009 http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html.

Resources for Probable Routes of Human and Occupational Exposure

Information regarding probable routes of human exposure and occupational exposure concerns may be found in several of the resources listed above in the chemical hazard profiling section. The following will also be useful:

1. Hazardous Substances Data Bank: http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB.
2. NIOSH Pocket Guide to Occupational Hazards: http://www.cdc.gov/niosh/npg/.

Supplemental Guidance for the Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.0

March 2015

Written in collaboration with MBDC, LLC.

TABLE OF CONTENTS

REVISION LOG

Section	Changes with respect to 2013 Guidance
2.1 Information Sources	• Clarified that certified GreenScreen profiles may serve as data sources • Clarified that weight of evidence approach can be used to reconcile conflicting list results • Clarified in which situations QSAR modeling is to be used
2.3 Additional Guidance on Specific Hazard Endpoints	• Added clarification regarding the criteria for the *Sensitization of Skin and Airways* hazard endpoint in the absence of toxicity studies
3 Exposure Assessment	• Clarified how exposure during manufacture is considered • Updated lists of chemicals of regulatory concern for which exposure is to be assumed when present in a product
3.1 Use and End-Of-Use Scenarios	• Added definition of intended and likely unintended use and end-of-use scenario
3.4 Combined Aquatic Risk Flag	• Clarified meaning of "worst" aquatic risk flag for purpose of deriving the Combined Aquatic Risk Flag • Rearranged rows in Table 4
6.0 Guidance for Assessing Polymers	• Added a new section outlining how polymers are to be assessed

1 INTRODUCTION

1.1 PURPOSE AND CONTENT

The purpose of this document is to provide guidance and clarifications regarding the application of the Material Health Assessment Methodology ('the Methodology') in the Cradle to Cradle Certified Product Standard, Version 3.0 ('the Standard') released in November 2012. This supplemental guidance provides clarification, additional guidance, and further interpretation on a number of criteria and process steps in the Methodology. It also includes general rules for assigning single chemical risk ratings, overall risk assessment ratings, and final material assessment ratings that are currently used in materials assessments but were inadvertently omitted from the original Methodology. Information in this document supersedes any conflicting information that may be present in the original Standard document and the Methodology.

1.2 SUPPORTING DOCUMENTS

The following documents are to be used in conjunction with this supplemental guidance document:

- *Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.0.*
- *Cradle to Cradle Certified™ Product Standard, Version 3.0*
- *Supplemental Guidance for the Cradle to Cradle Certified™ Product Standard, Version 3.0*
- *Any additional supporting documents and guidance posted on the C2CPII website*

Visit the Cradle to Cradle Products Innovation Institute website to download the standard documents and obtain the most current information regarding the product standard (http://www.c2ccertified.org/product_certification/c2ccertified_product_standard).

1.3 OVERVIEW

In accordance with the Methodology, materials and their chemical ingredients are assessed and rated on four levels:

1. A 'hazard rating' of either 'RED', 'YELLOW', 'GREEN', or 'GREY' is assigned to each hazard endpoint for each chemical ingredient assessed in a material. The rules for assigning hazard ratings are described in the Methodology and some clarifying points are provided in **Section 2** of this document.

2. Following the exposure assessment described in greater detail in **Section 3** of this document, these hazard ratings are used to derive 'risk flags' of either 'RED', 'YELLOW', 'GREEN', or 'GREY'.

3. Using the rules defined in **Section 4** of this document, for each individual chemical ingredient, a 'single chemical risk rating' of either 'a', 'b', 'c', 'x', or 'GREY' is derived based on the chemical's risk flags. This rating is referred to as 'single risk rating' in parts of the Methodology. To clarify that it

applies only to the level of individual chemicals and not the full material level, it is referred to as 'single chemical risk rating' in this document.

4. Every material obtains an 'overall risk assessment rating' of 'a', 'b', 'c', 'x', or 'GREY' based on its individual single chemical risk ratings, as well as a 'final material assessment rating' of either 'A', 'B', 'C', 'X', or 'GREY' based on its overall risk assessment rating and its 'cyclability rating'. A summary of this process, as well as clarification supplementing the Methodology, are included in **Section 5** of this document.

1.4 SCOPE OF MATERIAL HEALTH ASSESSMENTS

The Material Health evaluation generally applies to the chemicals in the finished product as it leaves the final manufacturing facility. Other product inputs that do not appear in the finished product are assessed to provide additional information for the manufacturer and these assessments may be factored into the Water Stewardship and/or Social Fairness categories, but do not impact a product's material health rating. The Material Health rating is based on the chemical species as present in the finished product and their reaction products during intended and likely unintended uses. The only process chemicals that must also be considered as part of the Material Health assessment (regardless of their concentrations in the finished product and even if they are not expected to be present) are the exceptions as stated in the Standard (finishes (coatings, plating, paints), blowing agents, textile auxiliaries, paper bleaching agents, and plating chemistry).

2 HAZARD RATING GUIDANCE

2.1 INFORMATION SOURCES FOR MATERIAL HEALTH ASSESSMENT

In deriving hazard ratings, Assessors are to rely on the best available, most recent, and most conservative information from sources including public and private databases, in-house modeling, government/agency reports, and the scientific literature. GreenScreen® assessments conducted by a licensed GreenScreen® Profiler (i.e., Certified GreenScreen assessments) may serve as a data source for completing the hazard assessment. In cases where a wide variety of study results are available, the most conservative value should be used, unless there is a compelling weight of evidence to do otherwise.

As a first pass to screen for widely recognized and well established hazards, the use of authoritative hazard lists such as those issued by the International Agency for Research on Cancer (IARC), California's Proposition 65 List, and lists maintained by various countries based on category criteria of the Globally Harmonized System for Classification and Labeling (GHS) will often be helpful. Some of these lists are explicitly cited in the Methodology and within endpoint criteria. In instances where multiple lists cited in the Methodology would lead to conflicting hazard ratings, as per the established

criteria, the result from the list yielding the most conservative Cradle to Cradle hazard rating (in the order RED, YELLOW, GREEN) is to be used. Alternatively, the assessor may look further into the data sources and criteria used by the list issuing agencies and evaluate it directly against the governing endpoint criteria using a weight of evidence approach.

QSAR modelling results are to be used for the endpoints of aquatic toxicity (chronic and acute), bioaccumulation or persistence – but only if no experimental data are available. For other endpoints, modeling results are not to be used and the endpoint rating shall remain 'GREY' in the absence of experimental data (note that not all 'GREY' endpoint ratings translate to 'GREY' single chemical risk ratings, see section 4).

2.2 CORRECTION TO ENDPOINT OVERVIEW TABLE

The Cradle to Cradle chemical hazard profiling methodology uses a total of 24 human health, environmental health, and chemical class hazard endpoints.

Single Organ Toxicity is incorrectly listed as an independent endpoint in Table 6 of the Methodology and Table 8 in the Standard. Single Organ Toxicity is not an independent endpoint and is assessed as a part of the Oral, Dermal, and Inhalative human health endpoints. Instead, 'Skin, Eye, and Respiratory Corrosion/Irritation' should have been listed as a hazard endpoint in Table 6 (Table 8 in the Standard). The remainder of the Methodology discusses endpoints (including Skin, Eye, and Respiratory Corrosion/Irritation) in individual subsections of Section 7.1. Note that in Section 7.1, Reproductive and Developmental Toxicity are discussed separately (while they are listed as a single endpoint in the tables), the six Aquatic Toxicity endpoints are combined in a single section (7.1.12), and the two 'Other' endpoints are not discussed. It is for this reason that the Methodology has 18 subsections devoted to the discussion of individual endpoints, rather than the 24, which is the overall number of hazard endpoints following the subdivision of the tables. A corrected overview of human health endpoints is shown in Table 1 below. Tables 2 and 3 show the original environmental health and chemical class endpoints to complete the overview.

Table 1 - Human health hazard endpoints used for the evaluation of chemicals.

HUMAN HEALTH ENDPOINTS	DESCRIPTION
Carcinogenicity	Potential to cause cancer.
Endocrine Disruption	Potential to negatively affect hormone function and impact organism development.
Mutagenicity	Potential to alter DNA.
Reproductive & Developmental Toxicity	Potential to negatively impact the reproductive system as well as the potential to affect pre- and post-natal

	offspring development.
Oral Toxicity	Potential to cause harm via oral exposure. Both short-term (acute) and longer-term (chronic) exposures are considered here.
Dermal Toxicity	Potential to cause harm via dermal exposure. Both short-term (acute) and longer-term (chronic) exposures are considered here.
Inhalative Toxicity	Potential to cause harm via inhalative exposure. Both short-term (acute) and longer-term (chronic) exposures are considered here.
Neurotoxicity	Potential to cause an adverse change in the structure or function of the central and/or peripheral nervous system.
Skin, Eye, and Respiratory Corrosion/Irritation	Potential to cause direct reversible or irreversible damage to the skin, eyes, or respiratory system upon short-term exposure.
Sensitization of Skin and Airways	Potential to cause an allergic reaction upon exposure to skin or via inhalation.
Other	Any additional characteristic (e.g., flammability, skin penetration potential, etc.) relevant to the overall evaluation but not included in the previous criteria.

Table 2 - Environmental health endpoints used for chemical profile evaluation.

ENVIRONMENTAL HEALTH ENDPOINTS	DESCRIPTION
Acute Fish Toxicity	Measure of toxicity to fish (both saltwater and freshwater) from single, short-term exposure.
Acute Daphnia Toxicity	Measure of toxicity to Daphnia (or other aquatic invertebrates) from single, short-term exposure.
Acute Algae Toxicity	Measure of toxicity to algae from single, short-term exposure.
Chronic Fish Toxicity	Measure of toxicity to fish (both saltwater and freshwater) from multiple, longer-term exposures.
Chronic Daphnia Toxicity	Measure of toxicity to Daphnia (or other aquatic

	invertebrates) from multiple, longer-term exposures.
Chronic Algae Toxicity	Measure of toxicity to algae from multiple, longer-term exposures.
Terrestrial Toxicity	Acute toxicity to avian species and soil organisms.
Persistence	Measure of how long a substance will exist in air, soil, or water. Can be biotic or abiotic.
Bioaccumulation	Potential for a substance to accumulate in fatty tissue.
Climatic Relevance	Measure of the impact a substance has on the climate (e.g., ozone depletion, global warming).
Other	Any additional characteristic relevant to the overall evaluation but not included in the previous criteria.

Table 3 - Chemical classes rated red if present at greater than 100 ppm within a material.

CHEMICAL CLASS ENDPOINTS	DESCRIPTION
Organohalogens	Presence of a carbon-halogen (i.e., fluorine, chlorine, bromine, or iodine) bond.
Toxic Metals	Presence of a toxic heavy metal compound (antimony, arsenic, cadmium, chromium VI, cobalt, lead, mercury, nickel, thallium, tin (organotins only), radioactive elements, and vanadium are considered toxic heavy metals).

2.3 ADDITIONAL GUIDANCE ON SPECIFIC HAZARD ENDPOINTS

The criteria for deriving hazard ratings for the 24 human health, environmental health, and chemical class endpoints are listed in Section 7.1 of the Methodology. This section provides additional guidance on specific hazard endpoints for which criteria may have been unclear or omitted.

Skin, Eye, and Respiratory Corrosion/Irritation

In the definition of this endpoint in Section 7.1.10 of the Methodology, the UN's Globally Harmonized System of Classification and Labelling of Chemicals (GHS) is cited. However, the relationship between GHS criteria/classes and the Cradle to Cradle hazard ratings for this endpoint is not explicitly established.

Chemicals falling under GHS Category 1 (including all sub-categories where they exist) for the GHS endpoints: *Skin Corrosion*, *Skin Irritation*, *Eye Effects*, and/or *Eye Irritation* would receive a RED hazard rating for the Cradle to Cradle endpoint Skin, Eye, and Respiratory Corrosion/Irritation.

Chemicals falling under GHS Category 2 or 3 (including all sub-categories where they exist) for the GHS endpoints: *Skin Corrosion*, *Skin Irritation*, *Eye Effects*, and/or *Eye Irritation* would receive a YELLOW hazard rating for the Cradle to Cradle endpoint Skin, Eye, and Respiratory Corrosion/Irritation.

Sensitization of Skin and Airways

In the definition of this endpoint in Section 7.1.11 of the Methodology, GHS is cited. However, the relationship between GHS criteria/classes and the Cradle to Cradle hazard ratings for this endpoint is not explicitly established.

Chemicals falling under GHS Category 1 (including sub-categories 1A and 1B) for the the GHS endpoint: *Sensitization* (including both respiratory and skin sensitization) would receive a RED hazard rating for the Cradle to Cradle endpoint Sensitization of Skin and Airways.

Another omission from the criteria table for this endpoint is that a substance may be assigned a GREEN hazard rating for *Sensitization of Skin and Airways* if no data from human or animal studies are available, provided the substance is not classified under GHS, H334/317, or MAK, and there is a long history of safe use (10 years or more) without reported cases of sensitization (documented via a signed statement from the substance manufacturer).

Aquatic Toxicity (Acute and Chronic)

The criteria for deriving hazard ratings for the six endpoints relating to aquatic toxicity (Acute Fish Toxicity, Acute Daphnia Toxicity, Acute Algae Toxicity; Chronic Fish Toxicity, Chronic Daphnia Toxicity, Chronic Algae Toxicity) are described in detail in Section 7.1.12 of the Methodology. As stated there, the hazard criteria differ between vertebrates (fish), invertebrates (daphnia), and aquatic plants (algae) for acute toxicity, but are identical for chronic toxicity. However, in the summary table of hazard criteria on (Table 9), criteria for both acute and chronic toxicity are listed together and provided separately for each organism (fish, daphnia, algae). In this table (Table 9), in congruence to the definition from Section 7.1.12, 'Same as above' included for the chronic daphnia and chronic algae criteria is meant to indicate that the chronic toxicity criteria for fish, daphnia, and algae are the same (Endpoint rating Green: NOEC > 10 mg/l; Yellow: NOEC = 1-10 mg/l; Red: NOEC < 1mg/l, or H410-H413).

Other (Human Health)

As stated in the hazard endpoint overview table, this endpoint is intended to cover any additional characteristic relevant to the overall evaluation of human health not covered by other endpoints. This endpoint was not described in Section 7.1 of the Methodology, which is why additional information is provided here.

Unlike for other endpoints, an assessor may assign a RED hazard rating based on any credible piece of information that suggests a human health hazard not addressed by other hazard endpoints. If additional information is deemed to be relevant by the assessor for this endpoint, this needs to be documented and only a RED hazard rating may be assigned. Information that is typically assessed within the scope of this endpoint includes a chemical's flammability, oxidation potential, reactivity, skin penetration potential, and volatility. Based on this information and the assessor's professional judgment, a hazard rating of either RED or GREEN is assigned. Note that YELLOW or GREY hazard ratings are not possible within this endpoint. As for all endpoints, if different information types considered (e.g., flammability, reactivity, etc.) would lead to the assignment of different hazard ratings, a RED rating trumps all other possible assignments. For example, chemicals that could be assigned to Category 1 or 2 based on GHS physical hazards criteria would typically receive a RED rating in this endpoint. However, other information that is too complex or too context-dependent to be amenable to the RED, YELLOW, GREEN rating scheme is also meant to be included here. For example, skin penetration potential or nanomaterial properties may or may not represent a hazard based on interactions with other hazard endpoints, material matrix composition, and the product's intended uses. In such cases, the assessor would note the relevant property and assign a RED hazard rating as a reminder to consider this additional information in the risk assessment step.

