# Certification Standard for Biodegradability

## SCS-104 Biodegradable Standard

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SCS standards

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## Disclaimer

## Record of Revisions

Changes from the previous version of the Standard (Version 6.1, February 2003) include:

- New terms and definitions (Section 3) for Acute Aquatic Toxicity, Bioaccumulation, Carcinogen, Mutagen, OCSPP, Persistence, Phosphates, Reproductive Toxicity, and US EPA Safer Choice Program,
- Updated Normative References (Section 4.1),
- Expanded Bill of Materials (BOM) requirements (Section 6),
- New criteria for Carcinogens (Section 10), Mutagens (Section 11), and Reproductive Toxins (Section 12),
- New criteria for Persistent, Bioaccumulative, and Toxic (PBT) substances (Section 13), and
- Editorial updates.

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## List of Tables

# 1. Introduction

1.1 The purpose of the Certification Standard for Biodegradability (hereinafter SCS-104) is to describe the requirements for a third-party certification of biodegradability claims.

1.2 The Standard provides requirements for determining whether a product is ready biodegradable. In addition, the Standard contains restrictions for acute aquatic toxicity, phosphates, and substances that are carcinogens, mutagens, and reproductive toxins (CMRs), and persistent, bioaccumulative, and toxic (PBTs).

1.3 Third-party certification against SCS-104 allows a manufacturer to:

1.3.1 Demonstrate that the product or products assessed by the certification body meet the quality assurance and traceability (See section 5), and the technical requirements for a biodegradable product (See sections 6 through 13);

1.3.2 Make claims about its product or products that conform to the Federal Trade Commission (FTC) Guides for the Use of Environmental Claims; and

1.3.3 Make Type I environmental claims (i.e., self-declared environmental claims as defined by ISO 14024:2018).

1.4 This Standard is voluntary. It is not intended to replace any legal or regulatory requirements that may be applicable to manufacturer operations.

# 2. Scope and Limitations

## 2.1 Scope

Products within scope of certification include liquid and powder products intended to be disposed down the drain. This includes, but is not limited to, cleaners, degreasers, detergents, soaps, personal care products, and cosmetics.

## 2.2 Limitations

### 2.2.1 Health and Safety

This Standard does not address all safety, health, comfort (e.g., odor) and performance concerns, if any, associated with its use. It is the responsibility of the user of this Standard to establish appropriate safety, health, and other performance conditions and to determine the applicability of federal, state, or local environmental and other regulatory requirements. Users shall note that compliance with the requirements of this Standard is no guarantee of regulatory compliance.

It is the responsibility of the user to establish appropriate conditions for such considerations and to determine the applicability of regulatory limitations prior to use.

### 2.2.2 Usage

The biodegradability requirements in this Standard consider the rate at which products break down after discharge to aquatic environments. However, it does not consider the way the product is used. No assumption of actual biodegradability of certified products should be made for all potential uses of a product.

### 2.2.3 Packaging

SCS-104 does not address environmental attributes of the packaging of the product undergoing certification.

### 2.2.4 Product Lifecycle

SCS-104 does not address all environmental benefits, compromises, or tradeoffs that may be associated with all life-cycle phases of the product.

## 3. Terms and Definitions

The term "shall" is used throughout the Standard to indicate mandatory requirements. The term "should" is used throughout the Standard to indicate preferred requirements.

**Acute Aquatic Toxicity.** "The intrinsic property of a substance to be injurious to an organism in a short-term, aquatic exposure to that substance." (Source: GHS)

**Bioaccumulation**. "A process in which a chemical substance is absorbed in an organism by all routes of exposure as occurs in the natural environment, e.g., dietary, and ambient environment sources. Bioaccumulation is the net result of competing processes of chemical uptake into the organism at the respiratory surface and from the diet and chemical elimination from the organism including respiratory exchange, fecal egestion, metabolic biotransformation of the parent compound and growth dilution." (Source: US EPA Safer Choice Master Criteria)

**Biodegradation.** The breakdown of a substance by biological activity, especially by microorganisms, into smaller compounds. The microbial organisms transform the contaminants through metabolic or enzymatic processes. Biodegradation processes vary greatly, but the final product of *aerobic* degradation usually is carbon dioxide, water, and minerals (salts). Other gases (e.g., $N_2$ or $H_2S$) may also result.

