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ADVISORY DOCUMENT

INFORMATION EXCHANGE ON COSMETIC PACKAGING MATERIALS ALONG THE VALUE CHAIN

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Regulatory Background

Obligations under the EU Cosmetics Regulation

- Products must be safe for the consumer
- Safety must be demonstrated via 'Safety Assessment'
- Safety assessment must
  - Be done by a qualified Safety Assessor
  - Consider exposure and toxicological profile of ingredients
  - Include assessment of impact of impurities on safety of the product; **specific reference to packaging**
  - Be justified, detailed and documented
- Additional details in EU Commission implementing Guidelines

Roles and Responsibilities

- Safety is the legal responsibility of the entity placing the cosmetic product on the market (Responsible Person)
- He needs to work with a suitably qualified safety assessor
- Relevant information on the packaging material is part of the information needed

- HOWEVER, packaging suppliers have no legal obligation to provide safety information under the Cosmetics Regulation – and only limited obligations under the Chemicals legislation.
- Data exchange is a Business to Business decision.

What information to be shared ? Full composition of the packaging ?

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- Very difficult to obtain along the supply chain
  - lack of knowledge of clients' legal obligations,
  - concerns over commercial secrecy,
  - high administrative burden,
  - lack of information from their own suppliers…
- Can be more substances than the cosmetic formulation
- Packaging safety assessment may become more complicated than the safety assessment of the cosmetic formulation

What information to be shared ? Targeted, Relevant Information

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EU Commission Guidelines :

- *… in direct contact with the formulation.*
- *… experience with similar formulation/packaging combinations already on the market*
- *… food packaging have often already been tested, so relevant information on stability and migration may be available.*

Opportunity for a common sense, harmonised approach

→focus on information that is relevant for the safety assessor

→facilitate exchange of information along the value chain

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How was the industry document developed ?

Cross sector platform

- AdHoc Group of EU Associations representing the packaging value chain : Plastics, adhesives, metals, alloys, paper, board, printing inks, varnishes
- **European Task Force on cosmetic packaging regulatory aspects :**
  COSMETICS EUROPE, CEFIC-FCA, COSMETICA ITALIA, ELLIPSO, EUROPEAN COUNCIL OF PAINT PRINTING INK AND ARTIST COLOURS MANUFACTUERS ASSOCIATION, EUROPEAN METAL PACKAGING, EUROPEAN PLASTICS CONVERTERS, EUROPEAN TUBE MANUFACTURERS ASSOCIATION, FEBEA, FLEXIBLE PACKAGING EUROPE, IKW, INDUSTRIEVEREINIGUNG KUNSTSTOFFVERPACKUNGEN, PLASTICS EUROPE, UNIONPLAST – FEDERAZIONE GOMMA PLASTICA
- 11 meetings from December 2013 – November 2016, numerous ‘final’ drafts and consultations within the respective organisations
- 2016: Beta-Trial with +/- 40 cosmetic companies
- 2017/2018: Full trial open to all interested companies
- 2019 June: Adopted by Cosmetics Europe BOD

Scope of the document and principle of the approach

What it is not …

- **Not an allocation of safety responsibility to suppliers**
  Cosmetic product remains the responsibility of the cosmetics Responsible Person
- **Not Guidelines on 'packaging safety assessment'**
  Rather identifies relevant information that can be transmitted along the supply chain to enable a safety assessment
- **Not Guidelines on physical risks of the packaging suitability of the packaging regarding product quality**
  Only addresses impact on the formulation (chemical risks)
- **Not an exclusive or mandatory approach to ensure compliance with the Cosmetics Regulation**
  Other approaches may be used – provided they enable an appropriate safety assessment of the cosmetic product

What it is …

- **Practical Guidance for suppliers of packaging raw materials and finished packaging items**
- **Tool to identify relevant packaging constituents whose presence needs to be known to the Cosmetic Safety Assessor**
- **Based on established practices in the area of food contact materials**
- **Approach that can be applied along the supply chain to aggregate relevant information**

Principle approach

- Main concern is the possible migration of substances from the packaging into the formulation

  Focus information on those components of the packaging that are in 'migrateable' contact with the formulation

- Most cosmetic products have similar physical chemical properties to typical foods/food simulants

  Where possible, benefit from established process on information exchange on food packaging materials (based on EU legislation and Commission/industry Guidance)

- Migration exposure scenarios from food packaging can be applied to cosmetic packaging

Principle approach

- If physical/chemical properties are similar, safety information justifying food contact use can also support use as cosmetic packaging
- In addition, information needed on packaging constituents that are of specific concern for cosmetic safety and compliance (banned, restricted substances, skin sensitisers)
- The approach can be applied at any step of the supply chain. From raw material to finished packaging !

