

COSMOS STANDARD Technical Guide

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www.cosmos-standard.org

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INTRODUCTION

This Guide is for companies to better understand the COSMOS-standard requirements through examples and illustrations of some of the criteria. It provides interpretations and clarifications approved by COSMOS-standard Committees.

The information in this Technical Guide is presented in 2 sections:

- **SECTION 1** is an overview of key requirements for COSMOS signatures. This is a summary based on all the relevant criteria presented in the COSMOS-standard, the COSMOS-standard Control Manual and the COSMOS-standard Labelling Guide
- **SECTION 2** gives guidance on interpreting technical points and criteria in the COSMOS-standard

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

SECTION 1: OVERVIEW KEY REQUIREMENTS FOR COSMOS SIGNATURES: COSMOS ORGANIC, COSMOS NATURAL, COSMOS CERTIFIED AND COSMOS APPROVED

The requirements as summarised here are based on the COSMOS-standard, the COSMOS-standard Control Manual and the COSMOS-standard Labelling Guide. The scheme documents are available on www.cosmos-standard.org.

COSMOS-standard signature	COSMOS ORGANIC	COSMOS NATURAL	COSMOS CERTIFIED	COSMOS APPROVED
Categories	COSMETIC FINISHE	PRODUCTS	COSMETIC INGREDIENTS	
Beneficiaries	Subcontractor, manufacturer and brand owner of organic products	Subcontractor, manufacturer and brand owner of natural products	Subcontractor, manufacturer and brand owner of raw materials with organic content	Manufacturer and brand owner of raw materials without organic content
Scope	Scope 1: certification of organic or natural cosmetic prod with organic content, base formulas		etic products, raw materials	Scope 2: approval of non- organic raw materials that can be used in certified references

Main criteria	Reference scheme documents	COSMOS ORGANIC	COSMOS NATURAL	COSMOS CERTIFIED	COSMOS APPROVED
Labelling and communi- cation	<i>Standard:</i> <i>Chapter 10</i> <i>Labelling</i> <i>guide:</i> <i>Chapter 4 to</i> <i>8</i>	 The following requirements are compulsory on labels: 'COSMOS ORGANIC' signature mention of the Certification Body mention of the % of organic and natural origin content indication of organic ingredients in the INCI list 	 The following requirements are compulsory on labels: `COSMOS NATURAL' signature mention of the Certification Body mention of the % of natural origin content 	 The following requirements are compulsory on labels: 'COSMOS CERTIFIED' signature mention of the Certification Body mention of the % of organic content 	 no claim to an organic certification allowed the 'COSMOS APPROVED' signature can be used
Ingredients	Standard: Chapter 5, 6, 7.4 and Appendix I to V, VIII	 precautionary principles: GMOs and irradiation are forbidden sustainability: specific criteria on palm oil, palm kernel oil and derivatives; requirements to be of organiorigin or from sustainable sources (CSPO) (not required for complex mixtures, such as perfumes and elements of perfumes or ingredients that are extracted using petrochemical solvents) all ingredients must be validated according to their category and process (Water, Minerals, PPAI, CPAI, other ingredients) 			ch as perfumes and nts)

Main criteria	<i>Reference scheme documents</i>	COSMOS ORGANIC	COSMOS NATURAL	COSMOS CERTIFIED	COSMOS APPROVED
Formulations	Standard: Chapter 7, Appendix V, Appendix VI	 minimum of 20% of organic content or at least 10% for rinse-off product, non-emulsified aqueous products, and products with at least 80% minerals or ingredients of mineral origin at least 95% of the PPAI must be organic origin the remaining PPAI must be organic if they are listed in Appendix VI the CPAI listed in Appendix VII must be organic maximum of 2% of petrochemical moieties (Appendix V) no minimum of organic content moximum of 2% of petrochemical moieties (Appendix V) 		 presence of organic ingredient base formulas without organic ingredients 	• no organic content
Packaging & Fabrics	<i>Standard: Chapter 8.3, 8.4, Appendix IX</i>	 primary, secondary packaging and fabric components must be validated and compliant minimisation of direct and indirect environmental impacts of packaging and revision compulsory each 3 years 		 primary packaging must be validated and compliant 	N.A.
Manufacturing and storage	<i>Standard:</i> <i>Chapter 8.1,</i> <i>8.2</i>	 avoid any confusion or risk to the integrity of the products prevent contamination of the ingredients and the products 		N.A.	
Environ- mental Management	<i>Standard:</i> <i>Chapter 9</i>	 an environmental management plan must be p every cleaning/disinfection product used must l 		pliant	N.A.