Ultimately, this endpoint also serves as a placeholder for other hazard endpoints that may be added to the standard in future revisions. As such, material assessors are expected to submit to the Institute a 'Other hazards and risks' report within two months of the Assessment Summary Report when a single chemical risk score of 'x' was assigned to a chemical based on a RED hazard flag in an 'Other' endpoint. The report has to provide sufficient context and documentation for an expert to understand the reasons that led to the specific chemical being considered hazardous in the situation. To protect confidential business information, generic terminology may be used to describe the material and the product in the context of the assessment that took place, but the evidence and reasoning that led to the decision must be clear. Such reports are then distributed in the Cradle to Cradle accredited Materials Assessment community and may be cited in future Assessment Summary Reports.

Other (Environmental Health)

Analogously to the 'Other' endpoint for Human Health hazards, this endpoint is intended to cover any additional characteristic relevant to the overall evaluation of environmental health not covered by other endpoints. This endpoint was also not described in Section 7.1 of the Methodology, which is why additional information is provided here.

Similar to the 'Other (Human Health)' endpoint, an assessor may assign a RED hazard rating based on any credible piece of information that suggests an environmental health hazard not addressed by other hazard endpoints. If additional information is deemed to be relevant by the assessor for this endpoint, this needs to be documented and only a RED hazard rating may be assigned. Information that is typically assessed within the scope of this endpoint includes a chemical's mobility in soils, ability to mobilize heavy metals from sediment (chelating agents), and its 'Wassergefährdungsklasse'

(WGK) if one has been issued by the German Federal Ministry for the Environment (Umweltbundesamt, UBA). The UBA maintains a public database of chemicals that have been assigned a WGK. The expectations regarding use and reporting of this endpoint are the same as those for the 'Other (Human Health)' endpoint.

Organohalogens

Table 8 in the Methodology defines this endpoint as applying to compounds with "…non-hydrolysable carbon-halogen […] bond[s]." However, as stated in the detailed endpoint criteria (section 7.1.16), the endpoint applies to any chemical with a carbon to halogen bond. If a chemical has a carbon-halogen bond in the finished product (i.e., not already hydrolyzed in the production process), it will obtain a RED hazard rating for this endpoint. This is consistent with the general scope of chemical species considered in deriving Material Health ratings.

Climatic Relevance

As stated in the summary table, this endpoint covers both a chemical's climate impacts (Global Warming Potential) and its impacts on the ozone layer (Ozone Depleting Potential). Section 7.1.18 in the Methodology describes the criteria for assigning hazard ratings based on a chemical's Ozone Depleting Potential; however, the criteria for Global Warming Potential are not specified.

Similar to the procedure for Ozone Depleting Potential, hazard ratings due to Global Warming Potential are also entirely list-based. A RED hazard rating in this endpoint is assigned if the chemical is included among the known greenhouse gases in the Intergovernmental Panel for Climate Change (IPCC) Third Assessment Report (Table 6.7) and/or is on the EPA's list of Ozone Depleting Substance substitutes with global warming potential. If a chemical is not on either of these lists and additionally not listed as either a Class I or II Ozone Depleting Substance by the Montreal Protocol, it receives a GREEN hazard rating for this endpoint.

3 EXPOSURE ASSESSMENT GUIDANCE AND DERIVING RISK FLAGS

Exposure assessment is restricted to those chemicals that have been assigned a RED or GREY hazard rating in any endpoint(s) other than Organohalogen, Persistence, and Bioaccumulation (see subsection entitled Combined Aquatic Risk Flag for a discussion of how the Persistence and Bioaccumulation hazard ratings are used). Note that while none of these three endpoints (Organohalogen, Persistence, and Bioaccumulation) are considered in the exposure assessment, risk

flags *are* assigned for the Organohalogen endpoint (they are equal to the hazard rating in this endpoint for the respective chemical).

For the exposure assessment, specific studies on the substance(s) in question are researched in the context of the material matrix in which the substance(s) is/are present, the function and location of these materials in the finished product, and the product's intended and likely unintended use and end-of-use scenarios. Additionally, exposure during manufacturing is considered based on the actual manufacturing conditions as observed during the site visit. Note that the exposure assessment conducted as part of Cradle to Cradle Certified Material Health Assessments is not an exposure assessment in the traditional sense, in that no attempt is made to quantify the magnitude of any potential exposure. Instead, the goal is to assess whether or not plausible avenues of exposure exist. Based on the precautionary principle, any amount of plausible exposure is deemed to be sufficient to rate a chemical as posing a risk due to identified, suspected, or unknown health hazards.

For each chemical that has been flagged with a RED or GREY hazard rating for one or more hazard endpoints, an exposure assessment is conducted as follows:

1. The product's intended and likely unintended use and end of life scenarios are defined (see section 3.1 for the definition of intended and likely unintended use and end-of-use scenarios). Furthermore, the manufacturing scenario is observed during the site visit and included in the set of scenarios to be evaluated for step 2.
2. The potential for exposure to the chemical (as present in the material) via all pathways relevant to any of the flagged hazard endpoints is assessed. If exposure is not plausible at any level, in any of the defined scenarios, via any exposure pathway relevant to a specific endpoint with a RED or GREY hazard rating, the risk flag for that endpoint will be YELLOW.
3. The environmental fate of the chemical is assessed along with its potential for migrating out of the material(s) in which it is present.
    - For this chemical within the specific material matrix, have credible studies been conducted on:
        i. leaching potential?
        ii. offgassing?
        iii. physical migration?
    - If yes, are these studies relevant to and do they cover all conditions for the scenarios identified in step 1?
    - If yes, is there a preponderance of evidence suggesting that the chemical will remain bound within its material matrix, precluding exposure via any pathway to humans or the environment for all scenarios identified in step 1?
    - If so, for any endpoints with a RED or GREY hazard rating, the risk flag for that endpoint will be YELLOW.

After the exposure assessment has been completed for each chemical that had one or more RED or GREY hazard ratings, any endpoint that has not been assigned a YELLOW risk flag based on the

exposure considerations above, is assigned a risk flag equal to it's hazard rating. This means that endpoints with a YELLOW hazard rating will generally receive a YELLOW risk flag (unless they can form hazardous reaction products, see Section 3.1, or an optional exposure assessment is conducted, see Section 3.2) and endpoints with a GREEN hazard rating will receive a GREEN risk flag (unless they can form hazardous reaction products, see Section 3.1). Endpoints with a RED hazard rating may receive a RED or YELLOW risk flag, depending on the exposure assessment (as described above). Similarly, endpoints with a GREY hazard rating may receive a GREY or YELLOW risk flag, depending on the exposure assessment.

3.1 INTENDED AND LIKELY UNINTENDED USE AND END-OF-USE SCENARIOS

The intended and likely unintended end-of-use scenarios must cover the end-of-use fate of 80% or more of the products sold by the applicant. For example, if the assessor deems that incineration is not a likely unintended use scenario because the applicant has a well developed take-back program or only sells the product in regions with the appropriate recycling infrastructure in place, then it must be demonstrated that 80% or more of the products sold during the certification period can reasonably be assumed to arrive in one of the other end-of-use scenarios that are considered likely. Alternatively, all common end-of-use scenarios: recycling, composting, landfill, incineration, and uncollected (including backyard burning) must be considered likely end-of-use scenarios for the purpose of the Material Health exposure assessment, in which case the percentage of fates covered by the assessment does not need to be quantified.

For the intended and likely unintended use scenarios, the material health assessor must consult with the applicant to understand the full extent of a product's intended and likely unintended uses. For each chemical that has been flagged with a RED or GREY hazard rating for one or more hazard endpoints, the assessor must apply their professional judgment to establish whether exposure is plausible to humans via oral, dermal, or inhalative pathways or to the environment via volatile emissions, water, or other pathways, given the product scenarios and material context. The scenarios must include all aspects of a product's reasonably foreseeable use and maintenance. The following additional guidelines apply to specific product groups and specific materials within products:

- For fabrics or parts of products composed thereof (includes upholstered furniture, rugs, apparel, etc.), washing in a machine or by hand across a range of temperatures must be considered.
- For solid, non-granular, non-powder homogenous materials which are not readily abraded during their intended use (i.e. not tires, brake-pads, etc.), inhalative exposure to substances contained in the material may be deemed as non-plausible
- For any parts that can be disassembled with common household tools, disassembly and dermal contact to any materials thus accessible must be considered.
- For any kitchen ware or containers intended for use with food or beverages, exposure and possible leaching under a variety of solvents (water, vegetable oil, alcohol, etc.) and pH ranges

(pH 3-10) must be considered, as must heating in the presence of liquids such as might occur on a stove, in an oven, dishwasher, microwave, or closed car, etc. where applicable.

- For products marketed towards infants, the possibility of oral exposure must be considered as a likely unintended use scenario in all cases.

3.2 REACTION PRODUCTS

As part of the exposure assessment, it should be noted if peer-reviewed studies exist suggesting that reaction products of concern to human or environmental health can be produced from a chemical in any assessed material during any of the scenarios defined in step 1. Noted potential reaction products are then individually assessed as if they were contained within the material being assessed. The reaction product then receives a risk flag for each hazard endpoint and these risk flags are combined with those of the parent chemical. In combining the risk flags of a parent chemical with those of its reaction product(s), the most conservative risk flag (in the order RED, GREY, YELLOW, GREEN) among them is used for each endpoint. For example, a chemical may receive a RED risk flag for carcinogenicity if it is deemed to have the potential for carcinogenic reaction products in the product scenarios considered, even if the chemical itself is not carcinogenic and received a GREEN hazard rating for the endpoint (i.e., a non-hazardous azo-dye with the potential for forming aromatic amines which are carcinogenic).

3.3 OPTIONAL EXPOSURE ASSESSMENT FOR ENDPOINTS WITH YELLOW HAZARD RATINGS

An exposure assessment as described above, may also be conducted for chemicals that do not have RED or GREY hazard ratings, but do have one or more YELLOW hazard ratings. To this end the same three steps would be followed as described above for the chemicals with RED or GREY hazard ratings; however, if no plausible routes for exposure exist, the resulting risk flag would be GREEN rather than YELLOW. As described in Section 4, such an assessment helps to differentiate between chemicals that would merit a 'b' single chemical risk rating due to lack of exposure potential, but would otherwise receive a 'c' single chemical risk rating based on their hazard.

This step is optional, since there are no criteria in the current standard that would differentiate between materials containing 'b' versus 'c' chemicals. However, certain manufacturers are striving to increase the number of 'b' chemicals in their products regardless of the requirements posed for certification. Additionally, when substituting for an 'x' chemical, a manufacturer may prefer a 'b' chemical over a 'c' chemical.

3.4 COMBINED AQUATIC RISK FLAG

A 'combined aquatic toxicity risk flag' is derived for each chemical based on the worst of its six Aquatic Toxicity risk flags (for Acute Fish Toxicity, Acute Daphnia Toxicity, Acute Algae Toxicity; Chronic Fish Toxicity, Chronic Daphnia Toxicity, Chronic Algae Toxicity), as well as its Persistence and Bioaccumulation hazard ratings. Table 4 illustrates how the worst Aquatic Toxicity risk flag (among all

six flags in the order RED, GREY, YELLOW, GREEN), the Persistence hazard rating and the Bioaccumulation hazard rating work together to generate a single combined aquatic toxicity risk flag. A chemical's combined aquatic toxicity risk flag corresponds to the bold value in the fourth column of the table within the row that contains the chemical's unique combination of hazard ratings for worst Aquatic Toxicity risk flag (column 1), Persistence hazard rating (column 2), and Bioaccumulation (column 3). Note that the six aquatic toxicity hazard ratings along with the hazard ratings for Bioaccumulation and Persistence factor into a chemical's single chemical risk rating through the combined aquatic toxicity risk flag (section 4), thus reducing the number of discrete endpoints used in deriving the single chemical risk rating from 24 to 17.

Table 4 - Matrix for the derivation of combined aquatic toxicity risk flags.

Worst Aquatic Toxicity Flag	**Persistence Hazard Rating**	**Bioaccumulation Hazard Rating**	**Combined Aquatic Toxicity Risk Flag**
RED	RED, YELLOW or GREY	RED, YELLOW or GREY	**RED**
RED	RED, YELLOW or GREY	GREEN	**RED**
RED	GREEN	RED, YELLOW or GREY	**RED**
GREY	RED	RED	**RED**
GREY	RED	YELLOW or GREY	**GREY**
GREY	YELLOW or GREY	RED	**GREY**
GREY	YELLOW or GREY	YELLOW or GREY	**GREY**
RED or GREY	GREEN	GREEN	**YELLOW**
YELLOW	RED, YELLOW or GREY	RED, YELLOW or GREY	**YELLOW**
YELLOW	RED, YELLOW or GREY	GREEN	**YELLOW**
YELLOW	GREEN	RED, YELLOW or GREY	**YELLOW**
YELLOW	GREEN	GREEN	**GREEN**
GREEN	ANY	ANY	**GREEN**

Chemicals of Regulatory Concern

In section 9.3 of the Methodology it is stated that chemicals of 'regulatory concern' always obtain risk flags equal to their hazard ratings, overriding any potential modifications of risk ratings based on the exposure assessment, as per the rules defined above. For this purpose a chemical of regulatory concern is defined as any chemical currently restricted under REACH (Annex XVII) or on the REACH candidate list for Substances of Very High Concern (SVHC), or on the POPs list of the Stockholm Convention. This set of lists is subject to change. The most current version of the lists or regulations is to be used at the time of the Material Health assessment is being conducted.

4 GUIDANCE ON DERIVING SINGLE CHEMICAL RISK RATINGS

Single chemical risk ratings are assigned using the following hierarchy of rules:

1. If the chemical has received a RED risk flag in any of the 17 endpoints resulting from the risk assessment (see Section 3 regarding the combined aquatic toxicity risk flag), the single chemical risk rating is 'x' and steps 2-5 do not apply.
2. Otherwise, if the chemical has received a GREY risk flag for any endpoint other than Carcinogenicity, Endocrine Disruption, Neurotoxicity, or Terrestrial Toxicity, the single chemical risk rating is 'GREY' and steps 3-5 do not apply.
3. Otherwise, if the chemical has received any YELLOW risk flags or any GREY risk flags for Carcinogenicity, Endocrine Disruption, Neurotoxicity, or Terrestrial Toxicity, the single chemical risk rating is 'c' and step 4 and 5 do not apply.
4. Otherwise, if the chemical has received any YELLOW hazard ratings, the single chemical risk rating is 'b' and step 5 does not apply (the chemical has received only 'GREEN' risk flags, but one or more YELLOW hazard rating).
5. Otherwise, the single chemical risk rating is 'a' (the chemical has received only 'GREEN' hazard ratings).

While single chemical risk ratings are assigned to individual chemicals, these ratings apply only in the context of the material and product for which they were assigned (see Section 3). They are not transferable to other materials or products.

