Biological Materials Assessment Methodology

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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
May 2017	2.3.2	Expanded scope of substances that may be considered grey if there is evidence for their safety to include those in which the traditional use is food	S. Klosterhaus
May 2017	2.3.2	Öeko-tex 100 certification included, with boundaries, as basis for C-assessment of plant-based materials.	S. Klosterhaus
May 2017	2.3.2	Coatings added to scope of tree-based substances eligible for a B-assessed rating.	S. Klosterhaus
May 2017	2.3.2	Clarified requirements for assessing plant, animal, and microbe-derived materials	S. Klosterhaus
May 2017	2.3.2	Bleaching agents added to the scope of plant-based materials as subject to review at any level	S. Klosterhaus
March 2018	2.3.2	Clarified the pesticide testing protocol for other bast fibers such as flax, hemp, jute, and ramie.	S. Klosterhaus
March 2018	2.3.2	Clarified that detection limits only apply to pesticides listed in either GOTS or the EU Ecolabel Textile Standard.	S. Klosterhaus
September 2018	2.3.2	Clarified the list of pesticides and insecticides/ectoparasiticides that are in scope for testing of certain animal-based materials	S. Klosterhaus
October 2020	2.3.2	Clarified that assessment requirements for live microorganisms and products containing these will be determined by C2CPII on a case by case basis.	S. Klosterhaus
October 2020	2.3.2	Clarified that potential exposure to wood dust during all use stages, including installation, must be considered when assessing tree-based materials. Clarified that if dust is likely produced, an X-assessment is required unless workers are protected and installers and/or users are informed (as applicable).	S. Klosterhaus

October 2020	2.3.2	Clarified when testing for insecticides/ectoparasiticides is required in animal-based materials and deleted bifenthrin from the table of insecticides/ectoparasiticides to test for.	S. Klosterhaus
October 2020	2.3.2	Clarified that soil is assessed separately from plants	S. Klosterhaus
November 2021	2.3.2	Furmecyclox removed from list of pesticides to test in animal-based materials	S. Klosterhaus
November 2021	2.3.2 Animal-Based Materials	Clarified process to reduce the list of required analytes in cases where pesticides are not used on materials.	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® Product Standard User Guidance
- Cradle to Cradle Certified® Material Health Assessment Methodology
- Any applicable 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, species, and strain, 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. This must include the use of laboratory and production best practices to avoid strain contamination.

Additional requirements for assessing products containing live organisms (including spores) will be handled on a case by case basis. Please contact C2CPII prior to conducting any assessment work for a product of this type.

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 and found in the finished product will result in an X assessment for that organism. Note that any soil in which the plant is growing must be assessed as a separate homogeneous material.

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, coatings, 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, installation, 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 final manufacture includes processes that may result in the release of wood dust, the requirements as detailed in the Exposure Assessment Methodology for the protection of workers (section 3.2.1) apply. If installation or use are likely to include processes that may result in the release of wood dust (e.g. sawing, sanding) the applicant must demonstrate that installers and/or users (as applicable) are adequately informed about the hazard of wood dust and appropriate protective measures during such processes are taken. If dust exposure is a concern (i.e. dust is likely produced and final manufacturing stage workers are not adequately protected or installers and/or users are not informed, as applicable), 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.

Plant-based materials with Öeko-tex 100 certification may be considered C-assessed if the sum pesticides in the material are < 0.5 ppm. If sum pesticides are > 0.5 ppm, the material must be X-assessed.

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 pesticides listed by either GOTS or EU Ecolabel criteria for textiles 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 (https://ec.europa.eu/environment/ecolabel/documents/EU%20Ecolabel%20-%20User%20Manual%20Textile%20Products.pdf). Testing must be conducted by an ISO 17025 accredited laboratory and the detection limit for pesticides listed by either GOTS or EU Ecolabel criteria for textiles 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. If any bleaching agents were used in processing, such as with cotton materials, these will also be subject to review at any level.

