Cosmetics Europe
the personal care association

COSMETICS EUROPE

ADVISORY DOCUMENT

INFORMATION EXCHANGE ON COSMETIC PACKAGING MATERIALS ALONG THE VALUE CHAIN IN THE CONTEXT OF THE EU COSMETICS REGULATION EC 1223/2009

13 June 2019

Aim and Scope of this document:

This document identifies a set of useful information from packaging/material suppliers that supports the assessment of the impact of the packaging on the safety of the cosmetic product contained therein.

There is no legal obligation that this information has to be collected by a cosmetic manufacturer by using this document. It is possible to apply other approaches, provided that they result in necessary, relevant information being available to the cosmetic product safety assessor.

The document concerns the exchange of information. It does not provide safety assessment methodologies for integrating such information into the cosmetic product safety assessment. This remains fully in the role of the cosmetic product safety assessor.

At the time of publication (June 2019), the principles described in this document have been thoroughly tested in a number of pilot studies, involving actors from all steps in the packaging / material supply chain. However, given the complexity and diversity of the supply chain, the approach cannot (yet) be considered as widespread industry practice. Implementation throughout the supply chain will take place over time and the document itself will evolve with the practical experience gained.

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Introduction

Regulatory context

In accordance with the EU Cosmetics Regulation (EC) No. 1223/2009, a cosmetic product made available on the market must be safe for human health when used under normal or reasonably foreseeable conditions of use. In order to meet this requirement, the person responsible for placing the product on the market must carry out a safety assessment, based on the intended use of the cosmetic product and the anticipated exposure to the individual ingredients:

> *Article 10 : In order to demonstrate that a cosmetic product complies with Article 3* (safety requirement)*, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I. …*

Annex I of the Cosmetics Regulation describes the information that needs to be considered FOR the Cosmetic Product Safety Report. Section 4 provides details with regard to impurities, traces, and information about the packaging material :

- *The purity of the substances and mixtures*
- *In the case of traces of prohibited substances, evidence for their technical unavoidability.*
- *The relevant characteristics of packaging material, in particular purity and stability.*

Commission Implementing Decision 2013/674/EU establishes guidelines on the practical application of the above requirements and, in its Annex provides further guidance with regard to the information about the packaging material and the potential release of substances from the packaging:

> *Section 3.4 Packaging material means the container (or primary packaging) that is in direct contact with the formulation. The relevant characteristics of packaging materials in direct contact with the final product are important for the safety of the cosmetic product. Reference to Regulation (EC) No 1935/2004 of the European Parliament and of the Council could be useful.*
>
> *Experience with similar formulation/packaging combinations already on the market provides useful indications. Materials that have been developed for food packaging have often already been tested, so relevant information on stability and migration may be available. Additional testing may not be required. However, more evaluation may be needed for new or novel packaging.*
>
> *The combination of packaging material, formulation of the cosmetic product and contact with the external environment may have an impact on the safety of the finished product, due to the following factors:*
>
> > *(a) interaction between the product and the packaging material;*
> >
> > *(b) barrier properties of the packaging material;*
> >
> > *(c) substance migration from/to the packaging material.*
>
> *The information on relevant characteristics of the packaging materials in direct contact with the product should allow an estimation of potential risks. Relevant characteristics could include, for example, the following:*
>
> > *(a) composition of the packaging material, including technical substances such as additives;*
> >
> > *(b) technically unavoidable impurities;*
> >
> > *(c) possible migration from the packaging.*

This information only indicates the hazard. It is up to the safety assessor to evaluate the risk. Studies on interactions/suitability between formulation and packaging allow testing of the potential migration of small amounts of substances from the primary packaging material to the product. These tests are performed under specific and relevant test conditions. There are, however, no standard procedures for cosmetic products. An appropriate assessment may be made based on knowledge of the formulation and primary packaging materials and experienced expert judgment. If migration is dependent on storage conditions, the correct conditions should be indicated on the product labelling. If the formulation is sensitive to light or air, and would degrade in a way that impacts product safety or product efficacy, appropriate packaging should be used.

Consequently, documentation provided by the packaging supplier is an important building block for the legally required safety assessment of the final cosmetic product by the responsible person's safety assessor. In the absence of detailed regulatory requirements on the information exchange along the value chain, a number of industry associations, representing the value chain of cosmetic packaging[1], worked out a common understanding of the relevant and appropriate information on packaging materials to be provided to the cosmetic product safety assessor.

The scope of the resulting document extends to the following types of materials used in the manufacturing of cosmetic packaging: plastics, adhesives, metals, alloys, paper, board, printing inks, varnishes, rubber, silicones, glass and ceramics.

The document aims at identifying which information regarding the packaging is relevant for conducting the safety assessment of the cosmetic product, where the main concern is the possible migration of substances from the packaging into the cosmetics formulation. It presents a common sense, harmonised approach for the exchange of information within the value chain. This information supports a safety assessor deliberation and conclusion if a packaging material / item has an impact on the safety of the cosmetic formulation. However, the document does not provide detailed methodology on how to integrate this information into the cosmetic product safety assessment.

The document does also not deal with technical performance, quality / stability issues arising from the use of a specific packaging for a specific cosmetic formulation. It is obviously vital in the product development process to assess compatibility between the formulation and the packaging, but this is not primarily a consumer safety issue and hence not dealt with in this paper.

[1] FLEXIBLE PACKAGING EUROPE, FEBEA, COSMETICSEUROPE, ELIPSO, IKW, EUROPEAN TUBE MANUFACTURERS ASSOCIATION, EUROPEAN METAL PACKAGING, EUROPEAN COUNCIL OF PAINT PRINTING INK AND ARTIST COLOURS INDUSTRY, INDUSTRIEVEREINIGUNG KUNSTSTOFFVERPACKUNGEN, UNIONPLAST – FEDERAZIONE GOMMA PLASTICA, COSMETICA ITALIA, EUROPEAN PLASTICS CONVERTERS, PLASTICS EUROPE, CEFIC FCA

Background and challenges regarding cosmetic products packaging

The development of a packaging for a cosmetics product needs to take account of a number of factors. It should meet:

a) The required technical performance of the pack, e.g. product protection, compatibility with product, filling line performance.
b) The requirements of the Cosmetics Regulation for safety assessment (i.e. the packaging must not negatively impact the safety of the cosmetic formulation)
c) Requirements regarding REACH, the Packaging and Packaging Waste Directive 94/62/EC and other legislation

Regarding a potential impact of the packaging on the safety of the cosmetic product, the main concern lies with the potential migration of substances from the packaging into the cosmetic formulation. Depending on the material combination used, such migration may be unavoidable – and indeed, the Cosmetics Regulation acknowledges in Article 17 that: "*The non-intended presence of a small quantity of a prohibited substance, stemming from … migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3"* (i.e. the requirement for products to be safe). It is therefore important that the cosmetic product safety assessor receives relevant information on the composition and migration behavior of the packaging material in order to be aware if any significant migration occurs and assess whether it would impact the cosmetic formulation safety.