5 GUIDANCE ON DERIVING FINAL MATERIAL ASSESSMENT RATINGS

As stated in the Methodology, the overall risk assessment rating of a material equals the "worst" single chemical risk rating of its ingredients. The rules are as follows:

1. If a material has received an 'x' single chemical risk rating for any of its ingredients, its overall risk assessment rating is 'x' and steps 2-4 do not apply.
2. Otherwise, if a material has received a GREY single chemical risk rating for any of its ingredients, its overall risk assessment rating is 'GREY' and steps 3 and 4 do not apply.
3. Otherwise, if a material has received a 'c' single chemical risk rating for any of its ingredients, its overall risk assessment rating is 'c' and step 4 and 5 do not apply.
4. Otherwise, if a material has received a 'b' single chemical risk rating for any of its ingredients, its overall risk assessment rating is 'b' and step 4 does not apply.
5. Otherwise, the overall risk assessment rating is 'a' (the material contains **only** ingredients without known, suspected, or undefined hazards in any of the evaluated endpoints).

The criteria for assigning a cyclability rating to a material are defined in Section 9.4 of the Methodology. The highest achievable rating during cyclability assessment should more appropriately be referred to as 'a/b', rather than 'b', as it is labeled in the standard. With this change in nomenclature, the derivation of a material's final material assessment rating from its overall risk assessment rating and cyclability rating is more easily understood. Table 5 illustrates how a material's overall risk assessment rating and cyclability rating are combined to obtain a final material assessment rating.

Table 5 - Deriving the final material assessment rating based on a material's overall risk assessment rating and cyclability rating.

Overall Risk Assessment Rating	Cyclability Rating	Final Material Assessment Rating
a	a/b	A
b	a/b	B
a/b/c	c	C
any rating	x	X
x	any rating	X
GREY	any rating other than 'x'	GREY

6 GUIDANCE FOR ASSESSING POLYMERS

Due to their large molecular weight and limited solubility, toxicity data for polymers is generally not available. Polymers are therefore assessed following the procedure described below.

Chemicals subject to review

The chemicals subject to review in a polymeric material are:

- the base polymer (e.g., PET, polyethylene, polycarbonate)
- residual monomers, when present above the relevant threshold (see below)
- all additives, residual catalyst, etc., when present at a concentration ≥ 100 ppm (the subject to review threshold for nearly all other chemicals in a homogenous material).
- intentionally added lead, mercury, hexavalent chromium, cadmium, halogenated organic compounds, phthalates, blowing agents, or colorants, when present at any concentration

All residual monomers other than formaldehyde are subject to review if present at a concentration ≥ 1000 ppm in the polymeric material. Formaldehyde monomers are subject to review if present at a concentration ≥ 100 ppm in the polymeric material.

Residual monomer concentrations in the polymeric material can be determined from supplier statements or analytical measurements.

Base polymer

Hazard ratings for the base polymer are assigned to each endpoint based on the toxicity data for the monomer(s) used in its production. For copolymers (i.e., polymers composed of more than one type of monomer), the hazard rating in each endpoint is based on the lowest hazard rating received by any of its constituent monomers for the endpoint (lowest in order of: 'red', 'grey', 'yellow', 'green').

When deriving risk flags for the base polymer, exposure is assumed to be "not plausible" and thus any red hazard ratings translate to yellow risk flags, and yellow and green hazard ratings translate to green risk flags.

Residual monomers

If present above their relevant subject to review thresholds, residual monomers are assigned separate hazard ratings, risk flags, and single chemical risk ratings. Plausible exposure is assumed for any residual monomers subject to review (i.e., the risk flags will be equal to the hazard ratings in each endpoint).

X Assessed Polymers

Bisphenol-A (BPA)-based polymers or coatings (e.g., polycarbonate, etc.) used in toys, skin contact furniture applications, food contact applications, and baby applications are always assessed as X, regardless of residual monomer content.

All halogenated polymers will be either X assessed (or banned if present on the banned list).

Guidance for Applying the Final Manufacturing Stage Requirements in the Cradle to Cradle Certified™ Product Standard, Versions 3.0 and 3.1

October 2015

TABLE OF CONTENTS

1 INTRODUCTION

1.1 PURPOSE AND CONTENT

The purpose of this document is to provide guidance regarding requirements in the Cradle to Cradle Certified Product Standard, Version 3.0 and 3.1 ('the Standard'), that refer to an applicant product's final manufacturing stage. This document defines the processes that constitute the final manufacturing stage by product type and describes how information from the facility or facilities at which these processes occur is to be used during the assessment of an applicant product.

1.2 SUPPORTING DOCUMENTS

The following documents are to be used in conjunction with this guidance document:

- *Cradle to Cradle Certified™ Product Standard, Version 3.0 or Version 3.1*
- *Supplemental Guidance for the Cradle to Cradle Certified™ Product Standard, Version 3.0*
- *Any additional supporting documents and guidance posted on the C2CPII website*

Visit the Cradle to Cradle Products Innovation Institute website to download the Standard documents and obtain the most current information regarding the product Standard (http://www.c2ccertified.org/product_certification/c2ccertified_product_standard).

1.3 OVERVIEW

A number of requirements in the Standard necessitate defining the processes that constitute the final manufacturing stage of a product in order to assess the product for certification. The sections below list the requirements for which the final manufacturing stage definitions must be applied.

1.3.1 MATERIAL HEALTH

Bronze level and above: A product's use, production, and end-of-use scenarios must be defined as part of the exposure assessment during the material health assessment process. The production scenarios must consider all relevant routes of exposure during the following processes:

(1) The processes that occur at the main final manufacturing facility. If there is more than one final manufacturing facility, the assessor determines which facility is the "main" facility based on which one performs the most significant manufacturing processes. The assessment summary submitted to C2CPII must explain how the assessor made this determination.

(2) Select additional manufacturing processes, regardless of where they occur. These select additional processes are those for which exposure concerns are considered exceptionally high. They are marked with a '*' in the final manufacturing stage definitions in Section 2.

Note that the processes that must be considered during the exposure assessment are the same as those that require a site visit. The site visit requirement is described further in Section 1.3.5.

Platinum level: The requirement states that all process chemicals are assessed and none have received a single chemical risk score of 'x.' This requirement applies to the process chemicals that are not subject to review in the materials of the final product, but come into direct contact with the product or any of its components or material inputs during any of the processes that are part of the final manufacturing stage.

1.3.2 RENEWABLE ENERGY AND CARBON MANAGEMENT

Basic level and above: When calculating the product-attributable purchased electricity and direct on-site emissions, only those processes that constitute the final manufacturing stage of the product are considered, rather than all of the product-relevant processes that may be used at a facility. If the processes that constitute the final manufacturing stage of the product occur at multiple facilities, then electricity and emissions data will need to be compiled from all of the facilities. This includes both situations in which the final manufacturing stage processes are distributed among multiple facilities, and situations in which the same processes occur in parallel at multiple facilities. The processes to include in the final manufacturing stage are those outlined in Section 2 of this document, as well as quality control, packaging and storage of final products, and on-site treatment of process wastes.

The total product-relevant renewable electricity is the sum of the product-relevant renewable electricity used at all facilities that are involved in the final manufacturing stage. The total product-relevant carbon offsets are the sum of the product-attributable carbon offsets purchased by the applicant or any contract manufacturers involved in the final manufacturing stage. The percentages of renewable electricity used and direct on-site emissions offset are based on these values and the total product-attributable purchased electricity and direct on-site emissions.

1.3.3 WATER STEWARDSHIP

Basic level: All three requirements at the Basic level necessitate addressing water stewardship at the product's manufacturing facilities. These requirements apply to each facility at which the processes that constitute the final manufacturing stage occur.

Bronze level: The requirement is for a facility-wide water audit to be completed. Audits are required for each facility at which the processes that constitute the final manufacturing stage occur.

Silver level: The requirement is that product-related process chemicals in effluent are characterized and assessed. The requirement applies to process chemicals used in the processes that constitute the final manufacturing stage.

Gold level: The requirement is that product-related process chemicals in effluent are optimized. The requirement applies to process chemicals used in the processes that constitute the final manufacturing stage.

Platinum level: The requirement is that all water leaving the manufacturing facility meets drinking water quality standards. The requirement applies to each facility at which the processes that constitute the final manufacturing stage occur.

1.3.4 SOCIAL FAIRNESS

Basic level: The requirement is for a streamlined self-audit to be conducted for each final manufacturing facility and tier one supplier facility. Tier one supplier facilities are defined as facilities that supply product-relevant materials, parts, or components to any of the final manufacturing stage facilities.

Bronze level: The requirement is for a full audit to be conducted by the applicant. If the UN Global Compact Tool is used, responses should be based on the conditions and practices at the final manufacturing stage facilities, even if the applicant does not own them. The applicant should work with any contract manufacturing facilities to collect the appropriate responses. If the B Impact Assessment is used instead, the applicant may complete the assessment based on its own operations, as the questions are more relevant to the applicant than to any contract manufacturing facilities.

Platinum level: The requirement is that a third-party audit must be completed against an internationally recognized social responsibility program. Where applicable, the audit program requirements must focus on all final manufacturing facilities.

1.3.5 SITE VISIT

Bronze requirement: A site visit is required for the main final manufacturing facility and any other facilities involved in select manufacturing processes for which exposure concerns are considered exceptionally high. These select manufacturing processes are marked with a '*' in the final manufacturing stage definitions in Section 2. If there is more than one final manufacturing facility, the assessor determines which facility is the "main" facility to be visited based on which one performs the most significant manufacturing processes. The assessment summary submitted to C2CPII must explain how the assessor made this determination.

Unless the product's final manufacture involves a process marked with a '*' in Section 2, only one site visit is required, regardless of how many individual facilities are included in the final manufacturing stage. For example, if five facilities are involved in the final manufacturing stage, and none of them performs a process marked with a '*,' only one of them needs to be visited.

1.4 SCOPE OF THE FINAL MANUFACTURING STAGE

Due to the variability of manufacturing processes, this document is not intended to be an exhaustive list of processes to include in the final manufacturing stage of each product. It serves instead as an outline of the basic processes to include (when applicable) during the assessment, to be supplemented with any other relevant production processes employed as per the assessor's professional judgment.

If a product does not appear to fit into any of the categories, the assessor must send a proposed list of final manufacturing stage processes to the Cradle to Cradle Products Innovation Institute (certification@c2ccertified.org). Where applicable, the proposed list should be based on the processes included in the "Other" field for the relevant industry. The Institute will review and approve proposed lists of processes and add the new product types to future revisions of this guidance document.

2 FINAL MANUFACTURING STAGE DEFINITIONS

The processes that constitute the final manufacturing stage are defined by industry category in Tables 1-8 below. The definitions were developed using the data sources referenced in Section 3 and the experience of the founding accredited assessment bodies in the certification program (MBDC and EPEA Internationale Umweltforschung GmbH).

Table 1: Multi-Component Products

Products that are assemblies of several components are considered "multi-component products." Examples include (but are not limited to) office chairs and other furniture. When assessing a multi-component product that does not fit into any of the categories outlined in Tables 2 – 8, please follow the general instructions in the table below.

Category	Final Manufacturing Processes	Product Examples	Reference #
Multi-Component Products	All Operations for Final Assembly (excluding operations occurring at the purchaser's site). "Final assembly" usually refers to assembly occurring at the last facility before the product is shipped to the customer. The assessor is responsible for determining the appropriate scope in cases in which the most significant assembly processes do not occur in the last facility or in which assembly processes are distributed among several facilities.	Office Systems, Tables, Bed Frames, Mattresses, Pens, Wires, Green Walls and Roofs, Dispensing Systems, Playground Systems	31, 32, 33, 34, 35

Table 2: Formulated Products

Category	Final Manufacturing Processes	Product Examples	Reference #
Soaps and Cleaners	Mixing, Pumping, Spray Drying, Extruding (for bar soaps), Filling, Heating, Grinding, Degassing, Cooling	Body Wash, Hair Care, Soaps, Detergents, Cleaning Products	1, 2, 3, 4, 5
Paints and Coatings	Formulation, Paint-Blending, Grinding, Mixing, Filling	Paints, Finishes, Fire-Proofing, Sealants	6
Other Formulated Products	Blending/Mixing, Heating/Cooling (of blending vessel), Filling	Admixtures, Tanning Agents, Coloring Agents, Latex	7

Table 3: Construction Products

Category	Final Manufacturing Processes	Product Examples	Reference #
Cement	Grinding, Mixing, Forming Clinker, Milking, Bagging	Cement	7
Concrete	Pre-Cast: Mixing Concrete, Casting, Curing Ready Mix: Mixing of Concrete, Bagging	Concrete	8
Engineered Stone	Crushing, Mixing, Molding, Leveling, Compressing, Heating in Kiln, Setting, Hardening, Grinding, Finishing	Quartz Countertops	9
Insulation	Fiberglass: Finishing, Sizing, Binding, Compression, Oven Curing, Cooling, Winding, Oven Drying, Oven Cooling, Fabrication, Packaging	Fiberglass Insulation	10
Natural Stone	Block Sawing, Polishing, Sizing, Reinforcement, Finishing	Granite, Marble	11
Tiles, Flagstones, Bricks	Blending, Forming, Finishing, Heating/Drying	Clay Products, Bricks	12
Other	Any processes involved combining/assembling inputs		13

Table 4: Forestry, Wood, and Paper

Category	Final Manufacturing Processes	Product Examples	Reference #
Absorbent Hygiene Products	Adding Polymer, Formation, Lamination, Shaping, Cutting, Pressing, Bonding, Finishing	Diaper Linings, Feminine Hygiene	14
Builder's Joinery and Carpentry of Wood	Cutting, Surfacing, Sawing, Forming, Special Cutting, Joint-Making, Finishing	Structural Wood, Shingles, Wall Guards, Hardwood Flooring	7, 15
Corrugated Paper and Paperboard	Layering, Pressing, Drying, Embossing, Impregnation, Printing and Pigment Coating, Finishing	Cartons, Boxes, Cases, Record Sleeves	16, 17
Processed Paper and Paperboard	Screening, Silting, De-Watering, Pressing, Smoothing, Drying, Cutting, Calendaring, Embossing, Impregnation, Coating, Printing, Packing, De-Inking	Toilet Paper, Copy Paper	7, 18, 19, 20, 21, 22, 23, 24, 25
Printed Materials	Printing, Binding	Journals, Books, Calendars	
Paper and Cardboard Packaging	Converting	Mailing envelopes	
Wood Particle and Fiberboard	**General:** Screening, Refining, Gluing, Layer Conformation, Boardpress, Coating, Pressing, Cutting, Sanding **Particleboard:** Raw Furnish Drying, Board Shaping by Screening, Blending, Forming, Pressing; Board Finishing by Cooling, Trimming and Sanding. **Laminate Flooring:** Bonding, Pressing, Cooling, Milling, Finishing	Fiberboard, Particleboard, Laminate Flooring	7, 25, 26, 27, 28
Other	Debarking, Cutting, Heating, Drying, Screening, Treatment, Resin Application, Pressing, Sawing, Finishing		29

Table 5: Glass and Ceramics

Category	Final Manufacturing Processes	Product Examples	Reference #
Glass and Ceramics	Batching, Melting, Coloring, Forming, Stretching, Chemical Treatments, Tempering, Annealing, Grinding, Polishing, Washing, Cutting, Finishing	Glass, Glass Products, Ceramics, Other Non-Metallic Products, Architectural Glass	7

Table 6: Metals and Metal Products

Category	Final Manufacturing Processes	Product Examples	Reference #
Metal Alloys	Processing, Melting, Mixing, Separation, Finishing	Steel Alloys	30
Finished Metal Products (products that are a single metal material type (same alloy), except for coatings, fasteners, and labels)	Fabrication (e.g. welding, cutting, bending, hammering, machining, etc.), Spinning, Blanking, Stamping, Annealing, Die-Casting, Molding, Calendaring, Coating, Blowing, Pressing, Forming, Finishing	Mechanical Systems, Structural Metals, Sheet Metals, Metal Products	7