Bast fibers such as flax, hemp, jute, and ramie are subject to the above requirements for pesticides, unless the assessor can justify that a different list of pesticides should be tested based on the research of the common pesticides used on the specific fiber plant in the region where the plant was grown, or it can be demonstrated through chain of custody documents that no pesticides were used on the fiber plant.

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. The assessor must determine whether these treatments have occurred in the supply chain, especially as it relates to the application of insecticides/ectoparasiticides.

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 **OR** insecticides/ectoparasiticides were

or may have been applied to the material at any point in its production[1], the following must occur. First, the assessor must attempt to determine the source of the fiber and request a list of pesticides used by the grower/farmer including any insecticides applied before and/or after harvest (shearing, etc.). Additionally, the assessor must obtain a list of any insecticides/ectoparasiticides applied during subsequent manufacturing steps if this has occurred. Once the assessor has these list(s), the active ingredient(s) in each pesticide/insecticide/ectoparasiticide 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 pesticides listed by either GOTS or EU Ecolabel criteria for textiles must be < 0.1 ppm.

- If the sum concentration of at least one of the classes of insecticides/ectoparasiticides is above the allowed sum total limits listed in the following table for insecticides/ectoparasiticides (derived primarily from EU Ecolabel for Textile Products[2], and Blue Angel Standard RAL-UZ-128[3]) **OR** the sum concentration of pesticides listed in EU Ecolabel for Textile Products is > 0.5 ppm, the fiber receives an X assessment. If the sum concentration of all of the classes of insecticides/ectoparasiticides is below the allowed sum total limits in the following table **AND** the sum concentration of x-assessed pesticides listed in the EU Ecolabel for Textile Products Standard is ≤ 0.5 ppm, the fiber receives a C assessment.

Class of insecticides/ecoparasiticides	**Sum total limit value**	**Source of value**
Permethrin	3 ppm	BlueAngel[3]
piperonyl butoxide, tetramethrin, cyfluthrin, cypermethrin, fenvalerate, deltamethrin	0.5 ppm	BlueAngel[3], EU Ecolabel[2]– sum total limit value corresponds to more conservative EU Ecolabel value
Diazinon, propetamphos, chlorfenvinphos, dichlofenthion, chlorpyriphos, fenchlorphos	2 ppm	EU Ecolabel[2]
Diflubenzuron, triflumuron, dicyclanil	2 ppm	EU Ecolabel[2]

[1] This means that if it can be determined that insecticides/ectoparasiticides were not applied, either by obtaining information directly from the relevant farms and/or processing facilities, or based on evidence of pesticides/ectoparasiticides used for the material type in question, then testing is not required.

[2] 2014/350/EU: Commission Decision of 5 June 2014 establishing the ecological criteria for the award of the EU Ecolabel for textile products (notified under document C(2014) 3677) Text with EEA relevance. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014D0350

[3] Der Blaue Engel. Basic Criteria for Award of the Environmental Label: Low-Emission Textile Floor Coverings, RAL-UZ 128. http://www.eco-institut.de/wp-content/uploads/2017/04/128-1602-e.pdf

- 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) and/or insecticide(s)/ecoparasiticide(s) receives 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 **AND** if the sum concentration of grey assessed insecticides/ecoparasiticides is below the sum total limit values in the above table for all classes, the fiber receives a C assessment. If the sum concentration of the grey assessed pesticide(s) is > 0.5 ppm **OR** the sum concentration of grey assessed insecticide(s)/ecoparasiticide(s) is above the sum total limit values for at least one class in the above table, the fiber receives a Grey assessment.