**Carcinogen.** Any substance, organism, or agent that has the potential to cause cancer in living tissue.

**CAS number.** A number generated by the American Chemical Society, which indexes and compiles abstracts of worldwide chemical literature that uniquely identifies a chemical compound, element, mixture, or alloy.

**Certification Audit.** An independent evaluation of a product claim using specific predetermined criteria and procedures with assurance of data reliability.

**Certification Body**. An SCS Standards approved independent, third-party organization providing auditing against this Standard.

**Certified Product.** A product, including its ingredients, that is in full conformity with the requirements of the standard, and for which the manufacturer is authorized to apply the Certification Label.

**Claim.** Oral, written, implied, or symbolic representation, statement, or advertising or other form of communication presented to the public or buyers of products that asserts a verified attribute of a product.

**Cleaner.** A formulated product designed to assist in removing undesirable matter—often from, but not limited to, a surface.

**US EPA Safer Choice Program.** The US Environmental Protection Agency's Safer Choice program aims to help consumers, businesses, and institutional buyers identify cleaning and other products that perform well, are cost-effective, and are safer for the environment.

**Eutrophication.** The process by which an increase in chemical compounds containing nitrogen or phosphorous promotes a proliferation of plant life (especially algae) in a lake, pond, or stream. This plant life reduces the dissolved oxygen content and can be harmful or lethal to other organisms.

**Ingredient.** Any component or additive of a product intentionally added or not, including any impurities. Synonymous with component, constituent, or additive.

**$LC_{50}$**. The Median Lethal Concentration, which is the published concentration of a substance required to kill half the members of a sample population of aquatic organisms. This measure is generally used as an indicator of a substance's acute toxicity when exposure to a chemical is through inhalation.

**Literature Review.** The process of surveying current documents and publications on a particular topic or subject of interest and undertaken for determining a variety of characteristics for each ingredient in a product, or the product itself. Manufacturer statements, MSDS, peer-reviewed scholarly publications, lab reports, test results, and government databases are primary sources of information for this review.

**Manufacturer.** Organization or individual responsible for the production of a product.

**Material Safety Data Sheet (MSDS).** A form containing data on the properties of a particular chemical, substance, or mixture, and may provide information on a variety of topics, including physical data; composition information; chemical properties; hazard information; health effects; toxicity; ecological information; first aid; stability and reactivity; handling, storage, and disposal of chemicals; first aid; protective equipment; spills and leak procedures; and may provide information on biodegradability.

**Mutagen.** Chemical or physical agent capable of inducing changes in DNA called mutations.

**OCSPP.** The Office of Chemical Safety and Pollution Prevention, which is part of the US EPA and "implements the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food, Drug and Cosmetic Act (FFDCA), the Toxic Substances Control Act (TSCA), the Pollution Prevention Act, and portions of other statutes." (Source: https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp)

**OECD.** The Organization for Economic Co-operation and Development, which is an international economic organization of 30 countries based in Paris. It defines itself as "a forum of countries committed to democracy and the market economy, providing a setting to compare policy experiences, seek answers to common problems, identify good practices, and co-ordinate domestic and international policies."

**Persistence**. "The length of time the chemical can exist in the environment before being destroyed (i.e., transformed) by natural processes." (Source: EPA PBT Final Rule)

**Personal Care Product.** A consumer product used for personal hygiene or beautification.

**Phosphates**. "In nature, phosphorus usually exists as part of a phosphate molecule ($PO_4$). Phosphorus in aquatic systems occurs as organic phosphate and inorganic phosphate." (Source: US EPA; https://archive.epa.gov/water/archive/web/html/vms56.html)

**Products of Concern.** Byproducts of degradation with high acute aquatic toxicity ($L/E/IC_{50} \leq 10ppm$) and a slow rate of biodegradation (greater than 28 days).

**Quality Assurance Plan.** A plan that sets out documented procedures that are established, implemented, and periodically audited to assure that production, handling, management, certification, and other quality practices of the manufacturer ensure consistent compliance with the requirements of this Standard.