Table 7: Plastics

Category	Final Manufacturing Processes	Product Examples	Reference #
Primary Forms	Polymer Production, Compounding	Resins, Plastic Filament	7, 36
Rubber and Plastic Products (products that are a single plastic type (e.g. PET), except for coatings, fasteners, and labels)	Molding, Mixing (e.g. mixing polymer pellets with a colorant), Extruding, Fabricating, Calendaring, Blowing, Pressing, Spinning, Blending, Thermoforming, Labeling, Foaming, Finishing	Membranes, Plastic Flooring, Wall Guards, Rubber Carpet Pads, Foam Carpet Pads, Composite Products	37

Table 8: Textiles

Category	Final Manufacturing Processes	Product Examples	Reference #
Carpet and Artificial Turf	Tufting, Carpet Dyeing* (yarn dyeing excluded), Coating*, Shearing, Weaving, Finishing, Tile or Roll Cutting	Carpet Rolls, Carpet Tiles, Artificial Turf	38
Apparel	Cutting, Sewing, Apparel Dyeing* (yarn dyeing excluded)	Garments	
Leather Footwear	Assembly of Footwear-Specific Components (Upper, Sole, Laces, etc.)	Suede Shoes	39
Nonwoven Textiles	Formation (Spun, Staple, Airlaid, Web etc.), Textile Dyeing* (fiber dyeing excluded), Lamination, Finishing	Nonwoven Upholstery, Sponges	40, 41
Plush Toys	Cutting, Sewing, Stuffing, Finishing	Stuffed Animals	42
Textiles (Woven, Knit, Crocheted)	Weaving, Knitting, Warping, Sizing, Ennoblement, Scoring, Thermofinishing, Fabric Formation, Wet Processing, Textile Dyeing* (yarn dyeing excluded), Printing*, Steaming, Chemical*/Mechanical Finishing	Shadecloths, Fiber Carpet Pads, Towels, Blankets, Polyester	7, 43, 44, 45, 46, 47, 48
Yarn	Sorting, Grading, Scouring, Spinning, Drawing, Extrusion, Texturing, Blending, Multiplying/ Folding/Cabling, Dyeing*	Natural and Synthetic Yarns	7, 49, 50

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Guidance for Determining Homogeneous Materials in the Cradle to Cradle Certified™ Product Standard

Version 1.0

March 2016

TABLE OF CONTENTS

GUIDANCE FOR DETERMINING HOMOGENEOUS MATERIALS IN THE CRADLE TO CRADLE CERTIFIED™ PRODUCT STANDARD REVISION HISTORY

REVISION	SECTION	TYPE OF CHANGE	DATE	AUTHORIZED BY
1.0	Initial Release		03/2016	S. Klosterhaus

1 OVERVIEW

1.1 PURPOSE AND CONTENT

This document explains how to determine a product's homogeneous materials for the purposes of applying the requirements in the Cradle to Cradle Certified™ Product Standard. Homogeneous materials are referenced in several requirements, summarized below:

- With some exceptions, homogeneous materials present in a product at weight fractions of 100 ppm or greater are subject to review.
- With some exceptions, chemical substances present in any of those homogeneous materials at 100 ppm or greater are subject to review.
- Banned list substances must not be present above designated thresholds in any of a product's homogeneous materials that are subject to review.
- For most products, the percentage assessed refers to the percentage of homogeneous materials that have been assessed.
- Each of a product's homogeneous materials is designated as a biological or technical nutrient.
- Recyclability is determined at the homogeneous material level.

The purpose of clarifying the homogeneous material definition is to improve consistency among assessments, as comparable products should be assessed in the same way regardless of the assessment body completing the work.

This document includes the homogeneous material definition and general guidance, as well as a set of interpretations indicating how the definition has been applied in ambiguous or borderline cases in the past. Assessors must apply these interpretations to their future work and contact the Institute (certification@c2ccertified.org) when assessing products with ambiguous homogenous material breakdown that do not yet appear in the list of interpretations. This document will be updated regularly to reflect such additions.

1.2 SUPPORTING DOCUMENTS

The following documents are to be used in conjunction with this guidance document:

- Cradle to Cradle Certified™ Product Standard
- Any additional supporting documents and guidance posted on the C2CPII website

Visit the Cradle to Cradle Products Innovation Institute website to download the Standard documents and obtain the most current information regarding the product Standard (http://www.c2ccertified.org/product_certification/c2ccertified_product_standard).

2 HOMOGENEOUS MATERIAL DEFINITION AND GENERAL GUIDANCE

2.1 DEFINITION

Homogeneous materials are defined in the Standard as follows:

Homogeneous materials are defined as materials of uniform composition throughout that cannot be mechanically disjointed, in principle, into different materials. Examples of homogeneous materials are polypropylene, steel, shampoo, glass cleaner, nylon yarn, finish, and coating. Examples of non-homogeneous materials are powder-coated steel, a printed bottle label, plywood, laminate, and chair casters.

The definition is based on the one used in the European Union's Restriction of Hazardous Substances (RoHS) legislation, which provides some additional context:

'homogeneous material' means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.[1]

Thus, a homogenous material does not necessarily possess uniform composition throughout, as long as the scale, structure, or distribution of the domains with differing composition do not allow for these domains to be separated from one another through mechanical means. Homogenous materials may be homogenous as viewed by the naked eye, but heterogeneous at a microscale.

Accordingly, assessors applying the definition to their projects must consider whether it would be possible to mechanically separate materials using one or more of these mechanical actions, regardless of whether the materials are likely to be separated in practice. For example, most layered products and coated products consist of multiple homogeneous materials because the layers/coatings could be separated, in principle, by sanding, even if this is not likely to occur.

While coated products are often more than one homogeneous material, this is not always the case because the scale of the substrate must be considered when determining whether the substrate and

[1] European Commission. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast). 2015. http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02011L0065-20150624&from=EN.

coating are separable. For example, a painted wooden table leg is considered two homogeneous materials because the paint could be sanded off, but a polyester fabric coated with liquid latex in conventional carpet construction is considered one homogeneous material because the latex will infuse the fabric surrounding individual threads in a way that makes it impossible to separate them from the latex matrix through mechanical means. Similarly, coated fiberglass is considered a homogenous material since individually coated fibers are too small to manipulate and remove the coating from through mechanical processes.

2.2 SCOPE

The Standard requirements pertain to the homogeneous materials in the finished product, rather than the homogeneous materials the applicant receives from suppliers and combines during the manufacturing process. For example, if the product under review is dyed fabric, the dyed fabric is a single homogeneous material, even though the dye and the fabric were separate homogeneous materials when purchased from suppliers.

3 INTERPRETATIONS BY PRODUCT TYPE

In some cases, the appropriate way of separating a product into homogeneous materials according to the definition and guidance in section 3 is unclear. To achieve greater clarity, the following table explains how to apply this definition to a variety of ambiguous cases.

Product Type	Homogeneous Materials Interpretation
Blended textiles (more than one thread or yarn type woven together)	Each yarn or thread type is its own homogeneous material. For example, if a fabric is composed of a polyester yarn and a cotton yarn woven together, the polyester and cotton are considered separate homogeneous materials (in principle, individual yarns could be physically separated from the fabric, e.g. by pulling them out one at a time). If fibers of different types are twisted together into yarn or different types of yarn are twisted together in a multi-ply yarn or thread, the resulting multi-ply yarn or thread is one homogeneous material, because the different fibers are not separable by any mechanical process.
Carpet backing	The primary backing fiber and precoat are considered the same

	homogeneous material because the primary backing fiber becomes permeated by the precoat during the manufacturing process and is thus embedded within a precoat matrix in the finished product. The secondary backing is considered a separate homogeneous material.
Composite wood products	Layered composite wood products (e.g. plywood) are considered more than one homogeneous material (each layer is a homogeneous material). Non-layered composite wood materials such as MDF or particle board, in which small wood particles or fibers are uniformly distributed within a binder matrix, are regarded a single homogeneous material. However, if such a material has a surface layers or coating (such as a veneer, varnish, or paint) then that surface layer or coating counts as a separate homogenous material.
Concrete, countertops made of glass and cement, and other mixtures of cement with structural or decorative rock or silica-based inclusions	Any mixture of cement, admixture, and/or rock or silica-based inclusions is regarded a homogenous material regardless of the size of the inclusions. While gravel and similar sizes inclusions could in principle be separated from the matrix through mechanical means, analogous geological materials (i.e. conglomerates) are treated as homogenous materials for the purpose of assessment. Additionally, assessing types of concrete differently based on aggregate size would greatly increase the challenge of ensuring consistent application of the homogenous material definition.
Dyed textiles	Dyes and their substrates usually form a single homogeneous material, though if the dyes are surface treatments only, they can be counted as separate homogeneous materials from their substrates. For example, if a pattern is printed onto a fabric, the print is considered a separate homogeneous material from the fabric because it is resting on top of the fabric as a distinct layer that could be separated through abrasion. If the dyes instead form a single homogeneous material with their substrate (this is the more common situation), then each colored fabric option (e.g. blue fabric, purple fabric, green fabric) is its own homogeneous material.
Fiberglass	Fiberglass is considered a single homogeneous material. While the glass fibers may be coated, and therefore the composition may not be uniform throughout at the scale of an individual fiber, the glass and coating are not separable by any mechanical process.

Supplemental Guidance for the Assessment of Colorants (Textile Dyestuffs and Pigments)

February 2016

Written in collaboration with EPEA Internationale Umweltforschung GmbH

TABLE OF CONTENTS

SUPPLEMENTAL GUIDANCE FOR THE ASSESSMENT OF COLORANTS REVISION HISTORY

REVISION	SECTION	TYPE OF CHANGE	DATE	AUTHORIZED BY
1.0	Initial Release		06/2015	C2CPII
1.1	1.1 & 3.2	Clarified purpose and preconditions for use of the assessment methodology contained in this document	02/2016	C2CPII
1.1	3.3.1	Added explanation of the exposure scenarios that were considered in the development of the assessment criteria	02/2016	C2CPII
1.1	3.5.5 & 3.5.6	Clarified situations in which irritation or sensitization testing for the dyed textile is not required despite a dyestuff product being sensitizing or irritating	02/2016	C2CPII
1.1	3.5.8	Clarified the trumping rules for various types of mutagenicity data that may be evaluated for the purpose of determining criteria compliance (the REACH approach is to be followed)	02/2016	C2CPII
1.1	3.5.11	Added explanation regarding permissible approaches in cases where neither experimental BCF data are available nor QSAR works	02/2016	C2CPII
1.1	3.5.14	Added explanation regarding what should be done when a dyestuff product is known to be toxic in endpoints not covered by this criteria set	02/2016	C2CPII

1 OVERVIEW OF THE GUIDANCE DOCUMENT

1.1 PURPOSE AND CONTENT

The purpose of this document is to serve as supplemental guidance to the Cradle to Cradle Certified Product Standard, Versions 3.0 and 3.1 (the 'Standard'). This supplemental guidance provides a customized methodology for the material health assessment of colorants, specifically textile dyestuffs and pigments. This methodology differs from the general Material Health Assessment Methodology ('the Methodology') for use with other substance types, but is aligned with the current practices used in product assessments for textile dyestuffs and pigments. Information in this document supersedes any conflicting information that may be present in the original Standard document, but only for the specific substance and material classes discussed and only if the preconditions for application of this guidance document have been fulfilled.

1.2 SUPPORTING DOCUMENTS

The following documents are to be used in conjunction with this supplemental guidance document:

- *Cradle to Cradle Certified™ Product Standard, Version 3.0*
- *Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.0*
- *Supplemental Guidance for the Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.0*
- *Cradle to Cradle Certified™ Product Standard, Version 3.1*
- *Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.1*
- *Any additional supporting documents and guidance posted on the C2CPII website*

Visit the Cradle to Cradle Products Innovation Institute website to download the Standard documents and obtain the most current information regarding the product Standard (http://www.c2ccertified.org/product_certification/c2ccertified_product_standard).

2 INTRODUCTION

Because toxicity data are limited, most colorants would receive a single chemical risk rating of GREY due to missing toxicological information using the general assessment Methodology outlined in the Standard. This would prevent products with colorant-containing materials as a primary component (25% by weight or more) from reaching the Bronze level of certification or higher, thereby preventing them from maintaining certification after the two-year, Basic-level provisional certification period has run its course. To allow for the inclusion of products containing textile dyestuffs and pigments in the certification program, customized assessment approaches were developed that take into consideration the specific aspects of potential exposure that distinguish these substance classes from others, as well as the amount and quality of toxicity data that is typically available. Because of the fundamental differences in their physicochemical properties and applications, two separate approaches were developed for these colorant classes, one for textile dyestuffs and one for pigments.

For dyestuffs, a modified methodology that yields a final ABC-X material assessment rating for the commercial dyestuff product was developed. This methodology applies to the assessment of textile dyestuff products applying for certification as such, or textiles that have been dyed with the dyestuff product. For the most part, this methodology was developed with the specific exposure scenarios that apply to textile dyestuffs already taken into account, therefore allowing the final assessment rating to be derived in one step. This is in contrast to the general assessment Methodology, in which hazard criteria are applied initially to derive hazard ratings for each chemical substance and exposure considerations follow in a secondary step. An exception to this is the assessment of the auxiliaries in the dyestuff product, for which the general assessment Methodology for deriving the single chemical risk ratings (abc-x), including the exposure assessment, must still be conducted. While the assessment criteria in this customized methodology are primarily hazard-based, their selection was informed by exposure considerations that have narrowed the endpoints to only those hazards that are directly relevant in the dyestuff manufacture, use, and end-of-use context. Because this assessment approach only considers exposure scenarios related to the use of dyestuff products on textiles, it does not apply to dyestuff products used for other applications (e.g., paper, foodstuff, or hair coloring). The general assessment Methodology must be used to assess dyestuff products in non-textile applications.

For pigments, a modified methodology that yields abc-x single chemical risk ratings for pigments as pure chemical substances was developed. This methodology consists of a set of customized screening criteria that are applied prior to following the general Methodology. If a pigment has passed all of the customized screening criteria, GREY hazard endpoint ratings are then ignored when deriving a pigment's single chemical risk rating. The rating obtained for each pigment is then rolled into the final ABC-X assessment rating for any material containing the pigment.

3 ASSESSMENT OF TEXTILE DYESTUFFS

3.1 DEFINITION AND PROPERTIES

Dyestuffs are colored compounds that are soluble or dispersible in a liquid (usually water) and have the ability to permanently adhere to a material by covalent, electrostatic, or van der Waals bonds or just by migration and distribution into the material itself.

The term "dyestuff" is used to describe two different types of substances:

1. Dyestuff molecule: The dyestuff molecule is the pure, active chemical compound itself. It is a colored compound that sticks to the fiber after being applied in the dye bath. It is a pure chemical substance with a certain color index (C.I.) number and a unique CAS number (e.g., *Acid Blue 1*, Color Index # 42045 with CAS # 116-95-0). In contrast to the CAS number, the C.I. designation is not a molecular identifier; thus, knowing the C.I. number alone is not sufficient. The CAS number is a prerequisite for the toxicity assessment.

