COSMOS

Trust in organic and natural cosmetics

COSMOS ORGANIC

COSMOS NATURAL

COSMOS-standard

COSMOS-standard
TECHNICAL GUIDE

Version 3.0 – 1 September 2018

Developed by leading associations and certifiers in organic and natural cosmetics

Table of Contents

1. INTRODUCTION

The information in this Technical Guide is intended to give guidance on interpreting technical points and criteria in the COSMOS-standard.

The numbering follows the same numbering as in the COSMOS-standard.

3. SCOPE OF OUR SERVICE

Table 1: In which case should I apply for certification?

Category of operator/client	Required to apply for certification	Not required to apply for certification
Distributor/ Brand owner	You are a brand owner and the person responsible for the release to market	▪ You are just a distributor and sell other brands' products but you are not responsible for the release to market ▪ You are the brand owner but not the person responsible for the release to market. The person responsible is certified and manages the complete process (production, sale and communication related to certified products) ". ▪ You are already certified by a COSMOS authorised certification body
Manufacturer/ sub-contractor	You are the person responsible for the release to market of the products you manufacture	▪ You manufacture products on behalf of a COSMOS certified brand owner ▪ You are already certified as sub-contractor by a COSMOS authorised certification body Note: in both cases the evaluation of this activity must be included
Handler	Handlers do not have an obligation to be certified, however, there must be evaluation of this activity somewhere	

Independent of the obligations in the table, voluntary application for certification is possible.

4. DEFINITIONS

« Base formulas »

Mixtures of ingredients formulated as a basis for making cosmetic products, e.g. Shampoo bases, soap bases, cream bases.

« Organic »

Examples of those organic standards and control systems that are considered as complying with the second bullet point in the organic definition (referring to Codex Alimentarius GL 32) are:

- National Program for Organic Production (NPOP), India
- National Organic Program (NOP), USA
- Canada Organic Regime (COR)
- Australian National Food standards
- Brazilian Organic Regulation
- Japanese Agricultural Standard (JAS).

5. GENERAL

If pesticide or other contamination is detected in an ingredient or product, then the authorised certification body must be informed. The contamination must be investigated to try to establish its cause and extent. The certification body will decide whether the ingredient/product keeps its certified status.

5.1.1 Nanomaterials

Particles with a coating (e.g. TiO_2 with coating) are allowed when the minimum particle size is above 100 nm. Otherwise, all nanomaterials, whether required to be labelled or not according to European cosmetic regulations, are not allowed.

TiO_2 and ZnO used as UV-filters are acceptable if the following conditions are met:

- The particle size distribution (number of particles) under 100 nm must be less than 50%
- The mass distribution (weight of particle fraction) under 100 nm must be less than 10%
- The raw material has to fulfill the opinions of the Scientific Committee on Consumer Safety (SCCS) published on, respectively, Titanium Dioxide (nano form)1, and Zinc Oxide (nano form)1
- In any case, TiO2 and ZnO as UV filters cannot be used in spray applications, such as aerosol, pump dispenser (but excluding those without spray nozzle), as recommended in SCCS opinion2.

[1] SCCS/1516/13 Revision of 22 April 2014 and SCCS/1489/12 Revision of 11 December 2012 http://ec.europa.eu/health/scientific_committees/consumer_safety

[2] Opinion for clarification of the meaning of the term "sprayable applications/products" for the nano forms of Carbon Black CI 77266, Titanium Oxide and Zinc Oxide.

5.1.2 Genetically Modified Organisms (GMOs)

The COSMOS-standard does not allow the use of GM plants to obtain cosmetic raw materials and ingredients. Therefore the manufacturer must indicate in the Raw Material questionnaire the name of the plant and the country of origin of the vegetable source which was used to produce that particular cosmetic raw material or ingredient.

Certification bodies will assess the GMO risk according to a common Geographical Risk Matrix developed by the Soil Association. If necessary, they may require additional information from the manufacturer.

The Regulation that COSMOS is referring to when discussing Genetic Modification is Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. Article 2 gives definitions of GMO. Annex 1A summarises what techniques are included as genetic modification.

6. ORIGIN AND PROCESSING OF INGREDIENTS

6.1.3 Physically processed agro-ingredients (PPAI)

Ingredients of animal origin

Milk, honey, beeswax, etc. are ingredients of animal origin that are allowed (as long as the processes comply with Appendices I, and in the case of CPAI also II, and other relevant criteria of the Standard).