Main criteria Reference scheme documents		COSMOS ORGANIC	COSMOS NATURAL	COSMOS CERTIFIED	COSMOS APPROVED			
	Application	<i>Control Manual: Chapter 8, 8.3.1</i>	application form completed	application form completed for every prospective client				
	Application review	<i>Control Manual: Chapter 8</i>		review of the application form to study the feasibility and the definition of the prospective client if possible, formalisation of the commitment				
tion process	Evaluation	Standard: Chapter 11.1, 11.2 Control Manual: Chapter 8, 8.3.2	initial on-site audit evaluat each R			documentary evaluation for each Raw Material		
Evaluation	<i>Review & Certification decision</i>	<i>Control Manual:</i> <i>Chapter 8, 8.3.3</i>	 review of the evaluation results to take the appropriate certification decision 					
	Certification documentation	<i>Control Manual:</i> <i>Chapter 8, 8.3.4</i>	 if the certification decision is positive, certification document edition 					
	Directory of certified products	<i>Control Manual: Chapter 8</i>	 the list of certified products/raw materials is available on the COSMOS website 					

Evaluation process	Main criteria	Reference scheme documents	COSMOS ORGANIC	COSMOS NATURAL	COSMOS CERTIFIED	COSMOS APPROVED
	Surveillance	<i>Control Manual: Chapter 8, 8.3.6</i>	 update of the applicher change 	 the evaluation process has to be renewed every year update of the application form if needed to declare any change annual surveillance audit re re 		
	Changes affecting certification	<i>Control Manual: Chapter 8, 8.3.7</i>	 information by the client of any change to evaluate the impact on the certification information of the clients by COSMOS of any change of the requirements of the scheme and the consequences 			
	<i>Termination, reduction, suspension or withdrawal of certification</i>	<i>Control Manual: Chapter 8, 8.3.8</i>	 termination, reduction, suspension or withdrawal of certification can be decided following client's demand or a Certification Body's decision 			
	Complaints and appeals	Control Manual: Chapter 8	 everyone can make a complaint or an appeal the complaint/appeal will be processed, and an answer/decision must be sent by the Certification Body 			

SECTION 2: GUIDANCE ON INTERPRETING TECHNICAL POINTS AND CRITERIA

1. INTRODUCTION

No further interpretations or clarifications for this section of the Standard.

2. **REGULATIONS**

3. SCOPE

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

- brand owner: the company owner of a brand that is made by a subcontractor according to the specifications required. Brand owner can be manufacturer as well
- distributor: a company who supplies products to sell for consumers. The products sold show the name of the distributor and/or brand owner
- service provider: the company that only provides services (eg. packing, filling, changing the bulk, storage) that may include manufacturing steps
- manufacturer: the company that makes products. Manufacturer can be brand owner or sub-contractor
- sub-contractor: the company subcontracted for manufacturing activities can purchase raw materials or packaging and sells products to the brand owner

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 company in charge of the release to market	 you are just a distributor and sell other brands' products, but you are not in charge of the release to market you are the brand owner but not the company in charge of the release to market. This company applies for COSMOS certification and manages the complete process (production, sale and communication related to certified products) your products are already certified by a COSMOS authorised Certification Body
Manufacturer/ sub-contractor	You are the company in charge of the release to market of the products you manufacture	 you manufacture products on behalf of a brand owner who has already applied for COSMOS certification as a sub-contractor your products have already been certified by a COSMOS authorised Certification Body Note — in both cases the evaluation of this activity must be included
Service provider	COSMOS authorise Activities of service Exemption accepte re-dispatch of palle Based on COSMOS	do not have an obligation to be in contract with a ed Certification Body. e providers must be audited to check conformity. ed if no intervention occurs on the product (storage then ets for example). a authorised Certification Body risk assessment, there udits on service provider site as well.

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

In any doubt, it is possible to contact the Certification Body to conduct a risk assessment of the commercial set-up in order to decide who should apply for certification.

4. **DEFINITIONS**

'Organic'

Ingredients certified according to these recognised standards are accepted by the COSMOSstandard. Nevertheless, the organic percentage according to the COSMOS-standard needs to be recalculated (eg. quantity of water added, preservatives).

5. GENERAL

If a pesticide or other contaminant 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. Depending on the outcome of the investigation, the Certification Body will decide whether the ingredient/ product keeps its certified status.

5.1 Precautionary principle

5.1.1 Nanomaterials

Particles with a coating (eg. TiO_2 with coating) are allowed when the minimum particle size without coating is above 100 nm.

TiO₂ and ZnO used as UV-filters are acceptable if the following conditions are met:

- the raw material has to fulfil 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 <u>https://health.ec.europa.eu/publications_en</u>

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

Silica used as coating agent of TiO2 and zinc oxide does not need a separate analysis.

Titanium dioxide used as coating agent of effect pigments does not need a separate analysis.

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 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 in the raw material questionnaire.