Packaging materials are not simple chemical substances or mixtures. The packaging of a cosmetics product may consist of a number of different components, some in direct contact with the cosmetic formulation, others not (or only for a brief time during use). Each component in itself may be made from a number of different raw materials. These raw materials may themselves have multi stage supply chains.

While the broad chemical nature of these components may be known, the details of the individual chemical substances and additives that are used to make them are often trade secrets. Hence an apparently straightforward enquiry of "what chemical substances does your packaging contain?" is often difficult to answer, both due to the complexity of the supply chain and due to justified concerns of suppliers over sharing business-sensitive information. A full breakdown of compositional detail would create a disproportionate administrative burden along the supply chain without being necessary for an adequate safety assessment by the cosmetic product safety assessor. There is therefore a need for a pragmatic approach that meets the need of the cosmetic responsible person and his safety assessor for accurate relevant information, while avoiding a flood of unnecessary detail on the composition of every packaging component.

The following approach was developed, which aims to provide the necessary level of information, while preserving the know-how of every supply chain member. It builds on the fact that a well-established process exists for providing information along the supply chain of food packaging materials.

General approach for the information exchange

The EU Framework Regulation for food contact materials (Regulation (EC) No 1935/2004) sets out the general principles of safety and inertness for all Food Contact Materials. It requires in particular that materials are manufactured according to Good Manufacturing Practices and do not release their constituents into food at levels harmful to human health and provides rules for compliance documentation and traceability. Moreover, additional EU as well as national measures exist for specific types of materials (e.g. plastics, ceramics, metals/alloys, etc.). Note that other regions in the world have similar requirements/approaches to food packaging safety (see Annex 2).

For the following reasons, the information generated under food packaging legislation can in principle also be used for the safety assessment of packaging used for cosmetic products (see Chapter A and Annex 6 for more details) :

- Physico-chemical similarities between many cosmetic formulations and typical food materials
- Manufacturing standards based on Good Manufacturing Practices
- Safety assessment of the food packaging based on its composition and potential migration of substances into the food
- Similar worst-case ratio of packaging surface to packaging content between food and cosmetics

Thus, it is possible in many instances that documented compliance with food packaging legislation becomes the main information to the cosmetics product safety assessor. Additionally, some limited information on the presence of specific substances of concern under the Cosmetics Regulation remains necessary. However, a complete composition breakdown of all packaging constituents would not be required,

In the case where a packaging material complies with food packaging legislation of a non-EU country, it is still possible to apply a similar approach to the one developed here. It may be necessary, however, that the supplier provides the cosmetics product safety assessor with information on the specific requirements and standards that these third country food regulations prescribe.

The present approach can also be applied in case of partial non-compliance with the food packaging legislation or incomplete information on the compliance of the packaging with food packaging legislation. In this case, the guidance can be applied as such for those materials of the packaging that are compliant, and additional information would be required on those materials/substances that create the non-compliance or uncertainty (see Chapter B).

It has to be emphasised that this document does not aim to set a requirement or recommendation that cosmetics packaging must be compliant with EU food contact legislation. Obviously, any packaging material / item that does not impact the safety of the cosmetics formulation is acceptable. However, the logic of the present approach may be difficult to apply/not applicable and the supplier needs to discuss on a case-by-case basis with the cosmetic company to identify the necessary information that the latter needs for their safety assessment.

Methodology

The following methodology for information exchange can be applied throughout the supply chain, regardless of whether it concerns supply of a packaging raw material, bulk material, or a packaging component[2] or packaging item.

Firstly, all specific items or materials (depending on what is supplied) should be described with their general chemical composition.

Note that the safety assessment of a cosmetic product must ultimately consider the potential impact arising from the transfer of substances from the packaging into the cosmetic formulation. Therefore it is usually only necessary to provide information to the cosmetic safety assessor on those components / materials used for the primary packaging (since the secondary packaging is typically not in contact with the cosmetic formulation). However, if the primary packaging does not provide a functional barrier, one should also consider the potential for transfer of substances from the secondary packaging into the cosmetic formulation, whether by migration or by vapour phase transfer.

Compliance with the requirements of the EU Chemicals Legislation and packaging/packaging waste legislation is mandatory, including certain information that the suppliers need to provide to downstream users. It is useful to include also the following relevant regulatory information for each material or component [3]:

> **REACH :** It is mandatory to declare the presence of Candidate list Substances of Very High Concern (http://echa.europa.eu/web/guest/candidate-list-table) when present in a component at a quantity at or above 0.1% w/w (i.e. ≥ 1000 mg/kg) and to provide the identity of such substances. (It is also useful to declare if such substances are not present).
> **Heavy Metals :** It is often required to confirm that the product is in compliance with the limit of 100 ppm laid down in Packaging Waste Directive 94/62/EC for the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium.

Secondly, all those components / materials which are potentially capable of transferring chemical substances to the cosmetics formulation should be identified.

Thirdly, having thus identified those packaging components / materials which can have a potential impact on the safety of the cosmetics product, adequate information needs to be communicated about them to allow the cosmetic product safety assessor to evaluate their impact (if any) on the safety of the cosmetic formulation. The following chapters describe the actions recommended in this approach (see also the flowchart in Annex 1):

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[2] Component: A part of the packaging system which can exist as a separate entity, either being assembled by the packaging supplier or being incorporated into the final pack by the packer

[3] Different component parts of the packaging are considered separately, in line with the CJEU position (Case C-106/14).

Chapter A. If possible, the supplier declares and documents compliance with food contact legislation/ standards.

Chapter B. Where food contact compliance cannot be claimed, the supplier provides relevant information for the safety evaluation of the packaging by other means.

In either case :

Chapter C. The supplier addresses substances that are of specific concern under to the cosmetic product safety assessor (i.e. banned or restricted under the Cosmetic Regulation Annex II, Annex III and CMR substances as well as substances classified as skin sensitisers).

Annex 5 provides an example for reporting of the relevant information by the final packaging supplier to the cosmetic responsible person.

Chapter A – Stating compliance with food contact legislation/ standards

The Food Contact supply chain has developed a practical approach based on existing legislation which can be adapted for Cosmetics. The principle has been adopted that, in the majority of cases, if the packaging is safe for a specific type of food, it should also be suitable for cosmetics that have similar physical chemical properties as this food (see Annex 6 for more details).

For each component where this is possible, the supplier should therefore state and document

- compliance with the general requirements of EU Framework Regulation (EC) No 1935/2004 on food contact materials
- compliance with the Good Manufacturing Practices (GMP Regulation (EC) N°2023/2006)
- compliance with requirements of EU or national legislation that are applicable for the specific type of food material (see below)
- the types of food (food simulants) for which this statement of compliance is valid. This allows the cosmetic product safety assessor to determine whether the information on food packaging safety is relevant for his specific cosmetic formulation.