Other ingredients of animal origin will be considered after submission of additional documents.

Bee venom is prohibited.

Snail slime is prohibited when produced using salt and electricity, but is otherwise permitted if the details are checked by the certification body.

6.1.4 Chemically processed agro-ingredients (CPAI)

Atom economy – Reaction mass efficiency

If several products are obtained (i.e. the oil is saponified into glycerol and fatty acid) and all products are used at the end of the manufacturing process, the weight of each of the products must be considered for the calculation, even if only one item is submitted as the raw material.

Stem cells

Stem cells, used as active ingredients only, are allowed as long as the culture media is also compliant with the standard. The following must be from natural or microbiological origin (and not be synthetic): substrates, culture mediums. The use of inputs (eg. hormones, growth factors or similar components) at low levels (ppm scale) is permitted in stem cell culture mediums. These inputs have to be metabolized/removed and not detectable in the final product. A specific statement from the supplier must be provided.

Ingredients from biotechnology

The culture medium must be in conformity with the COSMOS-standard. Therefore, each ingredient in the medium must be from mineral, vegetable, microbial, animal or marine origin (meeting the criteria of the Standard) and, where appropriate, must be guaranteed non-GMO origin.

Biotechnological processes are allowed as far as no genetically modified bacteria, fungi, yeast, etc. are used.

If enzymes derived from GMOs are used to produce the cosmetic ingredient, the manufacturer must prove they comply with the following conditions:

- Enzymes from GMOs are purified before use
- The GMOs must be used in closed vessel
- The GMOs are deactivated after the process
- Risk assessment of impact of GMO release into the environment is made
- Risk plan to deal with accidental release of GMOs into the environment is established
- PCR (-) or any other method must be provided to prove that no DNA of the GMO is present in the final raw material.

Defoamers and other auxiliaries can be used in biotechnology (as long as there are removed in final raw material).

Non-persistent, bio-accumulative and toxic products

Substances, known to be bio-accumulative and not biodegradable are prohibited. Those are substances that do not pass OECD 301; => TEGEWA classification III = high waste water impact.

6.2 Calculation rules for organic percentages - examples

6.2.3 Physically processed agro-ingredients (PPAI)

Alcohol as a single ingredient

When validating alcohol as a raw material (from the cosmetic manufacturer) the actual percentage of alcohol is counted as the CPAI % (and CPAI ORG % if the alcohol is organic). So the dilution and purification is taken in to account and the organic alcohol content could be various percentages. Note, if organic, % CPAI = % ORG CPAI.

The calculation of CPAI is made by weight (remaining water, etc) and not by volume.

Alcohol used in an extract

Organic alcohol (even if completely removed) must be used in organic extracts. If non-organic alcohol is used during the process, the ingredient cannot have an organic contribution.

Alcohol and extracts have to respect Appendix VI and VII for COSMOS ORGANIC certification.

As it is often difficult to obtain information about dilution and purification etc., in organic alcohol for extracts (already certified to organic farming) the alcohol content is counted as 100% organic (100% CPAI / 100% ORG CPAI). This is for consistency.

Aqueous extract (including hydrolates)

Standard:

Ratio = [organic fresh plant / (final extract - solvents)]

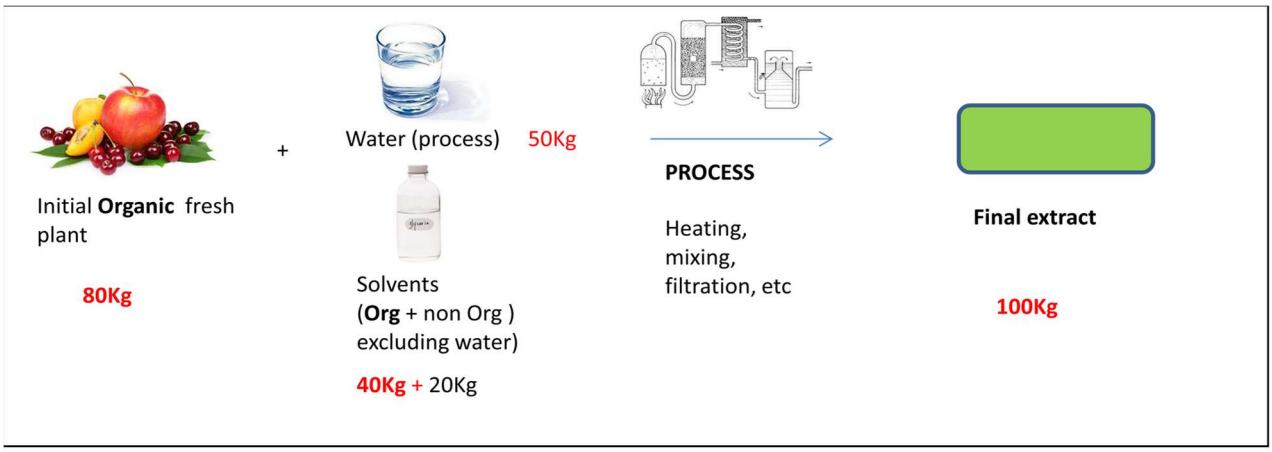
If the ratio is greater than 1, then it is counted as 1.