2. Dyestuff product: The dyestuff product is the commercial mixture containing the dyestuff molecule and the dyestuff formulation auxiliaries. Common dyestuff formulation auxiliaries include salts, solvents, de-dusting agents, preservatives, chelators, dispersants, and surfactants. A dyestuff product has a brand name and extension (e.g., *Drimaren® Yellow CL-S gr* produced by the dyestuff supplier *Archroma)*. The commercial mixture, including both the dyestuff molecule and the dyestuff auxiliaries, will be referred to as the dyestuff product in this document.

Textile dyestuffs are typically classified according to the dyeing mechanism and the substrate. The most important classes with respect to textiles are the following:

- Reactive dyes for dyeing cellulose fibers (e.g., cotton)
- Vat dyes for dyeing cellulose fibers (e.g., cotton)
- Disperse dyes for dyeing polyester fibers (e.g., PET or PLA)
- Acidic (*or* anionic) dyes for dyeing polyamide fibers (e.g., silk, wool, or nylon)
- Basic (*or* cationic) dyes for dyeing polyacrylonitrile (PAN) and certain types of polyamide fibers
- Direct (*or* substantive) dyes for various substrates
- Sulfur dyes for dyeing cellulose fibers (e.g., cotton)

Dyestuffs can also be classified with respect to the chemical group responsible for the color (i.e., the chromophoric group). Some examples under this classification are the following:

- Azo dyes
- Anthraquinone dyes
- Triarylmethane dyes
- Acridine dyes
- Nitro dyes

More detailed information on dyestuffs, classification systems, and the mechanism of dyeing can be found in standard technical literature, e.g. ULLMANN'S Encyclopedia of Industrial Chemistry[1] and Industrial Dyes[2].

3.2 PRECONDITIONS FOR THE USE OF THIS GUIDANCE FOR DYESTUFF PRODUCTS

In developing the assessment criteria contained herein, certain assumptions were made regarding the exposure of workers to dyestuff products during the textile dyeing process (see the following section). Specifically, the dyeing process in the dyehouse is assumed to be performed by trained personnel using protective equipment that prevents significant oral, dermal, or inhalative exposure to the dyestuff product. Consequently, these criteria may only be applied for the assessment of dyed textiles or products containing dyed textiles when lack of significant exposure to dyehouse workers is guaranteed. Furthermore, the ratings and achievement levels of dyestuff products assessed with this guidance will be based on an assumed lack of exposure during product application and only be valid in such contexts. If a textile manufacturer is not able to provide such a guarantee, or if plausible routes of exposure of workers to the dyestuff product are observed during the site visit in the context of a textile product being assessed for certification, the assessment criteria contained in this guidance document may not be used and the general Methodology must instead be employed to assess the dyestuff product. Even dyestuff products certified at the Gold level in Material Health cannot be assumed to be safe under conditions in which direct exposure of workers to the raw (i.e. non-textile bound) dyestuff product exists.

3.3 ASSESSMENT CRITERIA DEVELOPMENT

The methodology described in this section was developed for use in deriving A, B, C, X, or GREY assessment ratings for commercial textile dyestuff products. The methodology considers dyestuff-specific toxicity data and typical exposure scenarios during the life cycle of a textile dyestuff product, from the final textile manufacturing phase and textile use through to textile end-of-use.

3.3.1 Exposure Scenarios

The following exposure scenarios during textile dyestuff application, use, and end-of-use phases have been considered:

1. Dyehouse (final manufacturing step):
   The dyeing process in the dyehouse is assumed to be performed by trained and protected personnel, resulting in limited exposure of workers to the dyestuff product. Since some of the dyestuff molecule and most of the dyestuff auxiliaries reach the wastewater, a high level of

[1] Wiley: ULLMANN'S Encyclopedia of Industrial Chemistry. John Wiley and Sons, Inc. NY 2014

[2] Hunger K, (ed.): Industrial Dyes – Chemistry, Properties, Applications. WILEY-VCH Verlag GmbH&Co. KGaA, Weinheim 2003

environmental exposure to the dyestuff product is assumed.

2. Textile use:
   During use of the textile, oral and inhalative uptake of the dyestuff is assumed to be rather limited, as the dyestuff molecule adheres to the fiber. However, dermal exposure to the fiber-bound dyestuff molecule takes place and dermal uptake with sweat as a carrier may occur.
3. End-of-use scenario 1 (intended / biological nutrient):
   In the case of composting biodegradable textiles (e.g. a dyed cotton shirt), the dyestuff molecule is assumed to be slowly released and degraded. The dyestuff molecule must neither prevent biodegradation of the fiber nor form very toxic or persistent metabolites itself.
4. End-of-use scenario 2 (intended / technical nutrient):
   In the case of recycling of the dyed textile, the dyestuff molecule is assumed to be either regained (and reused) or combusted.
5. End-of-use scenario 3 (highly likely unintended / incineration):
   In the case of incinerating the textile after use, the dyestuff molecule is assumed to be completely destroyed.

3.3.2 Assessment Criteria

The assessment criteria described in this methodology differ from those in the general Methodology, as they are customized to apply to the limited amount and type of information typically available for dyestuff products. Toxicity data for dyestuffs are typically limited to the information that can be obtained from the dyestuff product material safety data sheet (MSDS) and from direct information from the dyestuff manufacturer.

The following hazard endpoints and other topics were selected for inclusion in the assessment of textile dyestuff products based on the specific exposure conditions that apply to dyestuff products, the specific hazards that are most frequently associated with dyestuff molecules, and the toxicity data that are typically available for these products:

- Toxic metal content (dyestuff molecule only)
- Organohalogen content (dyestuff molecule and formulation auxiliaries)
- Cleavable carcinogenic amines (azo dyestuffs only)
- Acute oral toxicity (dyestuff product)
- Irritant effect on skin/eyes (dyestuff molecule after application)
- Sensitization (dyestuff molecule after application)
- Aquatic toxicity (dyestuff product)
- Mutagenicity (dyestuff product)
- Carcinogenicity (dyestuff molecule)
- Degradation products (dyestuff product)
- Bioaccumulation potential (dyestuff molecule only)
- Dyestuff formulation auxiliaries
- Impurities of dyestuff product

3.4 ASSESSMENT METHODOLOGY

3.4.1 Data Collection

The following information is needed in order to conduct the assessment of a dyestuff product:

1. Dyestuff product MSDS
2. Structure of dyestuff molecule
3. List of dyestuff formulation auxiliaries and their CAS numbers from the dyestuff product manufacturer
4. Standard hazard data resources as specified in the general Methodology (for formulation auxiliaries only)
5. In case of incomplete MSDS data, a statement from the dyestuff manufacturer with toxicity data for endpoints not addressed in the MSDS

3.4.2 Assessment Rules

Using the assessment criteria in Table 1, an A, B, C, X, or GREY rating is assigned to the dyestuff product using the following rules:

1. The overall dyestuff product ABC-X rating is determined by the best (i.e., leftmost) rating column in which all criteria are fulfilled.
2. If any of the criteria are not fulfilled because the toxicological properties are worse than the condition in the rightmost column (i.e., column C), the rating for the dyestuff product is X.
3. Otherwise, if any of the criteria in the rightmost column (i.e., column C) are not fulfilled due to lack of data, the rating for the dyestuff product is GREY. The only assessment criteria that can be fulfilled without data or signed statements are carcinogenicity and degradation products (topics 9 and 10).

A more detailed description of each assessment endpoint and topic is provided in Section 3.5.

Note: When assessing a dyestuff product applied to a textile, the final assessment rating for the dyed textile is equal to the lower rating between the base textile material and the dyestuff product in the order X, GREY, C, B, A.

3.4.3 Material Assessment Ratings

A-rated dyestuff products are ideal from a Cradle to Cradle® perspective: They are fully defined, contain neither metals nor organohalogen compounds, are neither toxic nor ecotoxic, and cannot cleave off carcinogenic aromatic amines. All of their biodegradation products are known and do not pose a risk to human health or the environment.

B-rated dyestuff products largely support Cradle to Cradle® objectives: They are fully defined. However, they may contain moderately problematic (c-assessed) formulation auxiliaries and the dyestuff molecules' biodegradation products are not known.

C-rated dyestuff products have moderately problematic properties in terms of quality from a Cradle to Cradle® perspective: They are fully defined. The dyestuffs may contain copper when used in technical cycles or very low amounts of organohalogen compounds, and may have moderate toxicity

to humans or aquatic organisms. Their non-mutagenicity is indicated based on negative Ames test only and data on the biodegradation of the dyestuff molecules or the formulation auxiliaries are not available.

Table 1: Assessment Criteria for Textile Dyestuffs.

	Endpoint/Topic	A	B	C
1	Toxic metal content	Dyestuff molecule is free of toxic metals.	Dyestuff molecule is free of toxic metals.	Dyestuff molecule is free of toxic metals. For fibers going into the technical metabolism, copper complex dyestuffs are acceptable.
2	Organohalogen content	Dyestuff molecule(s) is(are) free of non-hydrolysable carbon-halogen bonds.	Dyestuff molecule(s) is(are) free of non-hydrolysable carbon-halogen bonds.	Content of non-hydrolysable organohalogen compounds is below 0.1% in the dyestuff product.
3	Cleavable carcinogenic aromatic amines	Dyestuff molecule cannot cleave off any aromatic amine listed either under last update of 2002/61/EC or under MAK III 3B or other carcinogenic aromatic amines (either reductively or hydrolytically).	Dyestuff molecule cannot cleave off any aromatic amine listed either under last update of 2002/61/EC or under MAK III 3B or other carcinogenic aromatic amines (either reductively or hydrolytically).	Dyestuff molecule cannot cleave off any aromatic amine listed under last update of 2002/61/EC under reductive conditions.
4	Acute oral toxicity	LD50 (oral, mammal) of dyestuff product > 2,000 mg/kg.	LD50 (oral, mammal) of dyestuff product > 2,000 mg/kg.	LD50 (oral, mammal) of dyestuff product > 300 mg/kg.
5	Irritation potential	Dyestuff product is <u>not</u> labelled with H314, H315, H318 or H319.	Dyestuff product is <u>not</u> labelled with H314, H315, H318 or H319.	Dyestuff product is <u>not</u> labelled with H314 or H318 (exception: dyestuff products that are irritating before application only, see section 3.5.5).
6	Sensitization potential	Dyestuff product is non-sensitizing as shown by test (such as Mouse Local Lymph Node Assay).	Dyestuff product is non-sensitizing as shown by test <u>or</u> no reported cases of sensitization*	Dyestuff product is non-sensitizing as shown by test <u>or</u> no reported cases of sensitization* (exception: dyestuff products that are sensitizing before application only, see section 3.5.6).

	Endpoint/Topic	A	B	C
7	Acute aquatic toxicity	LC50 fish (96 h) of dyestuff product > 100 mg/l and LC50 daphnia (48 h) of dyestuff product > 100 mg/l **	LC50 fish (96 h) of dyestuff product> 100 mg/l and LC50 daphnia (48 h)of dyestuff product > 100 mg/l **	LC50 fish (96 h) of dyestuff product > 10 mg/l or LC50 daphnia (48 h) of dyestuff product > 10 mg/l ** (at least one value available; MSDS values must be > 10 mg/l)
8	Mutagenicity	Dyestuff product or dyestuff molecule have been tested and are not mutagenic.	Dyestuff product or dyestuff molecule have been tested and are not mutagenic.	Dyestuff product is not suspected of being mutagenic based on a negative Ames test only.
9	Carcinogenicity	Dyestuff molecule is neither a known nor a suspected carcinogen.	Dyestuff molecule is neither a known nor a suspected carcinogen.	Dyestuff molecule is neither a known nor a suspected carcinogen.
10	Degradation Products	Information on degradation pathway exists for all formulation components (including the dyestuff molecule) and has been reviewed; no risks have been identified.	Information on degradation pathway exists at least for the dyestuff auxiliaries and has been reviewed; no severe risks have been identified	No information available.
11	Bioaccumulation potential	BCF of dyestuff molecule < 100 or solubility in water > 1 g/L (25°C)	BCF of dyestuff molecule < 100 or solubility in water > 1 g/L (25°C)	100 < BCF of dyestuff molecule < 500
12	Dyestuff formulation auxiliaries	All formulation auxiliaries are declared and assessed according as a or b.	All formulation auxiliaries are declared and assessed according as a, b or c.	All formulation auxiliaries are declared and assessed according as a, b or c.
13	Impurities	Dyestuff product meets ETAD standard for impurities.	Dyestuff product meets ETAD standard for impurities.	Dyestuff product meets ETAD standard for impurities.

* Sensitization: *"No reported cases of sensitization"* means that the dyestuff supplier has provided a signed statement that there have been no reported cases of sensitization.

** Acute aquatic toxicity: If the solubility of the dyestuff is lower than the LC50/EC50 value, the endpoint is not applicable.

3.5 ENDPOINT AND TOPIC DESCRIPTIONS

3.5.1 Toxic Metals

This endpoint applies to the dyestuff molecule only.

Certain dyestuff molecules, commonly referred to as metal complex dyes, contain metal atoms as a central part of their chromophore. As of the time of this writing, only four different types of metal atoms are typically used in metal complex dyes: nickel, cobalt, chromium, and copper. During

combustion, nickel, cobalt, and sometimes chromium complex dyes form carcinogenic compounds. Therefore, all dyestuff products containing these metal complex dyes receive an X assessment rating.

Copper compounds formed by combustion are less problematic. Copper complex dyes are therefore acceptable for use when used on textiles intended to enter a technical cycle after use. However, many copper compounds are ecotoxic. Copper complex dyes are therefore not acceptable for textiles intended to enter a biological cycle (e.g., through composting) after use.

If other metal atoms are used in a metal complex dye, the metal must be assessed following the general Methodology. Toxicity data for simple inorganic or the pure forms of the metal may be used, as chemical transformation is likely once the metal complex dye is released into the environment (during the dyeing process or likely unintended end-of-use scenarios of the dyed textile).

Data Source: Comprehensive data about the metal content in a specific dyestuff product can be obtained from the structure of the dyestuff molecule and from its product MSDS. A typical entry in the MSDS would be in section 12 (Ecological information): "The product does not contain heavy metals in concentrations of concern for waste water."

3.5.2 Organohalogens

This endpoint applies to the dyestuff molecule only. However, in the MSDS organohalogen content is sometimes specified as a percent of the dyestuff product overall.

Dyestuff molecules often contain stable halogen-carbon bonds for coloristic reasons. Several common dyestuff products will therefore be X-assessed for the purposes of Cradle to Cradle certification.

On the other hand, many reactive dyes contain halogens in the anchor group. This halogen-carbon bond is usually hydrolyzed during formation of the bond between dyestuff molecule and textile fiber, forming harmless halides (i.e., fluoride, chloride, bromide). If the organohalogen group in a dyestuff molecule is cleavable (hydrolysable), the dyestuff product is acceptable with respect to this endpoint.

Sometimes small amounts of additional organohalogen dyestuff molecules used for the final adjustment of shade are added to the dyestuff product. With typically 1% of the dyestuff molecule on the fiber, amounts of 0.1% halogen in the dyestuff product lead to approximately 10 ppm halogen on the fiber, which is deemed acceptable (i.e., C-rated dyestuff product).

Data Source: Comprehensive data regarding the halogen content in a specific dyestuff product can be obtained from the structure of the dyestuff molecule and from its product MSDS. A typical entry in the MSDS would be in section 12 (Ecological information): "Product does not add to the AOX-value of the sewage."

3.5.3 Cleavable carcinogenic aromatic amines

This endpoint applies to the dyestuff molecule only.

