Supplemental Guidance for the Cradle to Cradle Certified™ Material Health Assessment Methodology, Version 3.0

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Written in collaboration with MBDC, LLC.

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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).