% organic = {[ratio X (extract - solvents) / extract] + [organic solvents / extract]} X 100

- **Organic alcohol in organic extract**
- **No mixture of organic and non organic quality of the same plant**

Example 1:

Ratio: 80 / (100 - 60); Ratio >1, counted as 1



% Organic = {[1 X (100 - 60) / 100] + [40 / 100]} X 100 = **80%**

Example 2:

Used:

Organic dried flowers:	2.5 Kg → equivalent to 11.25 Kg of organic fresh plant
Water:	95.7 Kg
Citric Acid:	1.5 kg (CPAI)
Sodium benzoate:	0.2 Kg (NNI)
Potassium Sorbate:	0.1 Kg (NNI)
Total Extract obtained:	100 Kg

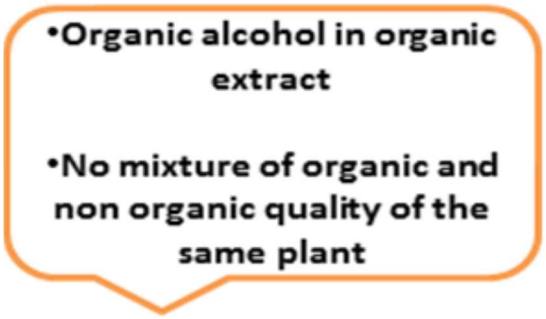
% ORG PPAI= (organic fresh plant/ extract) X 100 = 11.25%
% NNI = 0.3%
% CPAI = 1.5%
% ORG = 11.25%
% Natural origin = 100 - NNI = 99.7%

Non aqueous extracts (Oleolita/Macerate)

For non-water based extracts, the organic percentage is calculated as follows:

% organic = (organic plant* + organic starting solvents) / (plant* + all starting solvents) X 100

*fresh or dried plant



Example 1:

Used: 45 Kg organic fresh plant and 55 Kg organic oil

% Organic = (45 + 55) / (45 + 55) x 100

% PPAI (oil and plant) = 100%
% ORG PPAI (oil and plant) = 100%
% NNI = 0%
% CPAI = 0%
% CPAI ORG = 0%
% ORG = % ORG CPAI + % ORG PPAI = **100%**

Example 2:

If the plant is not available in organic form and not listed in Appendix VI, it can be permitted in COSMOS Organic products. As well as this, the overall product PPAI percentage minimums need to be met.

Used: 45 Kg non-organic fresh plant and 55 Kg organic oil

% Organic = 55/ (45 + 55) X 100

% PPAI (plant and oil) = 100%
% ORG PPAI (oil) = 55%
% NNI = 0%
% CPAI = 0%
% CPAI ORG = 0%
% ORG = % ORG CPAI + % ORG PPAI = 55**%**

Example 3:

If the oil solvent is not in organic form and not listed in Appendix VI, it can be permitted in COSMOS Organic products. As well as this, the overall product PPAI percentage minimums need to be met.

Used: 45 Kg organic fresh plant and 55 Kg non-organic oil

% Organic = 45/ (45 + 55) X 100
% PPAI (plant and oil) = 100%
% ORG PPAI (from plant) = 45%
% NNI = 0%
% CPAI = 0%
% CPAI ORG = 0%
% ORG = % ORG CPAI + % ORG PPAI = 45**%**

Example 4:

"Complex mixture" (three or more components, see Technical Guide Appendix VI and VII) in COSMOS ORGANIC products.

Note: "Complex mixture" included in a COSMOS ORGANIC product must have all the components from organic agriculture if all the components are listed in appendixes VI/VII. If "complex mixture" contains at least one component not listed in the appendixes VI/VII, then none of the components may be from organic agriculture.

Mixture of organic plant and two solvents (solvent A: organic; solvent B: non-organic).