Azo dyestuffs are characterized by their specific chromophore, the azo group: -N=N- . This dyestuff class is important because it encompasses more dyestuffs than all of the other dyestuff classes combined.

Azo dyestuffs may cleave off aromatic amines by reductive cleavage of the azo group. A number of such amines are known to be carcinogenic. Because reductive cleavage may occur within the human gut and under other conditions, it is important to evaluate the potential of an azo dye to cleave off carcinogenic amines when assessing its safety for humans and the environment. The use of azo dyestuffs that may cleave off certain carcinogenic aromatic amines has been forbidden in the European Union[3]; however, such dyestuffs may still be in use outside of the European Union. While category C just considers the specific aromatic amines referenced on the European legislation[3], categories A and B moreover consider any known or suspected carcinogenic aromatic amines that may be cleaved off under reductive or hydrolytic conditions.

Data Source: The structure of the dyestuff molecule provides sufficient information about cleavable aromatic amines.

3.5.4 Acute oral toxicity

This endpoint applies to the dyestuff product.

Acute oral toxicity is the standard indicator for toxicity. It has been determined for nearly every substance.

Data Source: Acute oral toxicity data for a specific dyestuff product can be obtained from the dyestuff product MSDS. A typical entry in the MSDS would be in section 11 (Toxicological information): "Acute oral toxicity: LD50 > 2,000 mg/kg (rat)."

3.5.5 Irritation potential

This endpoint applies to the dyestuff molecule only. However, in the MSDS the irritation potential is usually specified for the whole dyestuff product.

Irritation potential is an important parameter for the dyed textile due to intensive skin contact between textile and consumer. Therefore, irritating dyestuffs should not be used. However, if the dyestuff manufacturer can prove by testing that the dyed textile is not irritating, the dyestuff product may be used. Testing is not necessary if the irritation potential of the dyestuff product before application originates from one of the following:

- *dyestuff formulation auxiliaries that are known not to stay on the fiber after dyeing and rinsing, or*
- *reactive dyestuffs that form a chemical bond with the textile fiber during the dyeing process, after which the original dyestuff as such is no longer present*[4]

Data Source: Irritation potential for a specific dyestuff product can be obtained from the dyestuff product MSDS. A typical entry in the MSDS would be in section 11 (Toxicological information): "Irritant effect on skin: non-irritant (rabbit)." If the MSDS indicates irritation potential for the dyestuff product but the dyestuff manufacturer has conducted testing indicating the dyed textile is not irritating, the

[3] Point 43 of Annex I of Council Directive of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (76/769/EEC) (OJ L 262, 27.9.1976, p. 201) lastly amended on 21.11.2008. Available in consolidated form at: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1976L0769:20081211:EN:PDF.

[4] Hunger K, (ed.): Industrial Dyes – Chemistry, Properties, Applications. WILEY-VCH Verlag GmbH&Co. KGaA, Weinheim (p. 627) 2003

manufacturer may submit a report on the tests performed by a textile laboratory on textiles dyed with the product to the assessor. If the report indicates that the dyed textile is not irritating, the dyestuff product may qualify for a C assessment rating. In the case of reactive dyes, any irritation is assumed to be caused by the unreacted dyestuff molecule only and the dyestuff product can qualify for a 'C' rating based on this endpoint without any additional data being required.

3.5.6 Sensitization potential

This endpoint applies to the dyestuff molecule only. However, in the MSDS the sensitization potential is usually specified for the whole dyestuff product.

Similar to irritation potential, sensitization potential is an important parameter for the dyed textile due to intensive skin contact between the textile and the consumer. Therefore, sensitizing dyestuffs should not be used. However, if the dyestuff manufacturer can demonstrate via testing that the dyed textile is not sensitizing, the dyestuff product may be used. Testing is not necessary if the sensitization potential of the dyestuff product before application originates from one of the following:

- *dyestuff formulation auxiliaries that are known not to stay on the fiber after dyeing and rinsing, or*
- *reactive dyestuffs that form a chemical bond with the textile fiber during the dyeing process, after which the original dyestuff as such is no longer present*[5]

Data Source: Sensitization potential for a specific dyestuff product can be obtained from the dyestuff product MSDS. A typical entry in the MSDS would be in section 11 (Toxicological information): "Sensitization: Non-sensitizing (mouse); Method: Mouse Local Lymph Node Assay (LLNA)." If the MSDS indicates sensitization potential for the dyestuff product but the dyestuff manufacturer has conducted testing indicating the dyed textile is not sensitizing, the manufacturer may submit a report on the tests performed by a textile laboratory on textiles dyed with the product to the assessor. If the report indicates that the dyed textile is not sensitizing, the dyestuff product may qualify for a C assessment rating. In the case of reactive dyes, any sensitization is assumed to be caused by the unreacted dyestuff molecule only and the dyestuff product can qualify for a 'C' rating based on this endpoint without any additional data being required.

3.5.7 Acute aquatic toxicity

This endpoint applies to the dyestuff product.

During typical dyeing processes, a significant portion of the dyestuff molecule, as well as most of the dyestuff auxiliaries, reach the wastewater. Thus, there is a large potential for exposure to the dyestuff product in aquatic environments. As such, aquatic toxicity is an important parameter to consider in the assessment of a dyestuff product. If both acute fish and acute daphnia toxicity data are available, both need to be considered, with the overall assessment rating driven by the target species with the lowest LC50 value (i.e., highest toxicity). If data for only one target species is available, this is deemed sufficient for the assessment of a textile dyestuff product and the available data point will determine categorization for this endpoint. Chronic toxicity data is typically not available and does not need to be considered. Algae toxicity data are not appropriate, as light absorption by the dye solution always leads to reduced algae growth (the measured endpoint), thus obscuring possible toxicity impacts.

[5] Hunger K, (ed.): Industrial Dyes – Chemistry, Properties, Applications. WILEY-VCH Verlag GmbH&Co. KGaA, Weinheim (p. 627) 2003

Data Source: Acute aquatic toxicity for a specific dyestuff product can be obtained from the dyestuff product MSDS or from the dyestuff manufacturer. A typical entry in the MSDS would be in section 12 (Ecotoxicological information): "Fish toxicity: LC50 > 100 mg/l (96 h, guppy (Lebistes reticulatus))."

3.5.8 Mutagenicity

This endpoint applies to both the dyestuff molecule and the dyestuff product.

Mutagenicity is an important indicator for carcinogenicity. It is an essential endpoint, as many dyestuff molecules are derivatives of carcinogenic compounds, especially aromatic amines. Dyestuff products without mutagenicity data are GREY-assessed.

At a minimum, a negative Ames test (OECD 471) is required. This would be sufficient for a C rating. For a dyestuff product to receive an A or B rating, data on additional mutagenicity/genotoxicity tests are required. Any of the tests listed in section 7.1.3 of the general Methodology are acceptable for this purpose.

In contrast to non-dyestuff substances that are assessed following the general Methodology, dyestuffs are assessed following the REACH approach. This means that a positive Ames test can be superseded by a negative *in vitro* mammalian chromosomal aberration test plus a negative *in vitro* mammalian gene mutation test. A positive *in vitro* mammalian cell test can be superseded by a negative *in vivo* mammalian cell test. For details of the REACH approach, see "Proposed Integrated Decision-tree Testing Strategies for Mutagenicity and Carcinogenicity in Relation to the EU REACH Legislation" [6] and "Integrated testing strategy for mutagenicity under REACH."[7]

Data Source: Mutagenicity data for a specific dyestuff product can be obtained from the dyestuff product MSDS or from the dyestuff manufacturer. A typical entry in the MSDS would be in section 11 (Toxicological information): "Mutagenicity: No mutagenic response in the Ames-Test."

3.5.9 Carcinogenicity

This endpoint applies to the dyestuff molecule only. However, if addressed in the MSDS, the carcinogenicity of the complete dyestuff product is typically specified.

Carcinogenicity data are typically not available for dyestuff molecules due to the high costs of the required animal tests. Should data be available, they need to be considered for the rating of the dyestuff product. Rating of carcinogenicity is performed according to the hazard endpoint criteria specified for carcinogenicity in the general Methodology, i.e. if the dyestuff molecule meets the "red" criteria for the carcinogenicity endpoint, the dyestuff product will be rated X.

Data Source: While carcinogenicity data is rarely available for dyestuff products, it may appear on the dyestuff product MSDS or be provided by the dyestuff manufacturer. No additional sources need to be checked for the dyestuff molecule with regards to this endpoint.

6 R.Combes, C.Grindon, M.Cronin, D.Roberts and J.Garrod : Proposed Integrated Decision-tree Testing Strategies for Mutagenicity and Carcinogenicity in Relation to the EU REACH Legislation. Altern Lab Anim 35 ,267-287, 2007
7 http://www.prc.cnrs-gif.fr/reach/diagrams_en/testing_strategy_muta_en.pdf

3.5.10 Degradation products

This topic applies to the dyestuff molecule and the dyestuff auxiliary molecules.

Knowledge about the degradation products of the dyestuff molecule is important for the assessment of the environmental risk posed by the dyestuff in the textile's end-of-use phase, especially in case of release to soil. Unfortunately, these data on degradation products exist only for a small number of dyestuff molecules. Thus, this information is only required to obtain an A rating for the dyestuff product.

To obtain an A rating, all known degradation products of the dyestuff molecule and auxiliaries must have been assessed following the general Methodology and must have received an a or b single chemical risk rating.

To obtain a B rating, information on the degradation products of all dyestuff auxiliaries must have been obtained and they must have been assessed following the general Methodology. None of these degradation products may have received a single chemical risk rating of x.

As a substitute for knowledge of degradation products, the assumption is made that a dyestuff molecule that contains neither organohalogens nor toxic metal atoms will likely degrade into non-toxic and non-persistent molecules (metal and organohalogen content are already covered by the first and second endpoints, see above). Thus, a C rating for a dyestuff product can be obtained even if no additional information on degradation products is available.

Data Source: The identities of degradation products of dyestuff molecules and auxiliaries are to be obtained from peer-reviewed scientific papers on the topic such as [8] and [9].

3.5.11 Bioaccumulation potential

This endpoint applies to the dyestuff molecule only.

In contrast to their persistence, most textile dyestuffs are readily water-soluble and therefore not suspected of being bioaccumulative. However, certain dyestuffs (e.g., disperse and vat dyes) are not water-soluble. Their bioaccumulation potential needs to be known, especially if they are used for coloration of biodegradable fibers. If dyestuff solubility in water is higher than 1 g/L (25°C), the BCF value is assumed to be far below 100 and no specific BCF data is needed.

Data Source: Data on bioaccumulation potential can be found in the product MSDS or can be requested from the dyestuff supplier. Alternatively, bioaccumulation potential can be calculated by standard QSAR methods for substances with log $K_{ow} < 6$ (see Standard Section 7.1.15). However, experimental data always supersede QSAR data. In cases in which neither experimental BCF data are available nor QSAR works, additional dyestuff molecule properties (i.e. molecular weight, molecule size, and solubility in octanol) may be considered. In particular, a dyestuff molecule with molecular weight higher than 500 atomic mass units and solubility in octanol lower than 10 mg/l can be

[8] I K Konstantinou and T A Albanis. TiO2-assisted photocatalytic degradation of azo dyes in aqueous solution: kinetic and mechanistic investigations. Applied Catalysis B: Environmental 49 (2004) 1-14 Elsevier

[9] X Zhao, I R Hardin and H-M Hwang. Biodegradation of a model azo disperse dye by the white rot fungus Pleurotus ostreatus. International Biodeterioration & Biodegradation 57 (2006) 1-6 Elsevier

assumed not to be bioaccumulative.[10] A typical entry in the MSDS would be in section 9 (Physical and chemical properties): "Solubility in water: 40 g/l (25 °C)" – meaning good water solubility and consequently no bioaccumulation potential.

3.5.12 Formulation auxiliaries

This topic applies to the formulation auxiliaries in the dyestuff product.

As the majority of formulation auxiliaries will reach the wastewater during the textile dyeing process, knowledge of their fate and impact on the environment (particularly the aquatic environment), is crucial. Therefore, the dyestuff manufacturer needs to reveal all auxiliaries present in the dyestuff product at concentrations of 100 ppm or above. Without such disclosure by the dyestuff manufacturer, the assessment of dyestuff products is not possible, leading to a GREY rating for the dyestuff product. It is not necessary to reveal the exact percentages of each auxiliary in the dyestuff product, as long as all auxiliaries present at 100 ppm or above have been provided. If this is guaranteed by the dyestuff product manufacturer, it is sufficient to report approximate concentration ranges for each substance in the dyestuff product (i.e., <0.1%, 0.1 – 1.0%, 1.0 – 10%, and >10%). In cases in which multiple dyestuff products from the same manufacturer are being assessed, the manufacturer may submit one list containing all auxiliaries for a group of dyestuff products.

Auxiliaries are assessed following the general Methodology. For a dyestuff product to obtain an A rating, all auxiliaries must have received a single chemical risk rating of either a or b. For a dyestuff product to obtain a B or C rating, all auxiliaries must have received a single chemical risk rating of either a, b, or c.

Data Source: Formulation information must be obtained from the dyestuff supplier. Toxicity data can be obtained from the standard scientific data resources.

3.5.13 Impurities

This topic applies to the dyestuff product.

Dyestuff products may contain impurities due to impurities in reactants or raw materials, residues of solvents, reactants or reaction by-products, metal traces from the use of metal catalysts in synthesis, or from corrosion of manufacturing equipment. The concentrations of these impurities are a measure of product quality. The members of the dyestuff suppliers' association ETAD ("The Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers") guarantee that their products do not exceed certain, well-defined impurity thresholds.

Data Source: A dyestuff supplier must follow the ETAD limits to receive an A, B, or C rating for the dyestuff product. Dyestuff products from manufacturers that are ETAD members are preferred. If the manufacturer is not an ETAD member, they must sign and submit a written declaration guaranteeing that none of the impurities specified in ETAD guidelines are present in the product above their allowable concentration limit. Limit values are published in *ETAD recommendation for threshold limits on impurities in dyes, 2014* (http://www.etad.com/lang-en/publications.html).

10 R.Anliker, P.Moser, D.Poppinger: Bioaccumulation of dyestuffs and organic pigments in fish. Relationships to hydrophobicity and steric factors. Chemosphere, Vol.17, No.8, pp 1631-1644, 1988

3.5.14 Further Info

Should the MSDS or other data from the dyestuff manufacturer indicate high chronic toxicity, reproductive toxicity, or endocrine disruption potential of the product, this information needs to be considered and reflected in the final rating (i.e. the substances with this toxicity potential need to be evaluated separately following the general Methodology instead of the simplified Methodology contained herein).

4 ASSESSMENT OF PIGMENTS

4.1 DEFINITION AND PROPERTIES

Pigments are colored, insoluble chemical compounds with the ability to give color to another material. The fundamental difference between dyestuffs and pigments is that pigments are not intended to be soluble in order to adhere to a material. Pigments have to be dispersed in the material to imbue it with color. Alternatively, they can be dispersed within a binder matrix, which is then applied to the surface of a material. In contrast to dyestuffs, pigments keep their original shape (as small crystals) over the complete life cycle, a consideration that must be taken into account during the material health assessment process.