Compliance with the requirements of Regulation 1935/2004 Article 3 for a specific material type is usually documented by demonstration of compliance with specific European legislation, with appropriate National legislation, with Council of Europe Resolutions, European standards or with codes of practice, e.g. developed by Trade Associations. Such rules often feature:

- A general requirement that substances used in the manufacture of materials and articles "shall be of a technical quality and purity suitable for the intended and foreseeable use of the materials or articles",
- Positive lists of substances that may be used to make the material,
- Limits for the use levels of a substance in a material or, more often, specific migration limits with regard to the transfer into the food which are based on a risk assessment of the substance carried out by EFSA or other official body,
- A risk assessment of unlisted or non-intentionally added substances (worst case risk assessment).

A list of the main relevant legislative and other references can be found in Annex 2.

<u>Assessing Migration</u>

An important mechanism to ensure the safety of food contact materials is the use of migration limits. These limits specify the maximum amount of a substance allowed to migrate to food.

An **Overall Migration Limit** (OML) is a limit for the migration into food of all substances together. It is a measure for the inertness of the material.

'**Specific Migration Limits**' (SML) can be set in EU or national regulation on the basis of toxicity data for specific substances

For plastic food contact materials the rules for migration testing are clearly stipulated in the Commission Regulation EU 10/2011. (e.g. the OML is set at 60mg/kg food, or 10 mg/dm^2 of the contact material). For many other materials like paper & board, metals, rubbers or migration of printing inks through substrates, the rules for migration testing have been established in national regulations or in industry guidelines.

Migration results to demonstrate compliance with these limits can be obtained in food itself, or in food simulants, or can originate from migration modelling or worst case assumptions (i.e. assuming that 100% of the substance would migrate into the food).

Migration can also be estimated based on worst-case assumptions or conservative modelling. More detailed assessments and/or tests are only necessary when these assumptions proof to be overly conservative. If compliance has been based on modelling or worst case calculation, there is no need to further evaluate migration through testing.

If compliance has been based on migration into food / food simulants, the cosmetics assessor needs to decide whether the food/simulants and test conditions / assumptions are applicable to the cosmetics formulation. Regulation (EU) No 10/2011 on plastic materials and articles defines 5 food simulants representing the main food characteristics that are influencing migration (see Annex 6 for more information). Regarding food groups not specifically assigned to a food simulant, the Regulation encourages that expert judgement be used based on the similarities with other food groups to assign an appropriate simulant. For most cosmetic formulations, the physical/chemical properties relevant for migration from the packaging correspond to the properties of typical food stuff. Therefore, a similar expert judgement approach can be taken to decide whether information based on a particular food/simulant is applicable to the cosmetic formulation.

Note that some formulations, e.g. alkali preparations such as some hair care products, cannot be represented by existing recognised food simulants. If suitable simulants do not exist or if migration assessment using appropriate simulants mimicking the cosmetic product exceed OML and/or SML values, the “safe for food, safe for cosmetics” argument cannot be used. The packaging material must then be assessed as if it were a non-food contact compliant structure.

Information on migration that was established upstream in the supply chain can be transmitted and does not need re-established at all steps in the supply chain of the packaging item/material.

Chapter B - If food contact compliance cannot be stated

A Cosmetic packaging material might not be food contact compliant because of the presence of a substance that is not authorised for food contact materials or used outside of restrictions set for such use. Non-compliance could also be linked to the material not having been manufactured according to GMP Regulation (EC) N°2023/2006. Such packaging may still be perfectly safe for use in a cosmetic application after the performance of the safety assessment. References to other standards like e.g. pharmaceutical standards or food and feed additives might be helpful in generating useful support information.

Firstly it is important to demonstrate that the cosmetic packaging is produced in a consistent way. ISO 9001 or any other equivalent quality system are appropriate.

Secondly attention has to be paid to the non-authorised substance(s). It should be noted that the presence of such substance(s) render the packaging non-compliant for food, but it does not necessarily indicate that the packaging is less safe for cosmetics use than food law compliant packaging. The approach under Chapter A can still be followed for all those components and materials that are food contact compliant. However, for those materials or components that are not compliant, the supplier should inform the cosmetics product safety assessor on the reason(s) for non compliance :

- Presence of non-approved substance(s)
- Presence of approved substance(s) that do not respect the purity criteria of food contact legislation
- No evaluation of migration (by testing or other means of assessment)
- Presence of substance(s) above the SML / OML
- Material/item not manufactured according to EU Good Manufacturing Practice (EC) No 2023/2006 (or an equivalent GMP)

Additional information would need to be given only on the specific substances or circumstances that lead to the non-compliance with food contact legislation. If the non-compliance is related to a specific substance, its identity (chemical name, CAS Number) and concentration in the packaging material / component should be communicated. If the substance is present at in the material/component a very low level at which it can be considered as posing no appreciable risk to the safety, it may not be necessary to provide such information. Please see Annex 3 (“Threshold for Toxicological Concern, TTC) for guidance on relevant cut-off levels. If a TTC approach cannot be taken, substances should be communicated if they are present above 1 ppm.

The following additional information can give further guidance to the cosmetic product safety assessor to decide whether or not the non-compliance has an impact on the safety of the cosmetic formulation contained in the packaging. :

- Has the substance been evaluated by official bodies in relevant regulations (cosmetic, food additives…) and are there recognised safe levels to be considered?
- In absence of the above, what is the toxicity profile of the substance?
- If full toxicity profiles are not available, can other approaches based on read across, QSAR (Quantitative Structural-Activity Relationship)[4] be taken into account ?

[4] http://www.oecd.org/chemicalsafety/testing/oecdquantitativestructure-activityrelationshipsprojectqsars.htm

Chapter C - Addressing substances of concern to cosmetic safety assessors

The information exchange approach described above addresses most of the needs of the cosmetic product safety assessor. However, there are additional regulatory considerations arising from the Cosmetics Regulation 1223/2009/EC with regard to the presence/ limits of specific substances in the cosmetic formulation.

Article 14 prohibits or restricts the presence of certain substances in the cosmetic formulation. These substances are listed in Annex II and III. Similarly, article 15 prohibits the use of substances classified as CMR substances under Regulation 1272/2008/EC, unless they receive a specific exemption. CMR substances are systematically listed in the corresponding Annexes of the Cosmetics Regulation within 15 months after the entry into force of the chemical classification. If any of these substances were present in the packaging and migrated into the formulation, although usually at trace level, they could potentially impact compliance with the above restrictions.

It should be noted that it is neither useful nor possible under today's analytical technology to certify the absolute absence of any substance. This issue is addressed in Article 17 of the cosmetic regulation which stipulates:

> *The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3.* (i.e. safety of the product)

Thus, in order to allow the responsible person of cosmetic products to cope with the requirements of articles 14, 15 and 17, the supplier should provide information on the identity (chemical name, CAS Number) and concentration of Annex II and III, including CMR-classified, substances present in his packaging material / component.

Furthermore, the information generated under the approach described under Chapter A and B is addressing systemic toxicity concerns and does not allow evaluation of local effects (skin irritation, skin sensitisation) of substances migrating into the cosmetic formulation. Whilst skin irritation can generally be addressed through skin compatibility evaluation of the final cosmetic product, migration of skin sensitisers in to the formulation needs to be known to the cosmetic product safety assessor to carry out a predictive safety assessment.