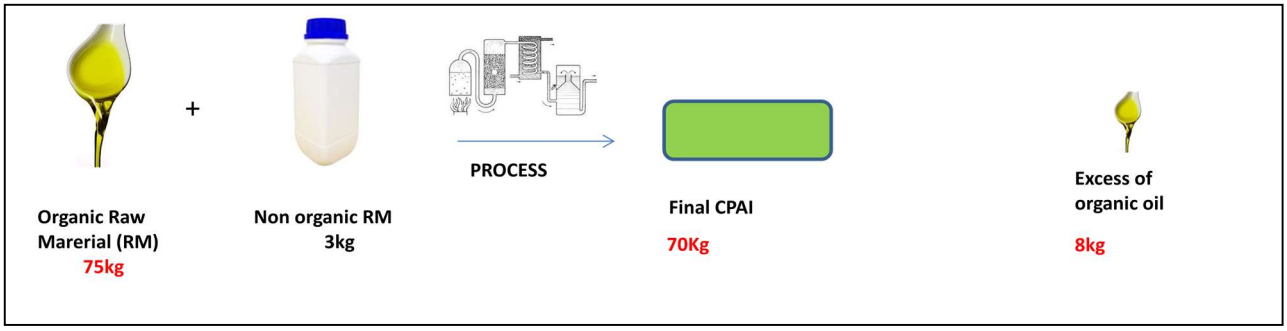
Used: 40 kg organic fresh plant and 40kg organic oil (solvent A) and 20kg non-organic oil (solvent B)

% Organic = (40 + 40) / (40 + 40 + 20) X 100

% PPAI (plant and oils) = 100%
% ORG PPAI (from plant and one of two oils) = 80%
% NNI = 0%
% CPAI = 0%
% CPAI ORG = 0%
% ORG = % ORG CPAI + % ORG PPAI = 80**%**

6.2.4 Chemically processed agro-ingredients

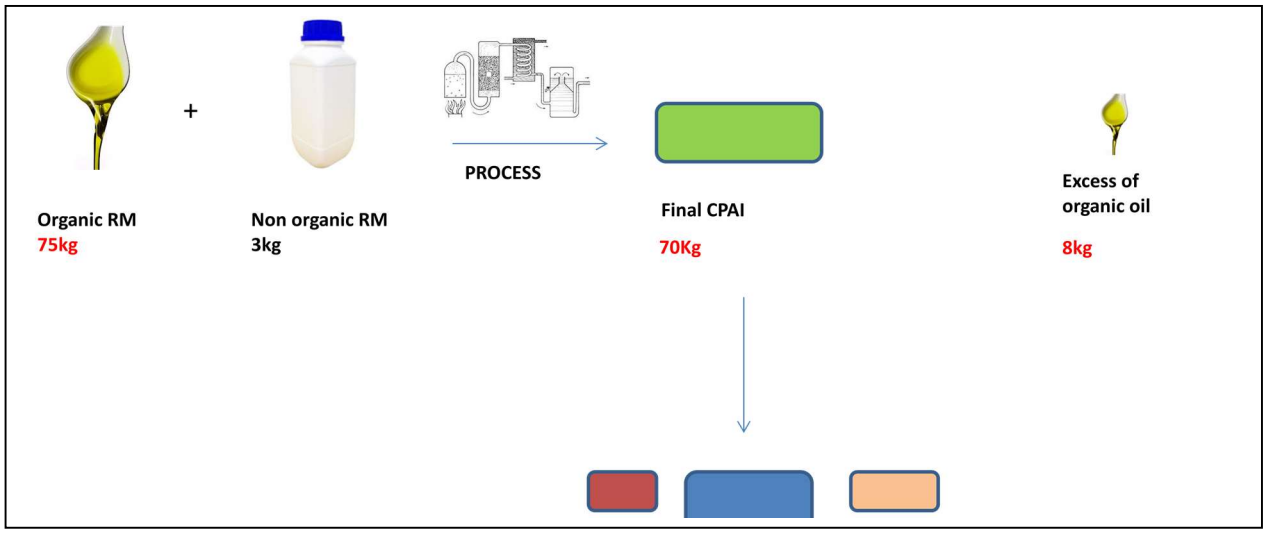
General case



Standard:
% organic = [(all organic starting primary raw materials - organic starting primary raw materials in excess) / (all starting primary raw materials – all starting primary raw materials in excess)] X 100