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.

5.1.3 Irradiation

5.2 Animal testing

No further interpretations or clarifications for this section of the Standard.

5.3 Sustainability

5.3.1 Palm oil

6. ORIGIN AND PROCESSING OF INGREDIENTS

6.1 Ingredients categories

6.1.1 Water

Water quality is checked by the Certification Body when used as single ingredient in COSMOS CERTIFIED products or COSMOS CERTIFIED raw materials (eg. analysis or meets regulation that is equivalent to COSMOS criteria).

There are no specific requirements when water is used in COSMOS APPROVED raw materials.

Chlorinated/dechlorinated water is allowed.

6.1.2 Minerals and ingredients of mineral origin

No further interpretations or clarifications for this section of the Standard.

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 Appendix I, and in the case of CPAI Appendix 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 and approved by the Certification Body.

Starfish extract as an ingredient of animal origin is prohibited.

Ingredients of plant origin

Mushrooms shall be counted as 100% PPAI unless, if possible, they have gone through a permitted chemical process, then they would be counted as CPAI.

Primary raw material

One example of primary raw materials that are harvested/collected by threatened species listed in the IUCN red list is the use of monkeys in the collection and harvest of coconuts in some regions.

6.1.4 Chemically processed agro-ingredients (CPAI)

Atom economy – Reaction mass efficiency

If several products are obtained (ie. 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. Substrates, culture mediums must be from natural or microbiological origin. 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 metabolised/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 a 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. These include substances that do not pass OECD 301; => TEGEWA classification III = high waste water impact.

6.1.5 Other ingredients

6.2 Calculation rules for organic percentages

6.2.1 Water

No further interpretations or clarifications for this section of the Standard.

6.2.2 Minerals and ingredients of mineral origin

No further interpretations or clarifications for this section of the Standard.

6.2.3 *Physically processed agro-ingredients (PPAI)*

<u>Cases of dehydrated aloe vera powder in products to reconstitute:</u>

- in cases where organic dehydrated aloe vera is mixed with other powders, when water is added to this mix of powders to reconstitute the final product, the organic percentage of hydrated organic aloe vera powder is not taken into account for the calculation of the organic percentage of the reconstituted formula
- in cases where end users are being asked to first reconstitute (hydrate) the organic aloe vera before adding the rest of the powders, the organic contribution of the reconstituted organic aloe vera is taken into account

Alcohol used 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 into account and the organic alcohol content could be various percentages. Note — if organic, % CPAI = % ORG CPAI.

The calculation of CPAI is made by weight. If no water (or other ingredient) is added during the manufacturing process of an organic alcohol, the alcohol content is counted as 100% organic (100% CPAI / 100% ORG CPAI).

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).

Aqueous extract (including hydrolates, distillated plant)

Standard:

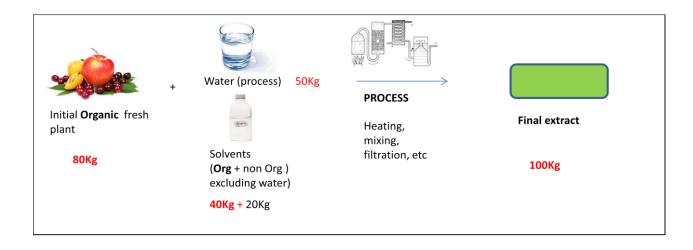
Ratio = [organic fresh plant / (final extract - solvents)] If the ratio is greater than 1, then it is counted as 1.

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



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 \rightarrow 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% Distillated plant

Used:

Fresh plant= 90 Kg (PPAI)Preservative= 1.1 Kg (NNI)Total distillated water obtained= 90 Kg

Ratio = [organic fresh plant / (final extract - solvents)] = 90/90 = 1

% organic = {[ratio X (extract - solvents) / extract] + [organic solvents / extract]} X 100 % organic = {[1 X (90 - 0) / 90] + [0 / 90]} X 100 = 100% Considering the % of preservative: Mass of preservatives/mass final extract = 1.1/90 = 1.2%PPAI = Org PPAI = 100-1.2 = 98.8%

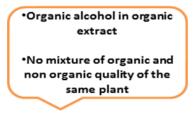
The distillated plant will be: % PPAI = 98.8% % ORG PPAI = 98.8% % NNI = 1.2%

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

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

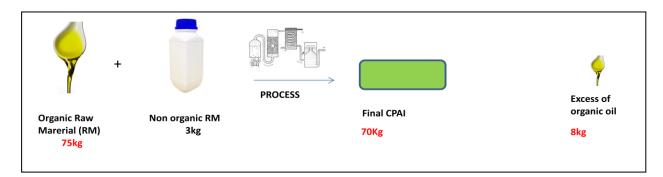
Used: 40 Kg organic fresh plant and 40 Kg organic oil (solvent A) and 20 Kg non-organic oil (solvent B)