**Ready Biodegradability.** A classification of biodegradability made by the OECD describing the degradation of an organic substance under aerobic conditions to carbon dioxide ($CO_2$), water ($H_2O$), and minerals by aerobic bacteria as determined by the measured change of Dissolved Organic Carbon (DOC), Biological Oxygen Demand (BOD), or $CO_2$ evolution over time. A Ready Biodegradable substance has to reach either a 60% BOD or theoretical $CO_2$ evolution, or 70% decrease in DOC, depending on test method, all of which use a 10-day window within a maximum 28-day test period.

**Records.** Any information in written, visual, or electronic form that documents the activities undertaken by a manufacturer to demonstrate conformance with this Standard.

**Reproductive Toxicity**. "The occurrence of biologically adverse effects on the reproductive systems of females or males that may result from exposure to environmental agents. The toxicity may be expressed as alterations to the female or male reproductive organs, the related endocrine system, or pregnancy outcomes. The manifestation of such toxicity may include, but not be limited to, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behavior, fertility, gestation, parturition, lactation, developmental toxicity, premature reproductive senescence, or modifications in other functions that are dependent on the integrity of the reproductive systems." (Source: US EPA Safer Choice Standard)

**Salts.** Ionic compounds composed of both positively charged ions (cations) and negative ions (anions) so that the product is electrically neutral.

**Standard.** When capitalized, refers to this Standard (SCS-104 Biodegradability Standard).

**Supplier.** Organization that supplies a material, product, or service to the manufacturer. Synonymous with vendor.

**Surfactants.** Organic compounds that contain both water soluble and non-water-soluble groups (oil soluble) and are used to reduce the surface tension of a liquid. Also known as surface active agents.

**Toxicity.** The ability of a chemical, substance, or mixture to cause adverse effects resulting in biological harm or death after exposure to, or contamination with, that substance.

# 4. References

## 4.1 Normative References

The following normative documents contain provisions that, through reference in this text, constitute provisions of this Standard.

- ISO 14024:2018, "Environmental labels and declarations – Type I environmental labeling – Principles and procedures."
- ISO 14020:2022, "Environmental labels and declarations – General principles."

## 4.2 Additional References

- Federal Trade Commission (FTC) Guides for the Use of Environmental Marketing Claims.
- ISO 9001:2015, "Quality management systems – Requirements."
- ISO 14001:2015, "Environmental management systems – Requirements with guidance for use."
- ISO/IEC 17025:2017, "General requirements for the competence of testing and calibration laboratories."
- US EPA's Safer Chemicals Ingredient List (SCIL) (https://www.epa.gov/saferchoice/safer-ingredients)
- EPA's Safer Choice Program Master Criteria for Safer Ingredients (https://www.epa.gov/sites/default/files/2013-12/documents/dfe_master_criteria_safer_ingredients_v2_1.pdf)
- US EPA Safer Choice Standard (https://www.epa.gov/sites/default/files/2013-12/documents/standard-for-safer-products.pdf)

## 5. Quality Assurance and Traceability

5.1 The manufacturer shall develop, implement, and maintain a documented Quality Assurance Plan that contains a product identification and traceability program.

5.2 The Quality Assurance Plan shall include documented procedures to ensure that the product is traceable to:

5.2.1 Relevant batch information, including production dates and lot sizes; and

5.2.2 Batch inspection or test reports on those processes and materials that may affect conformity of the product with this Standard.

## 6. Product Formulation Disclosure

6.1 The manufacturer shall maintain the complete detailed description of the product formulation which includes the following:

6.1.1 Common name and/or brand name of 100% of ingredients in the product formulation;

6.1.2 Supplier name of each ingredient;

6.1.3 Weight percent of the ingredient in the product formulation;

6.1.4 Function of the ingredient (e.g., surfactant, colorant, solvent);

6.1.5 Chemical name and CAS number of each chemical at or above 1000 ppm (0.01%) in the ingredient; and

6.1.6 Weight percent of the chemical in the ingredient.

## 7. Ready Biodegradability

7.1 The manufacturer shall maintain documentation for each ingredient in the product that definitively indicates that all ingredients demonstrate Ready Biodegradability using any of the following OCSPP or OECD acceptable test methods:[1]