It should be noted that there are currently about 4,000 substances which may fall into the above categories of Annex II and III (including CMR substances) or skin sensitisers (based on the publicly available lists under Regulation 1223/2009 and Regulation 1272/2008). However, many of those substances, such as for instance specific oil refinery streams, medicinal / toxic plants, prescription drugs, …) have no relevance for the manufacturing of packaging materials, be it as raw materials or as by products. Based on expert judgement and experience, such substances can be excluded to allow suppliers of food contact grade and non-food contact grade materials to work with a smaller list of substances to be considered.

For food contact grade materials, it is possible to reduce further the number of substances by cross referencing the remaining substances with inventory lists of substances that can potentially be used in food packaging materials or are known breakdown or reaction by products.

An expert group from Cosmetics Europe and Packaging Supplier Associations has been set up to combine its expert judgement to identify from the lists of Cosmetics Regulation Annex II, Annex III (including CMR substances) and/or skin sensitisers those substances that would never be expected to be present in packaging. This allowed to create a shorter list of substances of concern that can be used as a reference for providing information to the cosmetic product safety assessor. „Guidance List of Disclosable Substances Used in FCM"

This list is based on information which is publicly available and the opinions of experts in the packaging and cosmetics industries. It is only a guide and it remains under the responsibility of a supplier to disclose the presence of any substance present in food contact material which would be of interest for the evaluation of the packaging to its clients. Anyone discovering such a substance is invited to inform Cosmetics Europe so that it can be added to the list.

Note : The original database Excel spreadsheet on which the „Guidance List of Disclosable Substances Used in FCM" is based can be made available to members of the supply chain, together with a detailed explanation of how they are compiled, to allow individual refinement of the filtering settings to their company ingredient portfolio.

Several scenarios are possible for reporting of information on specific substances along the supply chain to allow the Cosmetics Safety Assessor to evaluate the possible impact of the packaging on the safety of the formulation. In all cases, the basis for considering/excluding substance from the scope of information exchange should be indicated, for instance by reference to the „Guidance List of Disclosable Substances Used in FCM

No presence of reportable substances:

Substances specifically banned or restricted in Annex II or III of the Cosmetics Regulation 1223/2009 (including CMR substances):

The packaging supplier states that the packaging component or material does not contain, such substances, intentionally added or known to be present at levels above 10 ppm. Alternatively, the packaging supplier can state that the packaging component or material does not contain, such substances, intentionally added or known to be present, migrating in levels above 100 ppb in a relevant simulant[5].

Substances classified as Skin Sensitisers category 1, 1A or B according CLP Annex VI table 3.1:

The packaging supplier states that the packaging component or material does not contain, intentionally added or known to be present, skin sensitisers Cat.1 or 1B

[5] Compliance with migration limits can be verified either by real migration tests with food simulants, either by extraction test with an adequate solvent, either by migration modelling experiments.
Reference: Annex I of the Plastic Regulation (EU) No 10/2011: If …the specific migration limit is non-detectable (ND) a detection limit of 0,01 mg substance per kg food is applicable unless specified differently for an individual substance.

at levels above 0.1 %, nor does it contain skin sensitisers Cat. 1A at levels above 0.01 %.

Alternatively, the packaging supplier can state that the packaging component or material does not contain skin sensitisers, intentionally added or known to be present, migrating in levels above 100 ppb or 1000 ppb for sensitisers categorised as Cat 1A or 1/1B respectively in a relevant simulant[5].

Presence of reportable substances:

The packaging supplier declares the identity and concentration in the relevant component of the packaging or packaging material of :

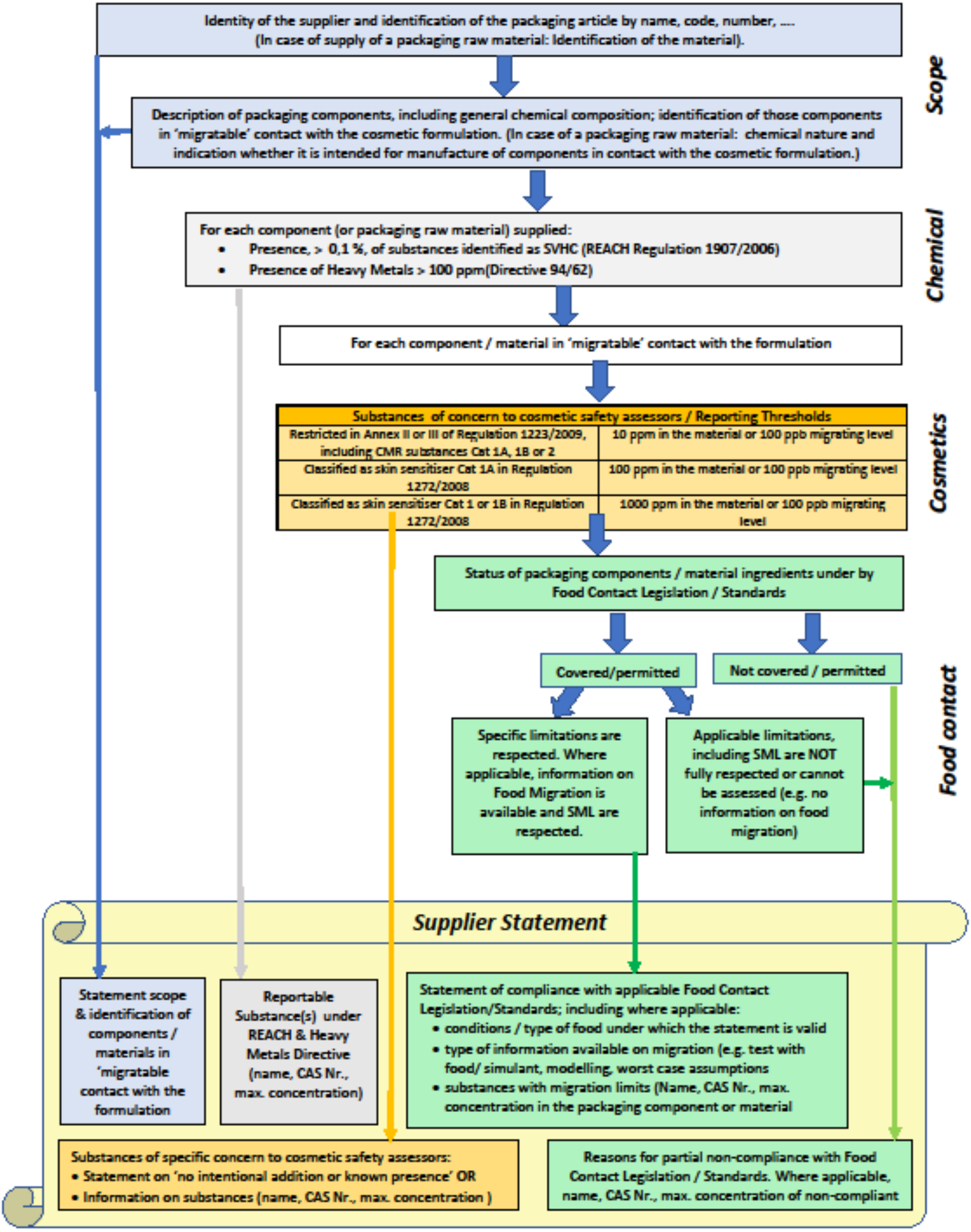
- Substances specifically banned or restricted in Annex II or III of the Cosmetics Regulation 1223/2009, including CMR substances, when present at above 10 ppm or , alternatively, when migrating in levels above 100 ppb in a relevant simulant[5].