% 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 (CPAI)

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

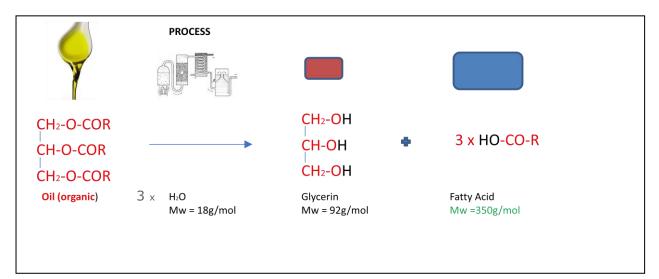
Organic RM 75kg	+ Non organic RM 3kg	PROCESS	Final CPAI 70Kg	Excess of organic oil 8kg

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 organisation, see below).

Hydrolysis 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

1) Total organic percentage of the extract:

• 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 = 0.75 Kg Total extract obtained = 1Kg including: Potassium Sorbate = 0.5% (NNI) and Sodium Benzoate = 0.5% (NNI)

% $Org = \left(\frac{0.25}{1 - 0.7} \times \frac{1 - 0.7}{1} + \frac{0.677}{1}\right) \times 100 = (0.25 + 0.677) \times 100 = 92.7\%$ % *PPAIOrg* = 92.7 - 67.7 = 25%

% PPAI = PPAI org

% Nat = 100 - NNI - PeMo = 100 - 1 = 99%

Hydroalcoholic extracts

1) Total organic percentage of the extract:

• 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:

Used:

Organic fresh plant	= 80 Kg
Water	= 50 Kg
Total 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 petrochemical moieties (PeMo)

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

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

- 1) % of petrochemical moiety of the molecule = $159/342 \times 100 = 46.4\%$
- 2) % of petrochemical moiety of the reference = $0.3 \times 0.464 \times 100 = 13.9\%$
- → The reference would be considered 16.1% CPAI and 13.9% petrochemical moiety.

Organic CPAI calculation of fermented extract

100g of organic rice + y g of water + z g of yeast + 10g of solvent => 90g of fermented extract

% Organic CPAI = Ratio x (extract - solvent)/extract Ratio = ORGANIC RICE /(EXTRACT - SOLVENTS) = 100/(90-10) = 1.25 Ratio is > 1 so is considered as 1. % Organic CPAI = (extract - solvent)/extract = (90-10)/90

= 88.9%

7. COMPOSITION RULES

GENERAL RULE

When there is a range given for raw materials concentrations, the following concentration values will be taken into account for the calculations of organic, natural and non-natural percentages:

- the minimum value of organic and natural = the less favourable value
- the maximum value of non-natural
- the maximum value for non-organic PPAI (the less favourable because of PPAI ORG / PPAI)

PARTICULAR CASE

of glycerin and the impact of this rule on the calculation for glycerin:

- if organic glycerin is COSMOS Certified as a single ingredient, Certification Bodies recalculate the organic percentage and ensure that the revised organic content is updated in the COSMOS-standard database
- if COSMOS Approved glycerin is used as single ingredient, Certification Bodies ensure that the percentage of non-organic CPAI is updated in the COSMOS-standard database

7.1 Cosmetic products under organic certification

7.1.1 Ingredients

For soaps

As a reminder, the term CPAI soap here in calculation relates to the part of CPAI derived just from the saponification.

The soap manufacturer may provide the remaining percentage of water in the soap. The Certification Body will consider that the remaining water cannot be less than 5% of the total soap weight.

Ingredients in the INCI list can be listed in two different ways:

- INCI before saponification (eg. the oils and sodium hydroxide)
- INCI after saponification (eg. sodium cocoate)

Example 1: soap made with saponification (100 Kg)

This calculation applies to liquid and solid soap.

Olive oil (org)	50%
Stearic acid (not part of the saponification process)	10%
Water	5%
Citric acid	1%
Diluted Caustic soda (50% active)	32%
Essential oil	2%
Mass of finale soap (after drying)	91%

2 steps have to be considered:

- calculation of the grade (COSMOS ORGANIC / COSMOS NATURAL), and
- final organic % (to be added on the label for COSMOS ORGANIC products)

Step 1: calculation of grade (COSMOS NATURAL / COSMOS ORGANIC) for the total product (7.1.1)

7.1.1: "When making soaps from raw materials into finished product (use of plant oils), no change of the criterion: organic PPAI / all PPAI > 95%''

Here in the example: organic PPAI / all PPAI = (50)/(50 + 2) = 96% > 95% = = > COSMOS ORGANIC grade

Step 2: calculation of organic percentage of the total product (7.1.2, based on 6.2.4 rules)

7.1.2: as reported in 7.1.2 of the COSMOS-standard for soap (rinse-off products), it is required to reach at least 10% org in the total product.