- OCSPP (formerly OPPTS) Harmonized Guideline 835.3110 - Ready Biodegradability
- OCSPP (formerly OPPTS) Harmonized Guideline 835.3140 - Ready Biodegradability - CO2 in Sealed Vessels (Headspace Test)
- OECD Test Guideline 301 A: DOC Die-Away
- OECD Test Guideline 301 B: CO2 Evolution (Modified Sturm Test)
- OECD Test Guideline 301 C: Modified MITI (I) (Ministry of International Trade and Industry, Japan)
- OECD Test Guideline 301 D: Closed Bottle
- OECD Test Guideline 301 E: Modified OECD Screening
- OECD Test Guideline 301 F: Manometric Respirometery
- OECD Test Guideline 310: CO2 in sealed vessels (Headspace Test)

7.2 Acceptable documentation demonstrating Ready Biodegradability that is collected during a literature review may include MSDS, laboratory test reports, government databases, and peer reviewed scientific articles.

7.3 If no data on biodegradability are available for the product ingredient, the manufacturer shall test the whole product and demonstrate Ready Biodegradability using any of the OCSPP or OECD acceptable test methods listed above.

7.4 Testing shall be performed by a laboratory that is accredited to ISO/IEC 17025 and shall have the test methods identified within this Standard listed in the scope of their accreditation. Testing from a non-accredited laboratory may be accepted if the laboratory is approved by the certification body.

[1] SCS Standards may approve alternative methods. Users can submit requests to the scheme via the website at www.scsstandards.org/interpretation-variation-request

## 8. Eutrophication and Phosphates

Organic and inorganic phosphate compounds are known to contribute to eutrophication of fresh water and estuarial ecosystems. To align with US EPA Safer Choice Master Criteria, this Standard includes a restriction for these compounds due to the potential for direct disposal of products down the drain that can make their way into aquatic ecosystems.[2]

8.1 The product shall not contain phosphate compounds (measured as elemental phosphorous) that total at or above 5000 ppm (0.5%) in the product.

8.2 The product shall not contain inorganic phosphate compounds at any level.

[2] Source: https://www.epa.gov/sites/default/files/2013-12/documents/dfe_master_criteria_safer_ingredients_v2_1.pdf

## 9. Acute Aquatic Toxicity

9.1 The manufacturer shall demonstrate, to a high degree of certainty based on current knowledge established through submittal of documentation or the literature review, that the product components and their degradation products do not demonstrate acute aquatic toxicity.

9.2 A product ingredient is considered not toxic to aquatic life if it meets the criteria of acute $LC_{50}$ for algae, daphnia, or fish greater than or equal to 100 mg/L through a literature review or acute aquatic toxicity testing of the whole product.

9.3 If a product ingredient demonstrates acute aquatic toxicity of less than 100 mg/L for algae, daphnia, or fish, the product may be eligible for certification if:

9.3.1 The product ingredient is included on the US EPA's Safer Chemical Ingredient List (SCIL)3 with a status of a green full-circle, green half-circle, or yellow triangle;[4] and,

9.3.2 The product ingredient represents no greater than 1% of the dry weight or volume of the finished product formula.

9.4 If no data on acute aquatic toxicity are available for a product ingredient, the manufacturer shall test the whole product and demonstrate acute aquatic toxicity of greater than or equal to 100 mg/L for algae, daphnia, or fish using one of the following acceptable test methods:[5]

- OECD Test Guidelines 203: Fish, Acute Toxicity Test
- OECD Test Guidelines 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test
- OECD Test Guidelines 202: Daphnia sp. Acute Immobilisation Test

9.5 Testing shall be performed by a laboratory that is accredited to ISO/IEC 17025 and shall have the test methods identified within this Standard listed in the scope of their accreditation. Testing from a non-accredited laboratory may be accepted if the laboratory is approved by the certification body.

9.6 Surfactant components that demonstrate an acute aquatic toxicity less than 100 mg/L and are not on the US EPA's SCIL may still be eligible for certification in exceptional circumstances, i.e., when the following criteria are met:

9.6.1 The manufacturer can reasonably demonstrate that no suitable substitute exists for the surfactant used;

[3] https://www.epa.gov/saferchoice/safer-ingredients
[4] See EPA website for definitions: https://www.epa.gov/saferchoice/safer-ingredients#greencircle
[5] Other test methods may be considered acceptable if the test conditions match the OECD method(s).