If insecticides/ectoparasiticides were or may have been applied to the material at any point in its production and it is not possible to determine the source of the fiber and obtain a list of the specific pesticides used, the raw fiber (for wool the raw fiber is greasy wool) must be tested for the insecticides/ectoparasiticides listed in the table above[4]:

- If residual insecticide(s)/ectoparasiticide(s) are detected, but the sum total concentration is ≤ the sum total limit values for all of the classes in the table above, AND the sum total for any additional residual pesticide(s)/insecticide(s)/ectoparasiticide(s) that are detected is ≤ 0.5 ppm the fiber will receive a “C” assessment.

- If residual insecticide(s)/ectoparasiticide(s) are detected and the sum total is above the sum total limit values for at least one of the classes in the above table, OR any additional residual pesticide(s)/insecticide(s)/ectoparasiticide(s) are detected and the sum total is above 0.5 ppm they must be assessed according to the conventional Material Health Assessment Methodology.

- If the sum total of “x” assessed pesticide(s) or insecticide(s)/ectoparasiticide(s) not contained in the table above is present above 0.5 ppm, this will lead to an “X” assessment for the fiber. If the sum total of any of the classes of insecticides/ectoparasiticides in the table above is above the respective sum total limit values, the fiber will also receive an “X” assessment.

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

[4] If information is available indicating that one or more pesticide(s) are not used on the material type in question, the list of required analytes (per the table above) may be reduced. Pre-approval from C2CPII is required. References that support excluding the pesticide(s) from testing must be provided. References may include published information and/or documented communication with individuals knowledgeable of the industry. Applicant companies may not be used as references.

prescribed in the EU Ecolabel for Textile Products, GOTS, Blue Angel Standard RAL-UZ 128, 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. **NOTE**: Insecticides/ectoparasiticides that are intentionally applied as part of the manufacturing process for performance reasons (e.g. mothproofing) are applied during or after the scouring step. Thus, it is required the assessor determine whether this has occurred, since testing the raw fiber will not account for insecticide/ectoparasiticide intentionally applied after scouring.

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:

- 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.

- 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).

- 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 listed by either GOTS or EU Ecolabel criteria for textiles 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:

- Identify the mixture or homogenous material (using CAS numbers if available), the genus and species from which the material is sourced, the part of the organism (e.g. root of the plant), and the method of extraction or processing. Also identify the source of the organism (e.g. agriculture, organic agriculture, wild collection)

- Perform a review of the information about the mixture or homogenous material, using standard sources, as well as sources dedicated to natural materials (e.g. botanical extracts) and their use.

- Identify the purity of the mixture from the supplier and obtain any other analytical information they may possess detailing potential contaminants and other chemical substances present in the mixture (e.g. residues of solvents used in the processing). Assess these substances using the conventional Material Health Assessment methodology and assign the overall corresponding risk rating.

- 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.

- Based on the purity analysis conducted in step 3, if the mixture or homogenous material is otherwise assessed as B or C and there is evidence related to the safe use of the mixture or homogenous material in traditional medicine, cosmetics, or food for 25 years or more (i.e. in Chinese medicine or similar applications), use the available literature toward establishing the overall risk rating as follows:

    - B-assessed – otherwise B-assessed AND the literature highlights the safety of the mixture or compound and affirms the lack of hazardous components or effects (without performing a detailed composition review).
    - C-assessed – otherwise B- or C-assessed AND a hazard or hazardous component was identified, but no significant risk is expected based on traditional use.
    - X-assessed – a hazard or hazardous component was identified and there is reason to believe a significant risk will occur in the current scenario.
- If evidence related to the safe use of the mixture or homogenous material is not found in the available literature, based on information gathered in steps 1-3 above and additional research done by the assessor for substances likely to exist in the mixture, list components that may be present above 100 ppm.

- If the organism-derived derived mixture/material is a component of a different mixture/homogeneous material in the final product, determine which, if any, of the substances (or mixtures with available hazard data) identified in the mixture are above the 100 ppm threshold for the homogeneous material and are therefore subject to review.

- Assess those listed substances identified in step 6 above using the conventional Material Health Assessment Methodology.

- 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 and/or read across methods must be used to try and derive a non-grey hazard rating.