6.2.4: "CPAI % 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)] × 100"

Organic CPAI % = (organic olive oil – 0) / (all ingredients – water evaporated) Excess is water lost during the drying step.

Organic CPAI % = (50 - 0) / (100 - 9) = 50/91 = 54.9% organic

Organic % of the final product = % of organic ingredients introduced of the dried soap weight

There will always be remaining water in soap.

In the case of organic essential oil used, the final organic content will be: Total organic % = (50+2-0) / (100-9) = 52/91 = 57.1% organic

Example 2: Soap (100 Kg) made with soap noodles

Organic Essential Oil	2%
Soap noodles	98%
Composition of soap noodles:	
Olive oil (org)	52%
Stearic acid (not part of the saponification process)	10%
Water	5%
Citric acid	1%
Diluted Caustic soda (50% active)	32%

If COSMOS certified noodles are used, please refer to the percentages declared by the suppliers and shown on COSMOS database. If soap noodles of your own manufacturing are used, please consider the previous example. CPAI: 52+10+1 = 63% Organic CPAI soap: 52/52 = 100% Organic CPAI: 52/ (100+0) = 52%

Step 1: Calculation of grade (COSMOS NATURAL / COSMOS ORGANIC) for the total product (7.1.1)

As reported in 7.1.2 of COSMOS-standard for soap (rinse-off products), it is required to reach at least 10% ORG in the total product.

(organic PPAI + organic CPAI soap) / (all PPAI + CPAI soap) > 95% using the following equations: Grade for final product: (2+100)/(2+100) = 100% = > COSMOS ORGANIC

Note - CPAI Soap will always be 100%

In the case of non-organic essential oil used, the final organic content will be: Grade for final product: (100)/(2+100) = 98% => COSMOS ORGANIC

Step 2: Calculation of organic percentage of the total product (7.1.2, based on 6.2.4 rules)

7.1.2: "By exception, for rinse-off products, non-emulsified aqueous products, and products with at least 80% minerals or ingredients of mineral origin, at least 10% of the total product must be organic"

Total organic % = organic PPAI + organic CPAI = 2 + [organic CPAI (noodle) x noodle's ratio in the final soap] = 2 + [(52 x 98)/100] = 2 + 50.9 = 52.9%

In the case of non-organic essential oil used, the final organic content will be 50.9 %.

7.1.2 Total product

There are two different cases for reconstituted products under natural and organic certification:

- 1) solid powders, with information from the cosmetic producer to mix the solid powder with a defined amount of water, in a bottle. Here the certification decision is made on the reconstituted product (adding the quantity of water clearly defined on the product label). Therefore, the reconstituted product must comply with the COSMOS-standard rules.
- 2) solid bars (soap, syndets, powders), that are used with water, but the quantity of water to use is difficult to define. This case is similar to the use of a classic shampoo/ shower gel. Here the certification decision is made on the dry product. Therefore, the dry product (before water is added) must comply with the existing COSMOS-standard rules.

7.2 Cosmetic products under natural certification

There are two different cases for reconstituted products under natural and organic certification:

- 1) solid powders, with information from the cosmetic producer to mix the solid powder with a defined amount of water, in a bottle. Here the certification decision is made on the reconstituted product (adding the quantity of water clearly defined on the product label). Therefore, the reconstituted product must comply with the COSMOS-standard rules
- 2) solid bars (soap, syndets, powders), that are used with water, but the quantity of water to use is difficult to define. This case is similar to the use of a classic shampoo/ shower gel. Here the certification decision is made on the dry product. Therefore, the dry product (before water is added) must comply with the existing COSMOS-standard rules

7.3 Calculation rules for natural origin percentage

No further interpretations or clarifications for this section of the Standard.

7.4 Palm oil, palm kernel oil and derivatives

Ingredients from Standard 7.4 do not have to be from palm oil as long as they comply with the COSMOS-standard.

Example: glycerine from 100% rapeseed oil is acceptable.

Please refer to the relevant section on Shortage on page 41 related to Appendix VI & VII.

7.5 Raw materials with organic content under certification

No further interpretations or clarifications for this section of the Standard.

7.6 Raw materials without organic content under approval

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.

Pencils that can be sharpened are to be considered as primary packaging. Therefore, criteria for packaging apply.

8.1 Storage

No further interpretations or clarifications for this section of the Standard.

8.2 Manufacturing

No further interpretations or clarifications for this section of the Standard.

8.3 Packaging

Each component of the finished product packaging must be compliant with the Standard: tubes, bottles, jars, caps, capsules, sachets, boxes, etc.