Example:
% Organic = [(75 - 8) / (75 + 3 - 8)] X 100 = **95.7%**

Specific case

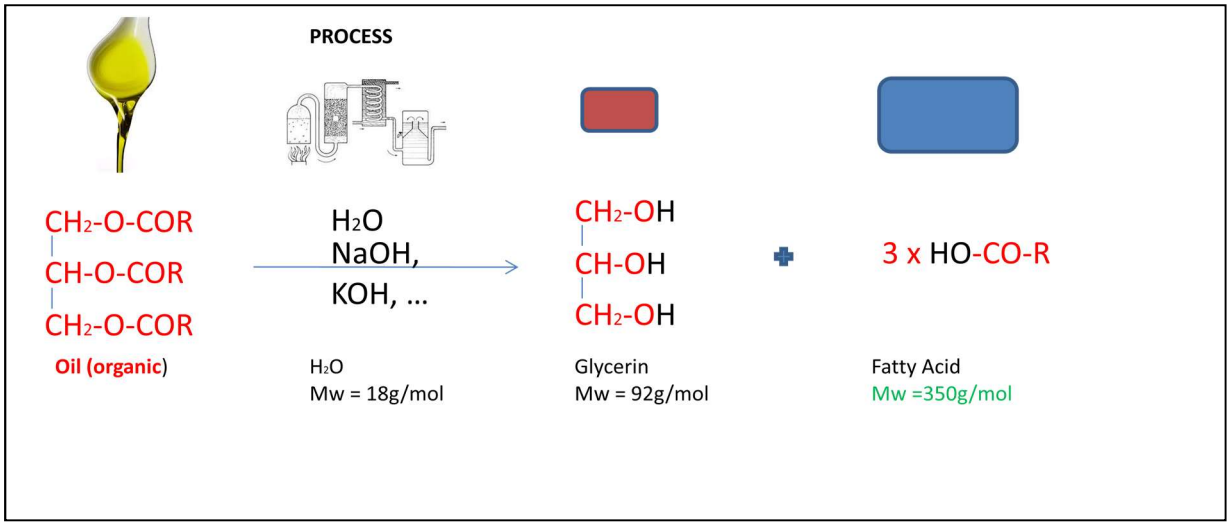


If the final CPAI obtained contains several different molecules, the organic % of each molecule can be different.

The main CPAI calculation can be used if the final product is a single ingredient, OR if the resulting mixture is not separated.

If the result produces more than one material, specific calculations are made based on the molecules obtained (considering the molecular organization, see below).

Saponification example



Example:

% organic Glycerin = Organic part / total = (Mw Glycerin – Mw 3 hydrogen) / Mw Glycerin

= (92 - 3) / 92
= **96.7%**

% organic Fatty Acid (FA) = Organic part / total = (Mw FA – Mw OH) / Mw FA

= (350 - 17) / 350
= **95.1 %**

Hydroglyceric extracts

To calculate the organic percentage of the total extract, it is necessary to calculate the PPAI organic percentage and CPAI organic percentage separately.

1) % ORG PPAI:

First step:

Ratio = [organic fresh plant / (extract - solvents)

If the ratio is greater than 1, then it is counted as 1.

Second step:

% organic = {[ratio X (extract - solvents) / extract] + [organic solvents / extract]} X 100

2) % ORG CPAI:

Glycerin in formula X organic index of the glycerin (0.967)

The total percentage of organic in an hydroglyceric extract is the sum of CPAI ORG% and PPAI ORG %

Example

Used:

Organic Plant seed extract (organic fresh plant) = 0.25 Kg

Organic glycerin = 0.7 Kg (100% CPAI and 96.7% CPAI ORG)

Water = 0.75kg

Total extract obtained = 1Kg including: Potassium Sorbate = 0.5 % (NNI) and Sodium Benzoate = 0.5 % (NNI)

% NNI= 1%

% CPAI = % Glycerin in extract = 70%

% CPAI ORG = % Glycerin in extract X 0.967 = 67.7%

R = [org fresh plant/(extract- solvent)] = [0.25Kg / (1Kg – 0.7Kg)] = 0.8

% PPAI = % PPAI ORG = (org fresh plant/extract) X 100 = (0.25Kg / 1Kg) X 100 = 25%

% ORGANIC = % PPAI ORG + % CPAI ORG = 92.7%

% NATURAL ORIGIN = 100 - % NNI = 99%

Hydroalcoholic extracts

To have the organic percentage of the total extract, it is necessary to calculate separately the PPAI organic percentage and CPAI organic percentage.