Pigments are typically classified according to their chemical make up and can be divided into two groups:

1. Inorganic pigments: Inorganic pigments, often metal oxides or metal sulfides, usually show high light fastness and temperature stability, but often limited brilliance. Important inorganic pigments are titanium dioxide, iron oxide, zinc oxide, zinc sulfide, barium sulfate, chromium(III) oxide, cobalt blue, lead oxide, cinnabar and cadmium yellow.
2. Organic pigments: Similar to dyestuff molecules, organic pigments can be classified according to their chemical structure. Classes of organic pigments include:

    - Azo pigments
    - Disazo pigments
    - Polycyclic pigments
    - Anthraquinone pigment
    - Dioxazine pigments
    - Triarylcarbonium pigments
    - Quinophthalone pigments

    Similar to azo dyestuff products, the azo pigments are the commercially most important group of organic pigments.

Pigments are often marked with a specific number, the color index (C.I.) number. In contrast to dyestuffs, there is a distinct correlation between pigment name, CAS number, C.I. name, and C.I. number (e.g., titanium dioxide, TiO2, CAS # 13463-67-7, Pigment White 6, C.I. 77891).

In contrast to dyestuff products, pigments are used in a wide range of applications. Applications include paints, inks, coatings, fiber bulk colorations, plastics, rubber, paper, cosmetics, and ceramics.

Pigments are applied as pure pigments or as pigment formulations (i.e., pigment masterbatches). Masterbatches are used to avoid dust formation in the factory (for occupational safety) and to simplify pigment dispersion in the matrix.

More detailed information on pigments, their use, and their classification systems can be found in standard technical literature, e.g. ULLMANN'S Encyclopedia of Industrial Chemistry [11] and Industrial Organic Pigments[12].

4.2 ASSESSMENT METHODOLOGY DEVELOPMENT

Several toxicity studies have been performed on pigments for select hazard endpoints including acute toxicity, mutagenicity, and irritation potential[13]. The results showed that very few pigments are hazardous. The main reason for this is that most pigments are poorly water soluble and predominantly chemically inert, and as a consequence are not bioavailable. In many applications (e.g., coatings, paints, colored plastics) pigments are embedded in a matrix and therefore exposure is limited. For this reason, there has been little attention devoted to the toxicological characterization of pigments and the availability of toxicity data for pigments is relatively poor. If pigments were to be assessed following the general Methodology, most pigments would receive a GREY rating due to a lack of toxicity data.

The general Standard Methodology was therefore modified to allow for the assessment of pigments when little toxicity information is available. This modified approach is based on the specific physicochemical properties of pigments and assumes that an ideal pigment is chemically stable (i.e., inert) and insoluble in any solvent. Due to its stability and insolubility, it is assumed that such a pigment does not change its macroscopic crystalline shape during use and the solid pigment crystals are too large to pass through biological membranes. As a consequence, an ideal pigment would not be bioavailable, would pass through the body unchanged in the event of ingestion, and as such would not be toxic via ingestion. These considerations apply to both organic and inorganic pigments.

Although these considerations are valid for ideal pigments only, it can simplify the toxicity assessment of pigments actually in use. For these, only deviations from this non-toxic ideal are considered with respect to assessing their toxicological impact. As a result, the primary questions that drive the assessment are:

- Can the pigment be dissolved, without changing its chemical structure, under any realistic and probable circumstances during its life cycle?, and
- Is the pigment chemically unstable and may it form, release, or cleave-off any toxic substance under any realistic and probable circumstances during its life cycle?

In addition, all probable chemical impacts on the pigment during its life cycle need to be considered:

- Elevated temperature (e.g., during extrusion of colored plastics)
- Acidic conditions (e.g., after ingestion of pigmented materials)
- Alkaline conditions (e.g., during reductive bleaching in paper recycling)
- Reductive conditions (e.g., during reductive bleaching in paper recycling)
- Oxidative conditions (e.g., during combustion of pigmented products)

[11] WILEY: ULLMANN'S ENCYCLOPEDIA OF INDUSTRIAL CHEMISTRY. JOHN WILEY AND SONS, INC. NY 2014

[12] Herbst W, Hunger K: Industrial Organic Pigments – Production, Properties, Applications. WILEY-VCH Verlag GmbH & Co. KGaA Weinheim 2004

[13] Herbst W, Hunger K: Industrial Organic Pigments – Production, Properties, Applications. WILEY-VCH Verlag GmbH & Co. KGaA Weinheim 2004

The last of these probable life-cycle conditions, oxidation, deserves special considerations. Organic pigments completely degrade during combustion and the main oxidation products are usually carbon dioxide, water, and nitrogen. However, if a pigment contains other elements as well, further combustion products are formed. In particular, if a pigment contains halogens, small amounts of volatile organohalogen compounds will be formed during combustion. These combustion products are likely to be persistent, bioaccumulative, and toxic. For these reasons, halogen-containing pigments should be excluded from use.

4.3 ASSESSMENT METHODOLOGY

4.3.1 Molecular Structure Screening

The first step when assessing pigments is to establish whether they are chemically stable (i.e., like an 'ideal' pigment) or whether they have the potential to form hazardous reaction products. Based on the common chemistries of pigments that are in use, the vast majority of pigments with the potential to form hazardous reaction products can be captured by screening against the following three endpoints, which are based on the molecular structure of the pigment:

- organohalogens
- toxic elements
- reductively cleavable aromatic amines

These three screening endpoints are applied as follows:

Organohalogens – A pigment containing a covalent fluoro-carbon, chloro-carbon, bromo-carbon or iodo-carbon bond will have a single chemical risk rating of x.

Toxic Elements – A pigment containing lead, cadmium, mercury, vanadium, chromium(VI), cobalt, nickel, arsenic, antimony or selenium will have a single chemical risk rating of x.

An exception to this rule is made for inert complex inorganic color pigments with a rutile, spinel or inverse spinel structure. These pigments show high chemical, light, and temperature stability and several contain toxic elements (e.g. antimony, cobalt, nickel). However, on a molecular level these potentially hazardous atoms are fixed firmly in a crystal lattice structure and cannot be released under normal use conditions, in alkaline or acidic media, or even during waste incineration [14,15]. Consequently, these pigments in their pure form do not pose any risk to human health or the environment, leading to a single chemical risk rating of c.

Reductively Cleavable Aromatic Amines – An azo pigment containing one or more carcinogenic aromatic amines as defined in European regulation 76/769/EEC (Annex / Point 43) [16] will have a single chemical risk rating of x.

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[14] Ullmann's Encyclopedia of Industrial Chemistry, "Pigments, Inorganic", Vol. A20; VCH, 1992.

[15] Bomhard, E. et al. Subchronic oral toxicity and analytical studies on Nickel Rutile Yellow and Chrome Rutile Yellow with rats. Toxicol. Lett. 1982, **14,**189–194.

16 Point 43 of Annex I of Council Directive of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (76/769/EEC) (OJ L 262, 27.9.1976, p. 201) lastly amended on 21.11.2008. Available in consolidated form at: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1976L0769:20081211:EN:PDF

4.3.2 Full Assessment

A pigment that has not received an x-assessment as a result of a functional group of concern in its molecular structure and does not belong to the complex inorganic pigment group (i.e., a pigment that has passed the screening described in section 4.3.1) must then be assessed following the general Standard Methodology. However, as a result of the considerations described in section 4.2, any endpoint data gaps remaining in the pigment's hazard profile after the assessor has exhausted all available resources (i.e., GREY ratings) may be ignored when deriving the pigment's single chemical risk rating. The single chemical risk rating assigned to the pigment is then rolled into the final assessment rating for the homogenous material in which it is present, as described in section 5 of the Cradle to Cradle Certified Material Health Assessment Methodology guidance document.

4.3.3 Limitations

This modified approach for assessing pigments has the following limitations:

1. It is only valid for pure pigments, meaning pure chemical substances with a single CAS number. Contamination of commercially available pigments with synthesis by-products is not considered in the approach. Such contaminants, if present at a concentration that makes them subject to review in a product, require a case-by-case review based on additional information from the specific pigment manufacturer. In such cases, contaminants are to be assessed separately following the general Standard Methodology.
2. It is not valid for pigments in the form of nano-particles, as nano-sized pigment particles could pass biological membranes in some cases and their toxicological effect could be fundamentally different. Specific assessment rules for nano-particles may be developed at a future time, but for the time being they are to be assessed following the general Standard Methodology, not the modified approach described in this document. The availability of toxicity information for nano-particles is relatively poor at present, even when compared to other pigment types. Thus, nano-sized pigments are very likely to obtain a single chemical risk rating of GREY.
3. It does not cover exposure by inhalation. In cases where dust loads are high, even dust from non-toxic substances may lead to toxic effects. For products in which pigments in an inhalable form are used as part of the final manufacturing stage, inhalative exposure needs to be considered as part of the assessment. Any relevant inhalative exposure based on insufficient protection or unsafe operating procedures at the facility will result in a single chemical risk rating of x for the pigment in that product.

Methodology for the Assessment of Biological Materials

July 2016

Written in collaboration with MBDC, LLC

TABLE OF CONTENTS

METHODOLOGY FOR THE ASSESSMENT OF BIOLOGICAL MATERIALS REVISION HISTORY

REVISION DATE	SECTION	TYPE OF CHANGE	AUTHORIZED BY
June 2016	Initial Release		S. Klosterhaus
July 2016	2.3.2	Clarified that when the pesticides used are known to the assessor, only the active ingredient(s) need to be assessed (not all substances in the mixture)	S. Klosterhaus
July 2016	2.3.2	Clarified what is to be done for animal-based fibers if information on the pesticides used can be obtained	S. Klosterhaus

1 OVERVIEW

1.1 PURPOSE AND CONTENT

This document outlines a customized methodology for the Material Health assessment of biological materials in the Cradle to Cradle Certified Product Standard. Biological materials include live microorganisms, live plants, plant tissues, animal tissues, microbial tissues, and plant, animal, and microbe-derived materials.

1.2 SUPPORTING DOCUMENTS

The following documents are to be used in conjunction with this document:

- Cradle to Cradle Certified™ Product Standard
- Cradle to Cradle Certified™ Material Health Assessment Methodology
- Any additional Cradle to Cradle Certified standard documents and methodology documents posted on the C2CPII website.

1.3 BIOLOGICAL MATERIALS

Within the Cradle to Cradle design paradigm, biological nutrients are those materials designed to stay within the biosphere, ultimately providing nutrients to microorganisms within sediment and soil. A subset of biological nutrients are biological materials which are derived from live microorganisms, live plants, plant tissues, animal tissues, microbial tissues, and plant, animal, and microbe-derived materials.

Biological materials provide a unique challenge for the Material Health evaluation, which is based on the hazard profiles of individual chemical substances. These materials tend to be chemically heterogeneous in and off themselves and chemical composition may also vary significantly between batches. Additionally, the primary metrics for evaluation, human and environmental health hazard endpoints, are rarely determined for raw materials of biological origin. However, hazards, and therefore risks, can still be associated with the use of these materials, often through the presence of contaminants or by-products. A well-defined method for assessing these materials in the absence of toxicity data and complete chemical composition information is essential for consistent evaluation of materials used in Cradle to Cradle Certified™ products.

1.4 SCOPE OF MATERIAL HEALTH ASSESSMENT FOR BIOLOGICAL MATERIALS

The Material Health evaluation for any material and/or product is limited to the chemicals contained within that product as it leaves the final manufacturing facility. Materials that are of biological origin may have variable composition and may be contaminated with problematic metals and/or other compounds such as residual pesticides. Other biological materials may be derived from organisms that produce allergens or toxins during their normal metabolic activities. In order to ensure that these

substances (if present) are below levels likely to impact human or environmental health, biological materials must be analyzed according to the methodology outlined in section 2.

2 DERIVING FINAL MATERIAL ASSESSMENT RATINGS

2.1 OVERVIEW

Biological materials are materials that consist of, or are derived from living organisms such as plants or animals. They are classified as biological nutrients and will enter the biosphere either directly during use or after one or more use cycles. Given the lack of toxicity data for these materials, the conventional Material Health Assessment Methodology as applied in the Cradle to Cradle Certified Products Program would lead to 'Grey' assessments in the majority of cases. In order to not limit the use of biological materials within the Cradle to Cradle Certified program, the following supplemental methodology has been developed to assign Material Health assessment ratings to biological materials for the purpose of Cradle to Cradle certification.

The following classes of biological materials are addressed by this methodology:

- Live microorganisms – this category includes live fungi, bacteria, and other microorganisms
- Live plants – any member of the kingdom Plantae in its live state
- Tree-based materials – wood planks/strips/pieces, bark, wood chips, and other wood products
- Plant-based materials – plant based fibers such as cotton, hemp, ramie, rice husks, and coconut fiber
- Animal-based materials – animal based fibers such as wool, silk, mohair, cashmere, and leather/skins
- Microbial tissue based materials – e.g., fungal mycelium
- Plant, animal, and microbe-derived mixtures – e.g., essential oils, natural rubber latex, and waxes

The protocol for deriving the final assessments of biological materials will vary depending on the class of material in question as defined by the classes listed above.

2.2 INFORMATION SOURCES

The information sources for the Material Health assessment of biological materials are consistent with those used for a typical Material Health assessment. Please see the Cradle to Cradle Certified Material Assessment Methodology for a detailed description. In addition, research papers, journal articles, and technical specification/data sheets will be helpful in identifying the typical composition of biological materials and/or contaminants such as pesticides that might be present in or on the biological material. Other sources focusing on the toxicity of natural materials (e.g., naturalmedicines.com) may also be helpful.

2.3 ASSESSMENT PROCESS

2.3.1 GENERAL REQUIREMENTS

- The materials must be pure and contain no other additives or colorants. If additives or colorants are present then these must be assessed separately following the general Material Health Assessment Methodology.
- Banned List requirements must still be met. In this case the Biological Nutrient Banned List is used. As per the Cradle to Cradle Certified Product Standard and methodology documents, these requirements pertain to substances *intentionally added* or mixtures/materials *known to contain* these substances. Assuming no Banned List substances are intentionally added to the biological material in question (this may be confirmed through signed Banned List declarations by the supplier) the only remaining issue is to determine whether or not the biological material being assessed is "known to contain" any Banned List substances. As they are all naturally occurring materials, the only Banned List substances they could reasonably be expected to contain are toxic metals. If the organism is known to be a hyper-accumulator of metals, or if there is any reason to believe metals may be present in/on the organism above background soil concentrations (i.e., by asking the supplier(s) to provide information on any substances that were applied to the material), analytical testing of the five Banned List metals (arsenic, cadmium, chromium VI, mercury, and lead) is required. If any of the five banned metals are detected at a concentration in excess of the allowable levels, the material will be banned from use in a Cradle to Cradle Certified product.
- Once it has been determined that the biological material in question is pure and does not contain toxic metals above the allowable Biological Nutrient Banned List thresholds, the next step is to determine the category or class of biological material from the list provided in section 2.1.

2.3.2 ADDITIONAL REQUIREMENTS FOR SPECIFIC CLASSES OF BIOLOGICAL MATERIALS

Live Microorganisms

At a minimum, it must be evaluated whether the organism in question is pathogenic or has the potential to produce any toxic substances during its normal metabolic activity. This will require identification by genus and species and a review of the microbiological and medical literature available on the organism by the material health assessor. Any organism with the potential to produce x-assessed substances or with the potential for pathogenicity will receive an X-rating; any organism for which insufficient studies are available will receive a Grey rating. The assessor must also be able to show that the organism strain is pure and is not contaminated by other organisms. No products containing live organisms have been Cradle to Cradle Certified to date, so any new application of such a product will be handled on a case by case basis.