The following items and examples of technical parts do not have to be checked:

- accessories sold with a product such as decorative cosmetic applicator, spatula, spoon, or attached to a product such as ribbon or rope
- all accessories in decorative cosmetic products such as brush, applicator, flock, rob...
- all the components working as joints
- all the components working as sealers
- coatings on card/paper
- droppers and their specific caps
- elements added inside the secondary packaging such as plastic moulds
- external part of a lipstick/ lip balm as long as available compliant alternatives do not exist widely
- gaskets
- internal flexible pouch
- labels material, ink, glue
- liners
- lubricant in the pump, glue in pencils as long as there is no contamination of the cosmetic formula, treatments and lacks
- manufacturing auxiliaries for the production of packaging materials (eg. tallow)
- mechanism for lipsticks: internal part used to turn / push the product
- multilayers
- packaging for free samples, packaging for bulk products (B to B), packaging for COSMOS APPROVED raw materials
- protection sleeves; however, it is allowed if around the closure system only. Full sleeve is not allowed. Exceptions could be granted for small products (eg. decorative cosmetics)
- pumps and specific associated caps (bottles have to be checked)
- secondary packaging only used for special event (gift boxes/ end of stocks, etc)

8.3.1 Examples of indicators

The below table shows possible indicators that can be provided to demonstrate how the criteria on packaging is being complied with.

The selected indicators (from below examples and/or beyond) are checked at documentary validation stage and then during the audit.

Examples of indicators	Case Nr 1 Jar	Case Nr 2 Glass	Case Nr 3
Examples of indicators	lar	Glass	
Examples of indicators		UIdss	Aluminium
Examples of indicators		Bottle	bottle
Case: 10ml bottle in a box for 30ml bottle with			
 use a 10ml box to avoid cardboard inside 			
• no box at all			
	✓		1
	1		
eg. Refill bag version of finished product	1		1
		~	
i.e. Primary packaging, secondary packaging,			
shipping materials			
eg. From vegetable fats/oils, corn starch,			
woodchips, foodwaste, cellulose, lactic acid.			
eg. FSC/PEFC			
eg. Sunflower oil based ink			
5			1
(RCS)/ Global Recycled Standard (GRS)			
		~	
· · ·			
separated before put in for recycling			
		1	
	eg. From vegetable fats/oils, corn starch, woodchips, foodwaste, cellulose, lactic acid. eg. FSC/PEFC eg. Sunflower oil based ink e.g. Certification Recycled Claim Standard (RCS)/ Global Recycled Standard (GRS) eg. Glass bottle with plastic cap that can be separated before put in for recycling	cardboard inside to protect the bottle Solutions for change: use bigger bottle in order to reduce ratio packaging/ product use thinner bottle/cap to reduce again ratio packaging/product use a 30ml bottle to avoid cardboard inside use a 10ml box to avoid cardboard inside no box at all eg. Refill bag version of finished product i.e. Primary packaging, secondary packaging, shipping materials eg. From vegetable fats/oils, corn starch, woodchips, foodwaste, cellulose, lactic acid. eg. FSC/PEFC eg. Sunflower oil based ink e.g. Certification Recycled Claim Standard (RCS)/ Global Recycled Standard (GRS) eg. Glass bottle with plastic cap that can be separated before put in for recycling	cardboard inside to protect the bottle Solutions for change: • use bigger bottle in order to reduce ratio packaging/product • use a 30ml bottle/cap to reduce again ratio packaging/product • use a 30ml bottle to avoid cardboard inside • use a 10ml box to avoid cardboard inside • no box at all eg. Refill bag version of finished product eg. Refill bag version of finished product

8.3.2

No further interpretations or clarifications for this section of the Standard.

8.3.3

No further interpretations or clarifications for this section of the Standard.

8.3.4

No further interpretations or clarifications for this section of the Standard.

8.3.5

No further interpretations or clarifications for this section of the Standard.

8.3.6

No further interpretations or clarifications for this section of the Standard.

8.4 Fabrics

Case of hydrogel masks:

- the hydrogel support for a face mask is not to be considered as fabric and therefore the criteria for fabrics do not apply. As a consequence, the hydrogel support does not have to be 100% organic for COSMOS ORGANIC finished products
- the combination [hydrogel support+lotion] is to be checked as one formula and needs to comply with the COSMOS-standard.

9. ENVIRONMENTAL MANAGEMENT

9.1 Environmental management plan

9.1.1

No further interpretations or clarifications for this section of the Standard.

9.1.2

No further interpretations or clarifications for this section of the Standard.

9.2 Cleaning and Hygiene

Cleaning products not involved in the processes (toilets, floors, conventional products, etc.) are not concerned.