1) % ORG PPAI:

First step:

Ratio = [organic fresh plant / (extract - solvents)
If the ratio is greater than 1, then it is counted as 1.

Second step:

% organic = {[ratio X (extract - solvents) / extract] + [organic solvents / extract]} X 100

2) % ORG CPAI:

% Org Alcohol – % denaturing agent

NB: the percentage of denaturing agent is counted as non-natural ingredient

Example:

Organic fresh plant = 80 kg

Water = 50 Kg

Extract obtained = 100 Kg with denaturated organic Alcohol = 60% (including denaturating agent at 1.2%: 58.8% CPAI + 1.2% NNI)

Ratio = 80 / (100- 60) = 2 --> ratio = 1
% ORGANIC = {[1 X (100-60) / 100] + [58.8/100]} X 100 = % PPAI ORG + % CPAI ORG = 98.8%
PPAI % = 100 – % CPAI – % NNI = 40%
PPAI ORG % = 40%
CPAI = 58.8%
CPAI ORG = 58.8%
NNI = 1.2%

Calculation of synthetic moieties

Example of a reference of cocoamidopropyl betaine at 30% in water:

Molecular weight of the whole molecule = 342 g/mol
Molecular weight of the petrochemical part = 159 g/mol

1. % of petrochemical moiety of the molecule = 159/342 X 100 = 46.4%
2. % of petrochemical moiety of the reference = 0.3 X 0.464 X 100 = 13.9%

➔ The reference would be considered 16.1% CPAI and 13.9% synthetic moiety.

8. STORAGE, MANUFACTURING AND PACKAGING

A company that fills samples in sachets for 'free giveaway' (eg. at trade shows) does not have to be audited or certified by a COSMOS authorised certification body, provided that the batch has been manufactured by a company that is certified.

9. ENVIRONMENTAL MANAGEMENT

9.2 Cleaning and Hygiene

Plant based cleaning products certified according to one of the following organic programmes may be used: Ecocert, Ecogarantie, ICEA, Nature & Progress, Soil Association, United States National Organic Program (NOP), or Australian Organic Standards (AOS).

Products endorsed by labels including Nordic Swan or Ecolabel may be used if the natural origin of their ingredients has been confirmed.

Other standards for cleaning products can be submitted to the Technical Committee for assessment.

If national regulations force the use of specific cleaning products, requests for exemption can be submitted to the Technical Committee.

11. CERTIFICATION AND APPROVAL

11.1 Certification

Documentary evaluation and preparation of on-site audits

For the certification scope (Scope 1), approval for all ingredients, formulas, labels and packaging used in certified products or ingredients is required.

Assessment of each ingredient is made through a number of different documents including technical data sheet, and a raw material questionnaire summarising all requested compliance points, and/or organic certificates.

During the audit, any non-conformities will be identified (though additional ones may be identified during the evaluation process). They are classified according to 2 categories:

"Minor" non-conformities

A minor non-conformity is one that does not alter the characteristics of the product to be certified, and/or does not conflict with the principles of the COSMOS-standard and its most important requirements and is not considered to be misleading to consumers.

"Major" non-conformities

A major non-conformity is one that alters or may later alter the characteristics of the product to be certified, and/or conflicts with the principles of the COSMOS-standard and its most important requirements and/or can be considered as misleading to consumers. Some major non-conformities may lead to critical measures (see correction plan) and de-certification of the product, or in extreme cases withdrawal of certification from the client.

Correction plan

The correction plan lists non-conformities and classifies them according to their degrees of severity ("major" or "minor"). It also identifies, for each non-conformity, the consequence for the certification, appropriate actions to be taken and any further conditions.

The consequence for the certification is defined according to the nature and severity of the non-conformity as well as its frequency and scale and the risk of fraud.

Appropriate measures may be:

- Continuation of certification under conditions
- Reduction of the scope of certification
- Suspension of the certification
- Withdrawal of the certification.

11.2 Approval of ingredients

Raw material questionnaire

For all non-organic raw materials (Scope 2), each certification body will use a questionnaire based on common questions defined by COSMOS for raw material approval. Please note that not all certification bodies are accredited for Scope 2.

Non organic raw materials available on the database

Compliant non-organic raw materials are available on www.cosmos-standard-rm.org.

Ingredients published on the COSMOS database are recognized and accepted by all certification bodies.