- Substances listed in classified as skin sensitisers according to CLP Regulation, Annex VI table 3.1 Annex VI table 3.1 when present at above 0.1 % (for skin sensitisers Cat 1B or 1) or 0.01 % (for skin sensitisers Cat 1A) or, alternatively, when migrating in levels above 100 ppb or 1000 ppb for sensitisers categorised as Cat 1A or 1/1B respectively in a relevant simulant[5]. If such substance has already been declared because of its listing in Annex II or III of the Cosmetics Regulation, it is not necessary to declare it again.

Note: the 10 ppm cut-off level for reporting of Annex II and III materials is chosen based on the safety related considerations presented in chapter A, B and Annex 3 as well as a reasonable traceability of such materials in the raw material supply chain for packaging materials. The 0.1 % and 0.01 % cut-off levels for skin sensitisers are based on Classification and Labelling thresholds under the CLP Regulation for sensitisers classified as category “1B or 1” and category “1A”, respectively.

For specific substances a different threshold may be determined due to specific requirements under the Cosmetics Regulation. For example, the presence of Nitrosamines in cosmetic products is strictly limited to 50 ppb. In a worst case, migration from packaging materials/components containing 10 ppm of nitrosamines could lead to levels above this limit in the cosmetic formulation. Similarly, the Cosmetics Regulation sets a limit for acrylamide monomer in a cosmetic formulation of 100 ppb (leave-on products) and 500 ppb (rinse-off products). Consequently, nitrosamines and acrylamide monomer should be reported to the cosmetic company if they are known to be present in the packaging above 1 ppm.

ANNEX 1 - Methodology Flow-Chart



ANNEX 2
Useful EU and non-EU reference documents

1. EU Food Contact References

1.1 General EU Legislation

Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food (Framework Regulation)

Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food

1.2 Plastics

1.2.1 EU Legislation

Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food (includes specific requirements for inks, adhesives, coatings) as amended by

Regulation (EU) No. 321/2011
Regulation (EU) No. 1282/2011
Regulation (EU) No 1183/2012

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4th Amendment, Regulation (EU) No 202/2014
5th Amendment, Regulation (EU) No 2015/174
6th Amendment, Regulation No 2016/1416
7th Amendment, Regulation (EU) No 2017/752

These seven amendments are included in a Consolidated Version of the Regulation

When relevant: Regulation EC 282/2008 on recycled plastic materials and articles intended to come into contact with foods

1.2.2 Guidance

Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

EU Guidance on information in the plastics supply chain. This gives information on the contents of the declaration of compliance.

Technical guidelines for compliance testing (not yet finalised)

1.3 EU Legislation on Other Materials

Regulation 1895/2005/EC on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food

Directive 2007/42/EC on regenerated cellulose film

Directive 93/11/EEC on release of N-nitrosamines and N-nitrosatable substances from rubber teats and soothers

1.4 National legislations (where existing and when relevant) for materials with no European legislation. The EU Commission publishes two overviews

EU and national laws

Summary of national legislation additional to EU legislation

1.5 Council of Europe Resolutions. Note that CoE resolutions are recommendations and are not legally binding. They either have to be adopted into EU law or into national legislations to become legally binding.

Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food

Resolution AP (92) 2 on control of aids to polymerisation for plastic materials and articles

Resolution ResAP (2004)5 on silicones used for food contact applications

Resolution AP(2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs

Framework Resolution AP(2004)1 on coatings intended to come into contact with food (replacing Resolution AP (96) 5)

Resolution AP(2005)2 on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with food

Resolution CM/Res(2013)9 on metals and alloys used in food contact materials. This is accompanied by a Technical Guide. This is not available for free. It can be bought from https://store.edqm.eu/index.html for €30.00.

1.6 Codes of practice issued by European Trade Associations. These can be found on their web sites, e.g.:

CEPE, the Conseil Européen del'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'Art

CEPI, the Confederation of European Paper Industries

EAA, the European Aluminium Association

EuPIA, the European Printing Ink Association

FEICA, the Association of European Adhesive and Sealant Industry

FPE, Flexible Packaging Europe

PlasticsEurope, the association of plastics manufacturers

2. Other EU References

Scientific Committee on Consumer Safety (SCCS), Scientific Committee on Health and Environmental Risks, (SCHER) Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) : OPINION ON Use of the Threshold of Toxicological Concern (TTC) Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_092.pdf

REACH (EU Chemicals Legislation)

European Parliament and Council Regulation (EC) No 1907/2006

Unofficial consolidation of the REACH legal text

CLP Regulation: the consolidated version of the Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) can be downloaded from: http://echa.europa.eu/regulations/clp/legislation
Note that the consolidated version may not always contain the latest amendments and technical adaptations which can also be found on this page.

Packaging Waste: Directive 94/62/EC on Packaging and Packaging Waste, as amended by Directive 2004/12/EC

3. Non EU References

Swiss Ink Ordinance: A revised Swiss Ordinance 817.023.21 on materials and articles intended to come into contact with foodstuffs came into force on 1st May 2017. At the time of writing, there was no official English translation. The following languages are available:

- French
- German
- Italian

Section 12 deals with packaging inks and there is a revised Annex 10 listing substances that may be used in their manufacture. So far, it is only available as a .pdf file

United States Federal Food Drug and Cosmetic Act § 402(a), 409(c)

Japanese Food Sanitation Law; Ministry of Health and Welfare Notice Vol. 20 and 85

Code of practice issued by Japanese Trade Association : Voluntary Standards PL (Positive Lists) for Food Contact Substances and Polymers, issued by Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA)

Chinese Food Contact Legislation : Introduction and overview can be found here :
http://www.cirs-reach.com/China_Chemical_Regulation/Food_Contact_Regulations_Food_Contact_Materials_in_China.html

ANNEX 3
TTC concept and Cramer Classification

The "TTC" (Threshold of Toxicological Concern) is a risk assessment tool that establishes human exposure levels for certain types of chemicals below which there is no appreciable risk to human health. It is a useful tool for assessing trace substances of unknown toxicity, where the structure of the compound is known, but no substance specific toxicity data or data on a similar substance exist. The TTC approach is used by EFSA for the safety assessment of flavouring substances and metabolites, degradation and reaction products of pesticides. Further applications are risk assessments for cosmetic ingredients, household products and impurities in therapeutic drugs. See SCCS opinion on TTC for application of the approach regarding cosmetics (SCCS Notes of Guidance, 10th Revision, SCCS/1602/18).