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

Products endorsed by environmental labels including Nordic Swan or Ecolabel may be used if the natural origin of their active ingredients (eg. alcohol, moisturising ingredients), solvents and surfactants has been confirmed. Preservatives, defoaming agents and perfumes do not need to be checked for natural origin.

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.

9.2.1

No further interpretations or clarifications for this section of the Standard.

9.2.2

No further interpretations or clarifications for this section of the Standard.

9.2.3

No further interpretations or clarifications for this section of the Standard.

9.2.4

10. LABELLING AND COMMUNICATION

10.1 General rules

A 'pseudo' logo can be understood as a logo that shows certification or quality although there is no standard and no evaluation by a third party. Standard examples are logos created by companies for their own use and without third party control.

Organic logos are not allowed in conjunction with COSMOS natural products or approved ingredients. For example, a COSMOS natural finished product should not bear a logo with the term 'bio' or 'organic'. Company names or brands are not considered as logos. If in doubt, request a clarification from the Technical Committee.

10.3 of the Standard also provides limitation of the indication of organic ingredients in case of natural products. In the case of a product which is organic certified, additional pseudo 'bio logos' might be acceptable, depending on the opinion of the Certification Body.

10.2 For products under organic certification

Under the Organic Foods and Farming Act (previously known as COPA-California Organic Products Act), 'salt' means sodium chloride.

10.3 For products under natural certification

Under the Organic Foods and Farming Act (previously known as COPA-California Organic Products Act), 'salt' means sodium chloride.

10.4 For raw materials with organic content

No further interpretations or clarifications for this section of the Standard.

10.5 For raw materials with no organic content

"Raw materials with no organic content that are approved must make no reference on the label or on relevant documents to the term certified or to organic."

COSMOS has implemented this requirement to avoid confusion to manufacturers of COSMOS CERTIFIED products when the ingredients are selected for the formulations. COSMOS APPROVED raw materials do not have any organic content and are not organic certified.

Thus, providers of non-organic raw materials are asked not to use the words certified (in any language), organic or bio (in any language) on raw material names, on labels and on relevant documents related to COSMOS approved raw materials (except in cases of company names). In cases where 'bio' or 'org' is within a word it may be acceptable if it is clearly not misleading. It is the Certification Body's responsibility to assess such cases.

Examples not allowed:

xxx BIO	ORGANIC xxx	xxx ORG
BIO-xxx	XXX ORGANIC	ORG-xxx
BIO xxx	ORGANIC-xxx	ORG xxx

Examples of operator responsibilities for the use of COSMOS APPROVED label

There can be three entities to consider:

- a. the manufacturer of the COSMOS APPROVED ingredient
- b. the intermediate distributor of the ingredient
- c. the cosmetic manufacturer who wishes to use the ingredient in a COSMOS formula

Example 1 The distributor repacks the ingredient, therefore the ingredient is no longer COSMOS APPROVED. The cosmetic manufacturer must ask the distributor to submit the raw material questionnaire to their Certification Body for internal evaluation.

Example 2 The intermediate distributor puts its own label on the ingredient: no repacking, but the ingredient manufacturer's label is removed. Therefore, the ingredient is no longer COSMOS APPROVED. The cosmetic manufacturer must ask the distributor to submit the raw material questionnaire to its Certification Body for approval.

Example 3 The intermediate distributor puts its own label on the ingredient: no repacking and the ingredient manufacturer's label is kept. Therefore, the ingredient is still COSMOS APPROVED. The cosmetic manufacturer can be allowed to use this ingredient without requiring the intermediate distributor to submit the raw material questionnaire.

In any case, the distributor cannot include the COSMOS APPROVED signature on its own label unless it is in contract with a Certification Body and applies to have the ingredient listed on the COSMOS raw materials database under its own name.

Other particular case: the ingredient manufacturer does not want to be on the COSMOS database and does not use any marketing information related to COSMOS; there is no mention of COSMOS on the ingredient label. Here, there is no need for the ingredient manufacturer to be in contract with a Certification Body. This is the case of cosmetic manufacturers wanting to use some ingredient that do not claim to be COSMOS APPROVED, in their COSMOS formula.

10.6 Supporting literature

No further interpretations or clarifications for this section of the Standard.

10.7 Organic in the name of a company or product range

No further interpretations or clarifications for this section of the Standard.

10.8 Use of the signature, name or term related to this Standard

11. CERTIFICATION AND APPROVAL

Process requirements applicable to authorised Certification Bodies in order to certify products and organic raw materials or to approve non organic raw materials can be consulted in the COSMOS-standard Control Manual Chapter §8, as from section §8.3.2. They can help companies understand how they will be audited.

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 two 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 could be:

- continuation of certification under conditions
- reduction of the scope of certification
- suspension of the certification
- withdrawal of the certification

11.2 Approval of raw materials

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.org/en/databases/approved-raw-materials/.