9.6.2 The surfactant component represents no greater than 1% of the dry weight or volume of the finished product mixture; and

9.6.3 The acute aquatic toxicity of the surfactant component(s) meets the following criteria in Table 1, which are modified from the US EPA Safer Choice Criteria for Surfactants.[6]

**Table 1. Toxicity Values and Rates of Degradation for Surfactants**

| Acute Aquatic Toxicity ($L/E/IC_{50}$ Value) | Rate of Biodegradation | Acceptable Component? |
|---|---|---|
| ≤1 ppm | n/a | No |
| >1 ppm and ≤10 ppm | Ready Biodegradability without Products of Concern | Yes |
| >10 ppm | Ready Biodegradability | Yes |

[6] Source: https://www.epa.gov/saferchoice/safer-choice-criteria-surfactants

## 10. Carcinogens

10.1 The product shall not contain chemicals at or above 1000 ppm (0.1%) in the product formulation that are classified as a carcinogen according to the hazard or risk classifications listed in Table 2 below.

**Table 2. Hazard & Risk Classification Restrictions for Carcinogenicity[7]**

| Authoritative Body | Restricted Classifications |
|---|---|
| National Toxicology Program (NTP)[8] | Known to be Human Carcinogen; Reasonably Anticipated to be Human Carcinogen |
| U.S. Environmental Protection Agency (EPA) IRIS Carcinogens[9] | (2005/1999) Carcinogenic to humans, Likely to be carcinogenic to humans, or Suggestive evidence of carcinogenic potential<br>(1996) Known/Likely<br>(1986) Group A – Human Carcinogen, Group B – Probable human carcinogen, or Group C – Possible human carcinogen |
| International Agency for Research on Cancer (IARC)[10] | Group 1 – Carcinogenic to humans<br>Group 2A – Probably carcinogenic to humans<br>Group 2B – Possibly carcinogenic to humans |
| EU - REACH Annex XVII CMRs[11] | Category 1 – Known to be carcinogenic to humans<br>Category 2 – Should be regarded as if carcinogenic to humans<br>Category 3 – Cause for concern for humans owing to possible carcinogenic effects |
| EU Risk Phrases[12] | R45: May cause cancer<br>R49: May cause cancer by inhalation<br>R40: Limited evidence of a carcinogenic effect<br>*And all combination risk phrases containing one or more of the above.* |
| EU Classification, Labeling, and Packaging (CLP) | H350: May cause cancer<br>H350i: May cause cancer by inhalation<br>H351: Suspected of causing cancer |
| NIOSH Occupational Carcinogen List | http://www.cdc.gov/niosh/topics/cancer/npotocca.html |
| Globally Harmonized System (GHS) | Category 1A – Known to have carcinogenic potential for humans<br>Category 1B – Presumed to have carcinogenic potential for humans<br>Category 2 – Suspected human carcinogens |

[7] Source: EPA's Safer Choice Program Master Criteria for Safer Ingredients (https://www.epa.gov/sites/default/files/2013-12/documents/dfe_master_criteria_safer_ingredients_v2_1.pdf)
[8] Source: https://ntp.niehs.nih.gov/whatwestudy/assessments/cancer/roc
[9] Source: https://cfpub.epa.gov/ncea/iris/search/
[10] Source: https://monographs.iarc.who.int/list-of-classifications/
[11] Source: https://echa.europa.eu/substances-restricted-under-reach
[12] Source: https://echa.europa.eu/advanced-search-for-chemicals

## 11. Mutagens

11.1 The product shall not contain chemicals at or above 1000 ppm (0.1%) in the product formulation that are classified as a mutagen according to the hazard or risk classifications listed in Table 3 below.