The TTC approach is valuable if a packaging material/component is not food contact compliant due to the presence of a specific substance, present at relatively low level.

As a first step, it should be determined if the TTC approach can be used to assess the substance of interest (see SCCS, 2018). If TTC is not suitable to assess the safety of this trace level substance, substance specific data should be provided.

If the TTC approach is applicable, it needs to be checked in which "Cramer Class" the substance falls; i.e. which default TTC value applies, depending on the chemical structure of the substance. ToxTree is a predictive software program which is freely available to download and is required to perform the Cramer classification(ToxTree, 2009, http://ihcp.jrc.ec.europa.eu/our_labs/eurl-ecvam/laboratories-research/predictive_toxicology/qsar_tools/toxtree). The Cramer decision tree is used to classify substances on the basis of their expected level of oral toxicity based on the answer to 33 questions. The trace substance is classified as either Cramer Class I, II or III. This classification is explained on the following internet site: http://ihcp.jrc.ec.europa.eu/our_labs/eurl-ecvam/laboratories-research/predictive_toxicology/background/TTC .

Note that the EU Scientific Advisory Bodies, including SCCS 2018 recommend that Cramer Class II is not used in the context of substances used in cosmetics. Cramer Class II substances should be treated like Cramer Class III.

Based on the worst-case assumption that the substance completely migrates into formulation, the appropriate reporting threshold can be determined from the table below.

	Exposure µg/person/day by ingestion	Acceptable safe level (ppm) in 1kg cosmetics packaging, taking the assumption that 17,4 g of cosmetics are packed in 10 g of packaging*
Cramer Class I	1800	180
Cramer Class II or III	90	10

**Final judgement should always be made based on the actual ratio of cosmetic weight to packaging weight*

If present below the threshold, the packaging suppliers may still inform the cosmetic company that a substance of "Cramer Class … " is present in the material/component, without necessarily disclosing its identity. Given that the application of the TTC concept requires experience and expert judgement, further information may be required from the supplier in the course of the safety assessment, e.g. regarding the chemical family of the substance.

The reasoning is based on the following data for a substance belonging to Cramer Class III (the reasoning is the same for class I or II, with the appropriate figures in the table):

a) 17.4 g of cosmetics are used per person per day
b) These 17.4 g are packed in 10 g of packaging per person per day (can be adapted to other ratio when more appropriate)
c) Cramer class III allows an exposure of 90 µg/person/day by ingestion
d) Worst case: all is migrating out of the packaging
e) 10g of packaging are containing 90 µg of substance belonging to Cramer Class III
f) 1kg of packaging contains 9000 µg of substance = 9 ppm (~10ppm)

If the ratio of packaging material to product is significantly greater than in the example (line b) above, a separate calculation should be made.

Note that TTC is developed for certain classes of organic molecules and is not a validated methodology for inorganic chemicals such as heavy metals. Furthermore, whilst scientific work is ongoing on a TTC approach for skin sensitisation, this is not yet validated.

ANNEX 4
Glossary / Definitions

Absolute Barrier: A materials at given thickness which excludes any permeation of potential migrants from outside into the packed product at any foreseeable contact condition. Examples include:

- Glass of any thickness (not: SiOx layers)
- Metal cans and lids
- Aluminium foils at thickness when pinholes or other damages can be excluded

CMR Substance: A substance listed as Carcinogenic, Mutagenic or toxic to Reproduction Category 1A, 1B or 2 in CLP Regulation 1272/2008 Annex VI table 3.1

Container : see primary packaging

EFSA: European Food Safety Authority

Consumer Exposure: the quantity of a substance that a consumer is exposed to, by ingestion, skin absorption, inhalation or other means. It can be further refined to refer to specific consumer groups, e.g. children or infants, or to a statistical fraction of the consumer population, e.g. those consumers exposed at the P95 level.

Functional Barrier: One or more layers of any material type which limits the transfer of relevant substances into the packed product to either a) less than 10 ppb or b) below another level of regulatory or safety concern. For example, in the context of the Plastics Regulation 10/2011, Functional Barrier means a barrier consisting of one or more layers of any type of material which ensures that he final material or article complies with Article 3 of Regulation(EC)No 1935/2004 and with the provisions of the regulation.

Migratable Substance: A chemical substance that is capable of transfer in detectable amounts from the packaging to the packed product. It is generally accepted that substances with a molecular weight greater than 1,000 Daltons are not migratable. Inert, insoluble inorganic substances embedded in a polymeric matrix are not migratable.

Packaging component: A part of the packaging system which can exist as a separate entity, either being assembled by the packaging supplier or being incorporated into the final pack by the packer

Packaging Material: Chemical substance or mixture of substances that is used for the manufacturing of packaging components

Primary Packaging: Packaging that is in direct contact with the product

Safety Assessor: The qualified person who is designated by the cosmetic product's "Responsible Person" to carry out a safety assessment

Secondary Packaging: Packaging that is used to collate, protect or display the primary pack. It does not come into direct contact with the product and may or may not be capable of transferring substances to the product

Sensitiser: A substance classified as a skin sensitiser in CLP Regulation 1272/2008 Annex VI table 3.1 (Hazard statement code H317). See section 3.4 of Annex I for definitions, classification criteria etc.

Simulant: A test medium used to represent a type of packed product when measuring the migration of substances from the packaging. Food simulants are specified in Annex III of the Plastics Regulation 10/2011.

Specific Migration Limit (SML): the maximum concentration of a substance that may transfer from packaging into food, as defined in the Union List (Annex I) in the Plastics Regulation 10/2011.

Tertiary Packaging: Packaging that is used to collate and protect primarily for transport and storage purposes

Worst Case Calculation: This assumes that all the migrant will transfer from the packaging material into the packed product. To do it you need:

- Maximum concentration (MC) of substance in the material layer (in ppm)
- Maximum grammage per square metre (G) of material layer (or thickness and density) (in g/m^2)
- Maximum surface area of packaging to weight of cosmetics packed (SV) (in dm^2/ kg)

The formula to calculate maximum amount of substance that could migrate into the cosmetics is

MC x G x SV ÷ 100000 mg/kg (ppm)

ANNEX 5
Example of Packaging Supplier Statement

Statements according to this example can be generated with the Excel Macro distributed together with this Guidance Document.

REGULATORY INFORMATION FILE FOR PACKAGING SUPPLIERS
TO FACILITATE COMPLIANCE WITH THE REGULATORY REQUIREMENTS
APPLICABLE TO THE EU COSMETIC PRODUCTS REGULATION
REGULATION 1223/2009 Art. 10 and Annex I)

SECTION I) DOCUMENT SCOPE	
SUPPLIER NAME	
PACKAGING ITEM/MATERIAL	
SUPPLIER REFERENCE NUMBER	
CLIENT REFERENCE NUMBER	
CONFIDENTIALITY AGREEMENT REFERENCE	

SECTION II) OVERVIEW OF COMPONENTS IN THE PACKAGING MATERIAL / ITEM								
Nr.	**Component Name**	**Type of material**	**General Chemical Description**	**Material Reference**	**Weight**	**Heavy metals sum of Pb, Cd, Hg, Cr(VI) < 100 ppm (Directive 94/62/EC)**	**SVHC substances (Regulation 1907/2006)**	**Contact with cosmetic formulation**
1		*e.g. plastic, silicone, steel, ...*	*e.g. LDPE with colorant and additives*	*internal refernce number*		*yes/no*	*identify substance and level OR state 'No SVHC > 1000 ppm'*	*yes/no*
2								
3								
...								