NB This database is password protected and is only available to applicants and clients of authorised certification bodies and to members of COSMOS member associations. Please contact your authorised certifier or association for the password.

Raw materials identified with an asterisk* relate to Appendix II (petrochemical solvents and/or halogenation processes in activating steps) or Appendix V.2. (petrochemical solvents for extraction of PPAI), Appendix V.3 (ingredients containing petrochemical moieties) or Appendix V.4 (other agro-ingredients under derogation). The same INCI can be with or without this identification depending on the manufacturing process.

On periodical review of the raw material database these raw materials may be removed, when raw materials which do not use these processes become available in sufficient amounts.

Re-assessment of non-organic raw materials needs to be made at least every 3 years (or as soon as any change) in order to confirm any change on process and origins of accepted raw materials. This can be done through a declaration.

Ingredients changing of status

For several reasons (change in process, error, etc), ingredients may change status (become non-compliant or remain compliant but with different percentages that may affect the final ingredients/products percentages). These cases are considered by the Technical Committee who may decide to allow a transition period, depending on the context, impacts and potential alternative. Non-compliant ingredients will be removed from the database and cannot be used in any new formula.

Appendix II

BIOTECHNOLOGY PROCESSES: (Fermentation, stem cells culture, etc)
Ammonia/Ammonium salts and other Nitrogen sources are allowed; Sodium Selenite is allowed as Selenium source.

NEUTRALIZATION: (allowed to obtain Na, Ca, Mg and K salts)

Ammonia is allowed in the neutralization process to form Ammonium Lauryl Sulphate and Ammonium Glycyrrhizate (and any other Ammonium salt – as long as the other criteria including biodegradability and aquatic toxicity are fulfilled).

Appendix III

All caustic sodas and potashes (INCI: Sodium Hydroxide, Potassium Hydroxide) are allowed. The decision will be reviewed depending on any technical developments.

Appendix VI and VII

PHYSICALLY PROCESSED AGRO-INGREDIENTS THAT MUST BE ORGANIC (Appendix VI)

Ingredients that must be ORGANIC for COSMOS ORGANIC certification (which belong to the lists):

- No mixture (one component)
    - Ingredients must be used in organic quality according to Appendix VI (example: Sunflower oil or Wax)
    - This also applies to single ingredients which are stabilized with additives or contain preservatives
      (example: Sunflower oil, stabilized with Tocopherol);

- Non-complex/simple mixture (two components) – Hydrolates with two plants are in this category
    - Ingredients must be used in organic quality according to Appendix VI (example: Herbal extract/macerate with Sunflower oil)
    - If one of the ingredients is added as a solvent to other active ingredients, to make them available, the ingredient does not need to be used in organic quality (example: Tocopherol dissolved in Sunflower oil);

- Complex mixture (three and more components);

- The criteria does not apply except when all certifiable ingredients of the mixture are listed in Appendixes VI/VII.

CHEMICALLY PROCESSED AGRO-INGREDIENTS THAT MUST BE MADE FROM ORGANIC ORIGIN AGRO-INGREDIENTS (Appendix VII)

Ingredients that must be ORGANIC for COSMOS ORGANIC certification (which belong to the lists):

- No mixture (one component)
    - This also applies to single ingredients which are stabilized with additives or contain preservatives
      (example: Ethyl alcohol with denaturing agent);

- Non-complex/simple mixture (two components) – Alcoholic extract are in this category
    - Ingredients must be used in organic quality according to Appendix VI (example: Herbal extract);

- Complex mixture (three and more components)
    - The criteria does not apply except when all certifiable ingredients of the mixture are listed in Appendixes VI/VII.

Shortage of an organic raw material

In the case of a shortage of an organic raw material listed in appendix VI and VII certification bodies may grant exemptions according to the rules as laid down in the Control Manual and below.

The client needs to inform the certification body that none is available, why and, if known, provide details of how long (e.g. poor harvest for certain year). The certification body needs to check their records and with the other partners that none is available. The client then needs to provide three written confirmations from reputable organic suppliers that the material is not available organically. Labels and promotional materials have to be changed temporarily so that it is clear at point of sale that the material's organic status has changed (for example by over-stickering of product labels, or a clear indication on the client's website for the product etc.). These indications must be verified by the certification body. Provided all of the above has been followed permission can be granted for a certain period.