Live Plants

As above, it must be evaluated whether the organism in question produces any toxic substances during normal metabolic activities. This will require identification by genus and species and a review

of all relevant literature available on the plant by the material health assessor. If the species is well studied in the botanical literature and none of the available publications indicate potential to produce any allergens/toxins, it will receive a "B" assessment. If toxins/allergens are produced, the assessor must assess them using the standard Material Health Assessment Methodology. Any x-assessed substance produced by the organism will result in an X assessment for that organism.

Tree-Based Materials

The most common tree-based materials are wood- and bark-based materials/products. All stains, treatments, and other coatings on the wood-based materials must be identified in terms of their constituent chemical substances, and these substances are then assessed according to the conventional Material Health Assessment Methodology. The single chemical risk ratings of these substances will factor into the material assessment rating for the treated material as described in the general methodology. Furthermore, the base wood material must be identified in terms of species and genus of the organism of origin. In the absence of c, x, or grey assessed substances in any applied stains or treatments, tree-based materials will then receive a B rating unless one or more of the following conditions apply:

- The tree-based material is from a species that is known to have sensitizing effects (e.g., certain species of blackwood or rosewood). The assessor must identify the species of tree from which the material originates and check for known sensitizing effects. The book, 'List of MAK and BAT Values' (Deutsche Forschungsgemeinschaft), is a good resource for this. If the tree-based material comes from a species with known sensitization effects the material will receive an X assessment, unless it can be demonstrated that there is no relevant route of exposure during the intended or likely unintended use and end-of-use scenarios for the material in question.

- The assessor will need to determine if wood dust exposure is a concern during the product's final manufacture, as well as intended and likely unintended use and end-of use scenarios. Oak and beech dusts are MAK 1 carcinogens and other types of wood dust are also potentially carcinogenic. If dust exposure is a concern, then the material will receive an X assessment. If not, the material receives a B rating.

- If others recognized hazards exist, the assessor must also consider these in their evaluation using the conventional Material Health Assessment Methodology.

Plant-Based Materials

This is potentially the largest category of biological materials as it includes all plant-based fibers, as well as plant-based materials coming from agricultural primary or secondary materials. All of the plant-based fibers can be considered polymers, and are largely polysaccharides that consist of monomer building blocks such as glucose and others.

Using the polymer rules that are part of the Cradle to Cradle Material Health Assessment Methodology, the pure polymer is assessed based on the hazards of the constituent monomer(s). In this case the monosaccharide components (the monomers) are not hazardous so the base "polymer" or plant-based fiber will be assessed as B. However, all plant-based materials have the potential to be contaminated with residual pesticide chemicals, and fibers are no exception.

Plant-based fibers with Global Organic Textile Standard (GOTS) or an equivalent organic certification receive a "B" assessment for the base fiber since the restrictions on pesticide use for GOTS certification are very rigorous (equivalence to GOTS must be demonstrated by the assessor and pre-approved by C2CPII). However, any dyes, auxiliaries, treatments or other chemical additives present on the fiber must be assessed separately according to the conventional Material Health Assessment Methodology.

If the fibers come from plants that were not grown according to organic farming practices and do not have GOTS or an equivalent organic certification, the following must occur. First, the assessor must attempt to determine the source of the fiber and request a list of pesticides used from the grower. Once the assessor has this list, the active ingredient(s) in each pesticide mixture must be assessed according to the conventional Material Health Assessment Methodology.

- If one or more pesticide(s) receives an x assessment, the raw fiber must be tested by an ISO 17025 accredited lab to determine if residues from the x assessed pesticide(s) are present. The detection limit for each target pesticide must be < 0.1 ppm. If the sum concentration of the x assessed pesticide(s) is > 0.5 ppm, the fiber receives an X assessment. If the sum concentration of the x assessed pesticide(s) is < 0.5 ppm, the fiber receives a C assessment.
- If one or more pesticide(s) receives a c assessment, the applicant has the option of testing the raw fiber. If an overall C assessment for the fiber is acceptable, no testing is required. If an overall B assessment for the fiber is desired, it must be shown via analytical testing (same lab and analytical testing requirements as above) that the sum of any residual c assessed pesticide(s) is < 0.5 ppm.
- If one or more pesticide(s) receive a grey risk rating, analytical testing on the raw fiber must be conducted (same lab and analytical testing requirements as above). If the sum concentration of the grey assessed pesticide(s) is < 0.5 ppm, the fiber receives a C assessment. If the sum concentration of the grey assessed pesticide(s) is > 0.5 ppm, the fiber receives a Grey assessment.

If it is not possible to determine the source of the fiber and obtain a list of pesticides used from the grower (which is common for conventionally grown crops like cotton), the raw fiber must be tested for the list of pesticides applying to conventional and IPM cotton as required by the most recent version of criteria for obtaining the EU Ecolabel for Textile Products (http://ec.europa.eu/environment/ecolabel/documents/User_manual_textile.pdf). Testing must be conducted by an ISO 17025 accredited laboratory and the detection limit for each target pesticide must be < 0.1 ppm. If the sum concentration of all x assessed pesticides is > 0.5 ppm, the fiber receives an X assessment. If the sum concentration of the x assessed pesticide(s) is < 0.5 ppm, the material can be assessed C. In addition, all other additives used on the plant-based material (such as dyes, spin finishes/lubricants, and soil/stain protection for fibers) will need to be assessed according to the conventional Material Health assessment methodology.

In the case of agricultural materials (either primary or secondary) such as rice hulls, corn or corn stalks, or coconut fibers, the main concern is also potential pesticide residues in the final material. The same procedure outlined above for fibers must also be followed for all other agricultural materials.

When applicable, analytical testing is required prior to initial certification and on an annual basis after that for 'B' and 'C' assessed materials.

For plant-based materials that have been modified on a molecular level (e.g., starch derivatives), the assessment method described in this section may need to be modified based on the expert judgment of the material health assessor.

Animal-Based Materials

The vast majority of materials in this category are fibers from animal sources (e.g., wool, mohair, silk, and cashmere). There are generally no concerns with the pure fiber itself, but rather with the residues that could be present on the fiber. Pesticides and other additives such as shrink-proofing treatments, bleaching agents, and dyestuffs are the major concerns.

Just like plant-based fibers, animal-based fibers with Global Organic Textile Standard (GOTS) or an equivalent organic certification receive a "B" assessment for the base fiber since the restrictions on pesticide use for GOTS certification are very rigorous (equivalence to GOTS must be demonstrated by the assessor and pre-approved by C2CPII). However, any dyes, auxiliaries, treatments or other chemical additives present on the fiber must be assessed separately according to the conventional Material Health Assessment Methodology.

If the fibers come from animals that were not raised according to organic farming practices and do not have GOTS or an equivalent organic certification, the following must occur. First, the assessor must attempt to determine the source of the fiber and request a list of pesticides used from the grower. Once the assessor has this list, the active ingredient(s) in each pesticide mixture must be assessed according to the conventional Material Health Assessment Methodology.

- If one or more pesticide(s) receives an x assessment, the raw fiber must be tested by an ISO 17025 accredited lab to determine if residues from the x assessed pesticide(s) are present. The detection limit for each target pesticide must be < 0.1 ppm. If the sum concentration of the x assessed pesticide(s) is > 0.5 ppm or above the sum total limit values allowed by the EU Ecolabel for Textile Products if applicable (see reference below), the fiber receives an X assessment. If the sum concentration of the x assessed pesticide(s) is < 0.5 ppm or below the sum total limit values allowed by the EU Ecolabel for Textile Products if applicable, the fiber receives a C assessment.
- If one or more pesticide(s) receives a c assessment, the applicant has the option of testing the raw fiber. If an overall C assessment for the fiber is acceptable, no testing is required. If an overall B assessment for the fiber is desired, it must be shown via analytical testing (same lab and analytical testing requirements as above) that the sum of any residual c assessed pesticide(s) is < 0.5 ppm.
- If one or more pesticide(s) receive a grey risk rating, analytical testing on the raw fiber must be conducted (same lab and analytical testing requirements as above). If the sum concentration of the grey assessed pesticide(s) is < 0.5 ppm or below the sum total limit values allowed by the EU Ecolabel for Textile Products if applicable, the fiber receives a C assessment. If the sum concentration of the grey assessed pesticide(s) is > 0.5 ppm or above the sum total limit values allowed by the EU Ecolabel for Textile Products if applicable, the fiber receives a Grey assessment.

If it is not possible to determine the source of the fiber and obtain a list of pesticides used from the farmer, the raw fiber (for wool the raw fiber is greasy wool) must at a minimum be tested for the list of ectoparasiticides applying to wool and other keratin fibers as required by the most recent version of

criteria for obtaining the EU Ecolabel for Textile Products (http://ec.europa.eu/environment/ecolabel/documents/User_manual_textile.pdf):

- If residual pesticide(s) are detected, but are less than the sum total limit values allowed by the EU Ecolabel for Textile Products, the fiber will receive a "C" assessment.
- If residual pesticide(s) are detected above the sum total limit values allowed by the EU Ecolabel for Textile Products, they must be assessed according to the conventional Material Health Assessment Methodology.
- An "x" assessed pesticide present above the sum total limit values allowed by the EU Ecolabel for Textile Products will lead to an "X" assessment for the fiber.
- A "c" assessed pesticide present above the sum total limit values allowed by the EU Ecolabel for Textile Products will lead to a "C" assessment for the fiber.

All analytical testing:

- Must be done by an ISO 17025 accredited lab. Wool testing must be conducted in accordance with the International Wool Textile Organization method DTM59-04. Testing on other materials must be conducted in accordance with the analytical methods prescribed in the EU Ecolabel for Textile Products, GOTS, or equivalent.
- Must be conducted on the raw fiber (for wool the raw fiber is greasy wool), as the scouring process removes much of the pesticide residue.

In the case of silk, another animal based fiber, the concern is not so much around the fiber itself, but rather the treatments that can occur. "Weighting" of the fiber is a common practice that introduces metal salts into the silk fiber. Commonly used metals include chromium, tin, lead, barium, magnesium and iron. Some have major toxicity concerns while others do not. The assessor must determine if the fiber has been weighted or not, and if so what metal salts were used.

- If the fiber has been weighted with a metal from the Biological Nutrient Banned List, testing must be done to determine the concentration. As these metal salts are intentional inputs, if detected above the allowable threshold, the silk fiber will be banned for use in Cradle to Cradle Certified products.
- If the fiber has been weighted with one or more non-banned, but x assessed, metals (e.g. antimony, barium, cobalt), testing must be done to determine the concentration. If detected in excess of 100 ppm, the silk fiber will be assessed X ***regardless of exposure scenarios,*** as these materials will always find their way back to the biosphere**.**

Another potential issue with silk is the use of pesticides on the mulberry leaves. As is the case with the other fibers, GOTS or an equivalent organic certification will lead to a "B" assessment for the silk fiber (equivalence to GOTS must be demonstrated by the assessor and pre-approved by C2CPII). If no organic certifications are present, the raw fiber must be tested using the same target pesticide list and analytical procedure indicated above for plant-based fibers, unless the assessor can justify that a different list of pesticides should be tested based on research of the common pesticides used on mulberry leaves in the region where the mulberry/silk was grown, or it can be demonstrated through chain of custody documents that no pesticides were used on the mulberry leaves. The assessor must also be sure to identify all additives used in the processing of the silk including dyes, auxiliaries, and finishing chemicals. Any x assessed pesticide or additive present at 100 ppm or higher will lead to an overall X assessment for the silk.

Other animal-based materials such as leather and other hides are essentially cross-linked polymers of protein building blocks in their "pure" state and are therefore "B" assessed based on the polymer rules. However, the vast majority of these materials do not exist in their pure state but must be "tanned" or treated so they will not degrade too quickly. Therefore all chemicals used in this preservation process must be assessed according to the traditional Material Health Assessment Methodology. The individual risk ratings of these substances will determine the overall rating for the material.

Microbial Tissue-Based Materials

This category includes materials such as fungal mycelium. The mycelium is comprised of hyphae, which are long chain, polymeric, materials typically comprised of cellulose/fatty acid complex with a chitin skin. None of these building blocks are considered problematic for human or environmental health, so applying the polymer assessment methodology part of the conventional Material Health Assessment Methodology leads to a "B" assessment for the pure mycelium. However, it is possible for the mycelium to contain toxins or allergens from spores, as well as pesticide residues, since fungal mycelium has been known to filter and break down certain synthetic pesticides. Therefore, to adequately assess these materials the assessor must do the following:

1. Identify the species of the fungal mycelium in use and research any known toxins or allergens associated with it. If the species of fungi is found to produce toxins or allergens, the mycelium must be tested for these. The presence of any "x" assessed toxin or allergen above 100 ppm will render the material X. Likewise, the presence of any "c" assessed toxin or allergen above 100 ppm (in the absence of x substances) render the material C.

2. Trace the mycelium back to the source, if possible. Once the source has been identified, request information on pesticide use. Follow the process for testing pesticides for plant-based materials from this point on. If the mycelium cannot be traced back to the source, it will be assumed that pesticides were used and analytical testing must be done for commonly used pesticides (i.e., the list of pesticides applying to conventional and IPM cotton as required by the most recent version of criteria for obtaining the EU Ecolabel for Textile Products).

3. The assessor can only assess the mycelium as "B" if it can be shown that the fungi species does not produce any toxins or allergens, OR there are no residual toxins or allergens present in the mycelium material above 100 ppm AND it can be documented that there were no pesticides used during the growing of the fungi OR the mycelium does not contain any pesticide residues above the detection limit.

Plant, Animal, and Microbe-Derived Materials

These materials tend to be mixtures rather than pure chemicals. Examples are essential oils, waxes, natural-based fragrances, natural rubber, plant extracts, and seaweed extract. In many cases there will be a CAS number, or set of CAS numbers, that define the substance or mixture. The key in all of these cases is for the assessor to understand the purity and composition of the material in question as well as possible, including substances originating from the organism and added contaminants. For example, Basil Oil (CAS 8015-73-4) will sometimes carry an H351 (suspected of causing cancer) label even though Basil Oil in its pure form is actually used in certain instances to treat cancer. The reason

for the H351 label has to do with the presence of other substances such as Estragole (CAS140-67-0), which is a suspected carcinogen. The different contents of something like Basil Oil is indicative of the challenges inherent in assessing these types of materials.

The following section outlines steps for the assessor to take in order to come to an accurate assessment for these types of materials:

1. Identify the main chemical substance and its CAS number.

2. Identify the purity of the mixture from the supplier and obtain any other analytical information they may posses detailing the other chemical substances present in the mixture.

3. Ensure that the toxic metals on the Biological Nutrient Banned List are not present in the mixture above the allowable thresholds following the procedure described in Section 2.3.1.

4. Based on information gathered in steps 2 and 3 above and additional research done by the assessor for substances likely to exist in the mixture, list all additional substances that may be present above 100 ppm.

5. If the mixture is not its own homogeneous material in the final product, determine which, if any, of the other substances identified in the mixture are above the 100 ppm threshold for the homogeneous material and are therefore subject to review.

6. Assess those substances identified in step 5 above using the conventional Material Health Assessment Methodology.

7. If there are grey endpoints for human or environmental health for either the main substance or any additional substances present and subject to review in the mixture, QSAR tools must be used to try and derive a non-grey hazard rating. However, if there is evidence related to the safe use of one such substance in traditional medicine or cosmetics for 25 years or more (for example in Chinese medicine or similar applications), any grey hazard endpoints may be ignored in deriving single-chemical risk ratings.

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