SECTION III) SPECIFIC INFORMATION ON COMPONENTS THAT ARE IN MIGRATEABLE CONTACT WITH THE FORMULATION	
Component Name; Material Type; Company Reference	
Packaging item/material compliant with the requirements of EU Food Contact Framework Regulation 1935/2004 EC, and in particular Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	*yes*
Compliance is valid for the following conditions:	*describe conditions*

Type of information available on migration (e.g. test with food, test with simulant, modeling, worst case asumptions, supplier information, ...)	*describe in general terms by which approach migration potential was assessed*		
Substances restricted under Food Contact Legislation (Regulation 10/2011 EC)by a specific migration limit (SML), a maximum concentration (QM) in the plastic or a "no detectable migration" requirement at a certain detection limit (DL) - with a residual quantity greater or equal to 1/10 of the SML / QM	*identify substances and their level*		
The component is / is not manufactured according to EU Good Manufacturing Practice (EC) No 2023/2006. (if not, indicate if another GMP standard has been followed)			
This component contains the following substances of concern (see Note below)	*Substance name*	*Type of concern*	*Refernce list used to identify substances of concern*
	Substance name	*Type of concern*	*Refernce list used to identify substances of concern*
Component Name; Material Type; Company Reference			
Packaging item/material compliant with the requirements of EU Food Contact Framework Regulation 1935/2004 EC	*no*		
Reason for non compliance	*describe reasons for non-compliance*		
The component is / is not manufactured according to EU Good Manufacturing Practice (EC) No 2023/2006. (if not, indicate if another GMP standard has been followed)			
This component does not contain substances of concern (see Note below)			
Component Name; Material Type; Company Reference			
… etc			

Note : Substances of concern:
(a) = classified skin sensitiser Cat1A in Regulation 1272/2008 at/above 1000 ppm, or alternatively, migrating at levels above 100 ppb in a relevant simulant
(b) = classified skin sensitiser Cat1 or 1B in Regulation 1272/2008 at/above 100 ppm, or alternatively, migrating at levels above 1000 ppb in a relevant simulant(c) = banned/restricted in Cosmetics Regulation 1223/2009 Annex II/III at/above 10 ppm, or alternatively, migrating at levels above 1O0 ppb in a relevant simulant

SECTION IV) ADDITIONAL INFORMATION
e.g. reference to DoC

SECTION V) DATE AND SIGNATURE
DATE:
CONTACT & FUNCTION:
SIGNATURE:

ANNEX 6

Application of food contact material compliance information to cosmetics packaging

The Food Contact supply chain has developed a practical approach based on existing legislation which can be adapted for Cosmetics. The principle has been adopted that, in the majority of cases, if the packaging is safe for a specific type of food, it should also be suitable for cosmetics that have similar physical chemical properties as this food. However, this principle requires some justification and considerations.

Note that, whilst this present guidance document was developed around the EU Food Contact Legislation, a similar approach can be taken for packaging that is compliant with equivalent, non-EU food packaging legislation. It may be necessary, however, that the supplier provides the cosmetics product safety assessor with information on the specific requirements and standards that these regulations prescribe.

A short description of the approach for Food Contact Materials is given by the European Commission
(https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation_en**)**

The Food Contact Material Framework Regulation

Regulation (EC) No 1935/2004 provides a harmonised legal EU framework. It sets out the general principles of safety and inertness for all Food Contact Materials (FCMs).

The principles set out in Regulation (EC) No 1935/2004 require that materials do not:

- *Release their constituents into food at levels harmful to human health*
- *Change food composition, taste and odour in an unacceptable way*

Moreover, the framework provides:

- *for special rules on active and intelligent materials (they are by their design not inert)*
- *powers to enact additional EU measures for specific materials (e.g. for plastics)*
- *the procedure to perform safety assessments of substances used to manufacture FCMs involving the European Food Safety Authority*
- *rules on labelling including an indication for use (e.g. as a coffee machine, a wine bottle, or a soup spoon) or by reproducing the appropriate symbol. For more information, please refer to the following document on Symbols for labelling food contact materials.*
- *for compliance documentation and traceability*

Regulation on Good Manufacturing Practices

Regulation (EC) No 2023/2006 ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation:

- *premises fit for purpose and staff awareness of critical production stages*
- *documented quality assurance and quality control systems maintained at the premises, and*
- *selection of suitable starting materials for the manufacturing process with a view to the safety and inertness of the final articles*

Good manufacturing rules apply to all stages in the manufacturing chain of food contact materials, although the production of starting materials is covered by other legislation.

Physical chemical characteristics of cosmetics vs food

Regulation (EU) No 10/2011 on plastic materials and articles assigns 6 different food simulants representing the main food characteristics that are influencing migration.

A Ethanol 10 % (v/v)
B Acetic acid 3 % (w/v)
C Ethanol 20 % (v/v)
D1 Ethanol 50 % (v/v)
D2 Any vegetable oil containing less than 1 % unsaponifiable matter
E Poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm

Food simulants A, B and C are assigned for foods that have a hydrophilic character and are able to extract hydrophilic substances. Food simulant B is used for those foods which have a pH below 4.5. Food simulant C is used for alcoholic foods with an alcohol content of up to 20 % and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic. Food simulants D1 and D2 are assigned for foods that have a lipophilic character and are able to extract lipophilic substances. Food simulant D1 is also used for alcoholic foods with an alcohol content of above 20 % and for oil in water emulsions. Food simulant D2 is used for foods which contain free fats at the surface. Food simulant E is assigned for testing specific migration into dry foods.

Regarding food groups not specifically assigned to a food simulant, the Regulation ecourages that expert judgement be used based on the similarities with other food groups to assign the appropriate simulant.

Cosmetics are usually chemically inert, water based / oil based mixtures with a pH that is neutral or slightly acidic. For most cosmetic formulations, the physical/chemical properties relevant for migration correspond to the properties of typical food stuff described above. Therefore, a similar expert judgement approach can be taken to . (However, some formulations, e.g. alkali preparations such as some hair care products, cannot be represented by existing recognised food simulants.)

Comparison of consumer exposure scenario's between food packaging and cosmetic packaging

It is reasonable to assume that consumer exposure to the same substance from a cosmetic, typically by absorption through the skin, is not intrinsically more hazardous than exposure from food, typically by ingestion (except potentially for skin sensitisation, see below).