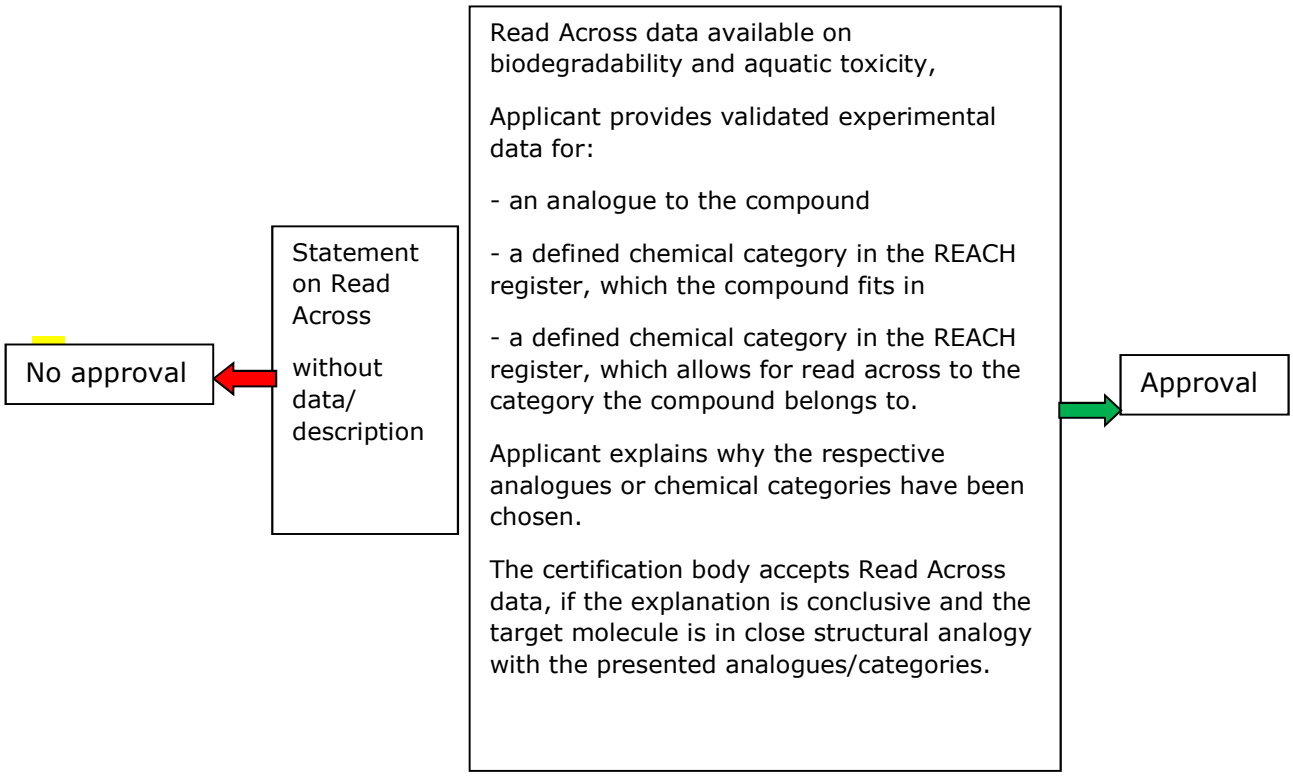
Appendix VIII

Follow this link for available data of compounds registered for REACH:
http://www.echa.europa.eu/web/guest/information-on-chemicals/registered-substances.

What to do if no data is available

If the required ecological data (biodegradation and aquatic toxicity) is not available in the literature (ECHA database or other publication sources), the following alternative methods can be used:

- Analogy approach - read across:



Structural analogy of molecules can be determined based on:

- The functional groups present in a molecule
- The chemical class the molecule belongs to
- The carbon skeleton of the molecule; the most reactive functional group in the molecule determines the chemical class membership.

With the same functional groups present, properties do not differ too much with slight changes in the carbon skeleton (4 to 8 carbons).

For Read Across data, only really close analogues based on the above basic criteria will be accepted.

Example

Myristyl Myristate: REACH category: Fatty acids, C10-18 and C12-22-unsaturated, C14-18 and C16-18-unsaturated alkyl esters.

- QSAR (Quantitative Structure-Activity Relationship):

Data coming from QSAR computational approach can be accepted under the following conditions:

- The results provided are derived from a validated model (link to Reach guidance)
- The chemical falls under the applicability domain of the validated model.

Both alternative methods have to be well documented to be accepted.

COSMOS-standard AISBL, Rue du Commerce 124, 1000 Brussels, Belgium

info@cosmos-standard.org

www.cosmos-standard.org