Raw materials published on the COSMOS database are recognised and accepted by all Certification Bodies.

The 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 Certification Body or association for the password.

Raw materials identified with an asterisk* relate to Appendix II (petrochemical solvents), 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 with an asterisk 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 three 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 could 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.

11.3 Certification Bodies

12. IMPLEMENTATION OF THE STANDARD

12.1 Coming into force

The date indicated is the one on which the version 4.1 of the COSMOS-standard takes effect and is valid. For Version 4.1, this date coincides with the date of publication.

12.2 Application date

The date indicated is the one from which all the criteria of the COSMOS-standard version 4.1 must be applied for any new cosmetic product or raw material submitted for certification or approval from that date. For Version 4.1, this date coincides with the date of publication. Refer to section §12.3 for all specific transition measures.

12.3 Transitional measures

Appendix I

At any step of the manufacturing process: preservation or treatment of primary plant materials are not checked for non-organic raw materials such as ethanol, algae and beetroot.

Appendix II

BIOTECHNOLOGY PROCESSES (fermentation, stem cells culture, etc):

Ammonia/Ammonium salts and other Nitrogen sources are allowed. Sodium Selenite is allowed as a Selenium source.

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

Ammonia is allowed in the neutralisation 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).

Use of petrochemical solvents: preservation or treatment of primary plant materials are not checked for non-organic raw materials such as ethanol, algae and beetroot.

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 IV

No further interpretations or clarifications for this section of the Standard.

Appendix V

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 available in the Standard Appendices):

- no mixture (one component)
 - ingredients must be used in organic quality according to Appendix VI (example: sunflower oil or wax)
 - single ingredients which are stabilised with additives or contain preservatives
 - (example: sunflower oil, stabilised 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 ingredients of the mixture are listed in Appendices VI/VII

It is considered as a mixture or a blend only if it is a commercial reference and not a mixture made by the cosmetic manufacturer itself.

Specific case of refined oil

A refined oil can have the same INCI name as a non-refined oil. Appendix VI is based on INCI names, therefore, a refined oil with an INCI name listed in Appendix VI must comply with the criteria.

Examples:

- hybrid helianthus annus seed oil ► not listed in Appendix VI, therefore does not need to comply with the criteria
- helianthus annus seed oil ► listed in Appendix VI, therefore needs to comply with the criteria

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 available in the Standard Appendices):

- no mixture (one component)
 - this also applies to single ingredients which are stabilised 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 and VII (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 a certified (organic or CSPO) raw material

A shortage is the lack of availability of the required volume of compliant materials; a higher price of an alternative compliant material does not constitute a shortage.

In the case of a shortage of a certified raw material listed in Appendix VI and VII, Certification Bodies can 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 (eg. 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 suppliers that the certified material is not available.

Regarding the organic raw material, 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 and checked at each new raw material purchase.

Ensure records are kept by the clients to include monitoring practices and procedures, such as periodic review of the availability, to ensure that the plan is effectively implemented.

Appendix VIII

Toxicity and biodegradability data are not required for naturally occurring molecules obtained by fermentation, biotechnology or bio-enzymatic reactions.

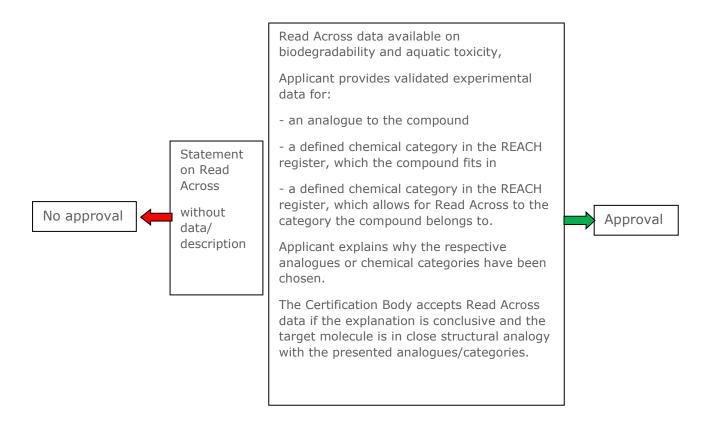
Follow this link for available data of compounds registered for REACH: http://www.echa.europa.eu/web/guest/information-on-chemicals/registered-substances.

Due to the lack of biodegradability of PLA and other solid plastics, these raw materials are not allowed in COSMOS certified products. PLA is therefore excluded from the exemption for *Polymers, only obtained by esterification of monomers, that meet the criteria for non-persistent products as defined in 6.1.4'*, listed in the Appendix VIII of the COSMOS-standard.

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.

Appendix IX



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