Thus, any difference in risk from food packaging vs. cosmetic packaging will arise from differences in exposure between these uses. The calculation of exposure to substances in food contact materials is based on the assumption of a consumer eating each day 1 kg of a food packed in 6 dm^2 of a particular material. Cosmetics packs tend to be much smaller than food packs and hence may have a higher surface area to weight ratio than 6 dm^2/kg. However, the usage of cosmetics is much lower, the generally accepted figure being 17,4 g of cosmetics rather than 1 kg of food per consumer per day (SCCS Notes of Guidance for testing of cosmetic substances and their safety evaluation, 8th Revision 2012, SCCS/1501/12).

As a common worst case of a high surface area to weight ratio, a 40 mm x 70 mm sachet could contain 2 g of product, giving a surface to volume ratio of 280 dm^2/kg. The consumer using 17.4 g of this product would, in theory, be exposed to migration from 280 x 0.0174 = 4,9 dm^2 of packaging. This is still less than their exposure from 6 dm^2 of food packaging.

On this basis, it is reasonable and conservative to consider that the surface area's to be used in consumer exposure scenarios are comparable for food packaging and for cosmetics. Furthermore, systemic availability of substances in food via the oral route is typically higher than availability of dermally applied substances.

APPENDIX 1

Guidance List of Disclosable Substances
Version December 14, 2015

The Information Exchange Guidelines require the packaging supplier to disclose the identity and concentration of certain substances if they exceed defined limits so that the cosmetics packer can conduct a safety assessment:

- Substances that are listed in Annex II and III (including CMR substances), and/or classified as skin sensitiser according to CLP Annex VI table 3.1 at levels above 10 ppm, or migrating in levels above 100 ppb in a relevant simulant

There are over 3,000 such substances and there is a practical difficulty for the packaging supply chain to ascertain which of them may be present in their materials. The Working Group therefore decided to:

a) Create a single Excel format listing of these substances
b) Create shorter list of those substances which are known to be used as substances in food contact materials (FCM) and articles. Note that this also includes those substances which are not used in layers that are in direct contact with the food but which are used in the outer layers

Figure 1 illustrates the process of how the Excel files were built up. In summary:

1. A list of Disclosable Substances was built from
    a. ECHA's C&L Inventory for
        i. CMR substances
        ii. Skin sensitisers
    b. Annex II and Annex III of 1223/2009

2. Substances used in FCM were identified from

    a. Annex I of 10/2011
    b. Annex 6 of the Swiss Ink Ordinance
    c. The FACET Inventory List which was built up from:
        i. EU and European National positive lists
        ii. Submissions by the plastics, coatings, adhesives, ink and paper industries

3. These lists were combined into a tool that enables the identification of substances that appear in both lists

4. This tool has been used to make a shorter list that can be used by the entire supply chain – i.e. Appendix I – "The Guidance List of Disclosable Substances Used in FCM".

Note that this list is based on information which is publically available and the opinions of experts in the packaging and cosmetics industries. It can only act as a guide; the possibility will always exist that it does not include a substance which should be disclosed and which may be found in FCM. Anyone discovering such a substance should inform Cosmetics Europe so that it can be added to the list.

GUIDANCE LIST OF DISCLOSABLE SUBSTANCES USED IN

Appendix I v4 221215.xlsx

FOOD CONTACT MATERIALS (click on icon to open Excel File) :

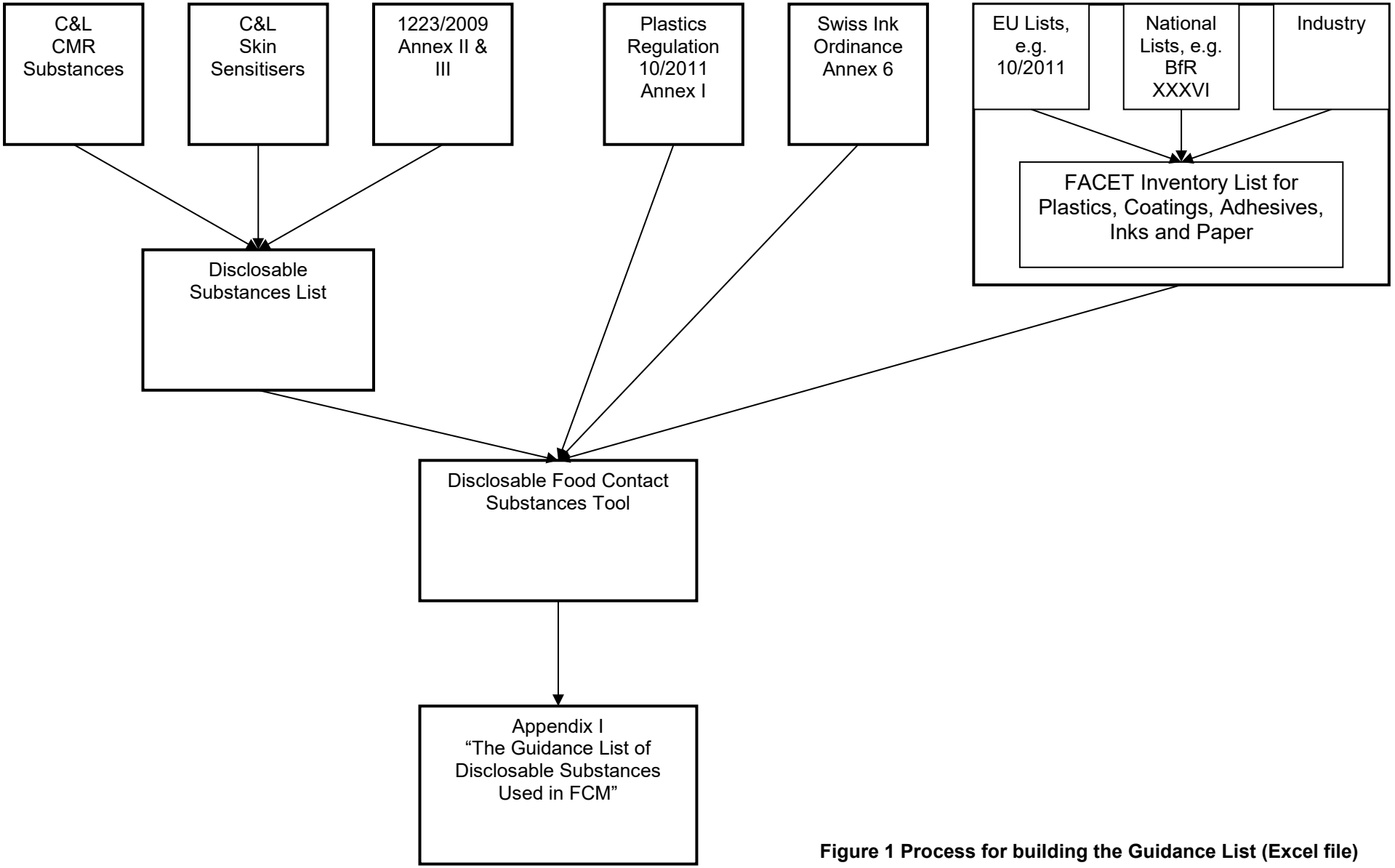

Figure 1 Process for building the Guidance List (Excel file)