**Table 3. Hazard & Risk Classification Restrictions for Mutagenicity[13]**

| Authoritative Body | Restricted Classifications |
|---|---|
| EU - REACH Annex XVII CMRs[14] | Category 1 – Substances known to be mutagenic to humans<br>Category 2 – Substances which should be regarded as if they are mutagenic to humans<br>Category 3 – Substances which cause concern for human owing to possible mutagenic effects |
| EU Risk Phrases[15] | R46: May cause heritable genetic damage<br>R68: Possible risk of irreversible effects<br>*And all combination risk phrases containing one or more of the above.* |
| EU Classification, Labeling, and Packaging (CLP)[14] | H340: May cause genetic defects<br>H341: Suspected of causing genetic defects |
| Globally Harmonized System (GHS)[14] | Category 1A – Chemicals known to induce heritable mutations in germ cells of humans<br>Category 1B – Chemicals which should be regarded as if they induce heritable mutations in the germ cells of humans<br>Category 2 – Chemicals which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans |

[13] Source: EPA's Safer Choice Program Master Criteria for Safer Ingredients (https://www.epa.gov/sites/default/files/2013-12/documents/dfe_master_criteria_safer_ingredients_v2_1.pdf)
[14] Source: https://echa.europa.eu/substances-restricted-under-reach
[1515] Source: https://echa.europa.eu/advanced-search-for-chemicals

## 12. Reproductive Toxins

12.1 The product shall not contain chemicals at or above 1000 ppm (0.1%) in the product formulation that are classified as a reproductive toxin according to the hazard or risk classifications listed in Table 4 below.

**Table 4. Hazard & Risk Classification Restrictions for Reproductive Toxicity[16]**

| Authoritative Body | Restricted Classifications |
|---|---|
| EU - REACH Annex XVII CMRs[17] | Category 1 – Known to impair fertility in humans or known to cause developmental toxicity in humans<br>Category 2 – Should be regarded as if they impair fertility in humans or cause developmental toxicity to humans<br>Category 3 – Cause concern for human fertility or possible developmental toxic effects |
| EU Risk Phrases[18] | R60: May impair fertility<br>R61: May cause harm to the unborn child<br>R62: Possible risk of impaired fertility<br>R63: Possible risk of harm to the unborn child<br>R64: May cause harm to breastfed babies<br>And all combination risk phrases containing one or more of the above. |
| EU Classification, Labeling, and Packaging (CLP)[17] | H360: May damage fertility or the unborn child<br>H361: Suspected of damaging fertility or the unborn child<br>H362: May cause harm to breast-fed children |

[16] Source: US EPA, "Criteria for Biodegradability Claims on Products Registered under FIFRA"
[17] Source: https://echa.europa.eu/substances-restricted-under-reach
[18] Source: https://echa.europa.eu/advanced-search-for-chemicals

## 13. Persistent, Bioaccumulative, Toxic (PBT) Chemicals

13.1 The product shall not contain any PBT chemical(s) at or above 1000 ppm (0.1%) that are listed on the following authoritative hazard lists:

- EU REACH Substances of very High Concern (SVHCs) (Authorisation and Candidate lists)[19]
- US EPA – Toxics Release Inventory (TRI) PBTs[20]
- UNEP Stockholm Convention – Persistent Organic Pollutants (POPs)[21]

[19] Annex XIV of REACH ("Authorisation List") (https://echa.europa.eu/authorisation-list); and Candidate List of substances of very high concern for Authorisation (https://echa.europa.eu/candidate-list-table)
[20] https://www.epa.gov/toxics-release-inventory-tri-program/persistent-bioaccumulative-toxic-pbt-chemicals-covered-tri
[21] https://www.pops.int/TheConvention/ThePOPs/AllPOPs/tabid/2509/Default.aspx

## 14. Claims and Labelling

14.1 The biodegradability claim is allowed on products that have met all requirements in the SCS-104 Standard.

Example claim: “Certified Biodegradable. Breaks down into $CO_2$, minerals, and water.”

14.2 All uses of the Certification Label or references to the certification either on-product or in product advertising shall be conducted in conformance with U.S. Federal Trade Commission guidelines or other national guidelines if outside of the U.S.

14.3 The manufacturer shall comply with the requirements of the Labeling and Language requirements of the certification body at all times.

14.4 A certified and non-certified product cannot have the same trade name or trademarked designation.

## 15. Complaints and Appeals

15.1 A manufacturer has the right to appeal a certification decision within 30 days of receiving the final report. Appeals shall be submitted to the certification body for evaluation and resolution.

15.2 Complaints shall be handled directly by the certification body. If a satisfactory resolution is not found, a complaint may be elevated to SCS Standards.