Step-by-Step

Following slides are based on ‘Macro’

- Interactive questionnaire that allows to build a packaging statement according to the guidelines.
- No obligation to use, but helpful for some companies

Raw Material vs Finished Packagin Item

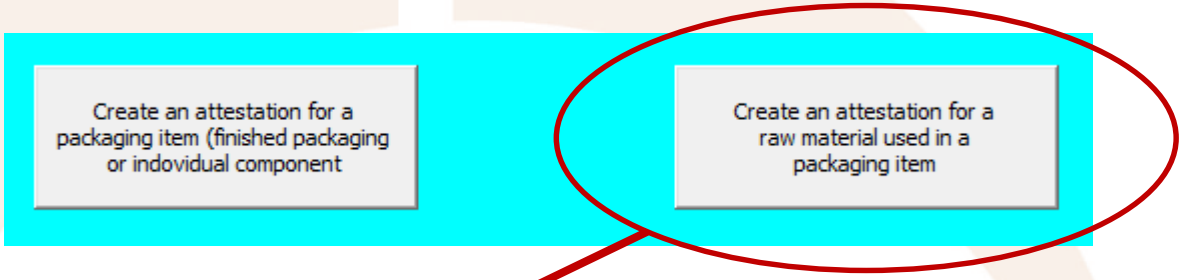
Approach can be used for all steps in the supply chain:

Raw material → compounded raw materials → packaging components → final packaging

Mixture

Article

Scenario of a Raw Material



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Step 1 – Identification

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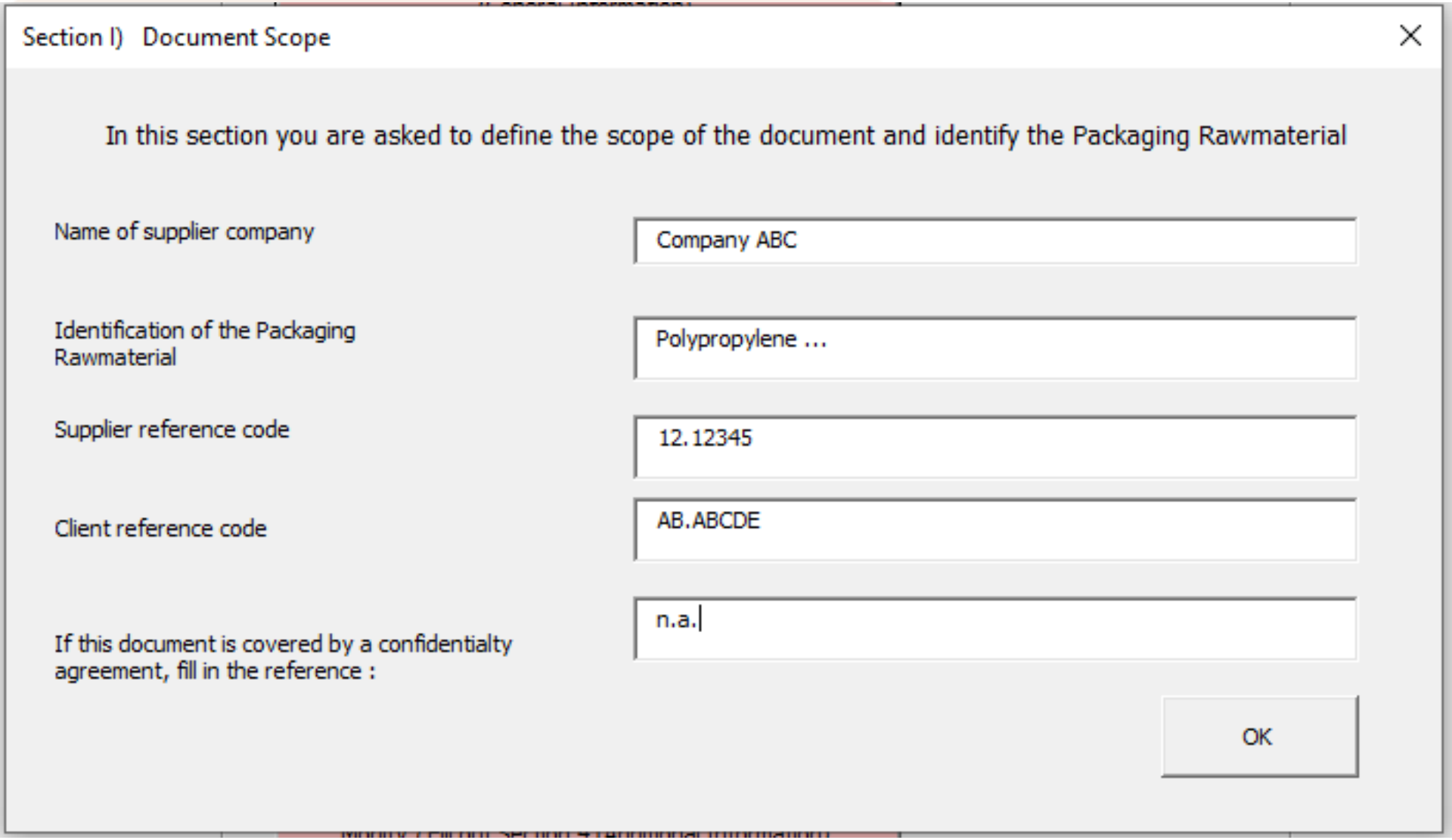

Step 2 – General Chemical information

Raw Material Name: **Polypropylene ...**

Change name

Material Type

- Plastic
- Glass/Ceramics
- Rubber
- Silicone
- Coatings
- Steel
- Decoration (e.g.label, ink)
- Other - define

General Chemical Description: Polypropylene

Company reference: 1212345

Weight or concentration: n.a.

Is the component in direct or indirect contact with the cosmetic formulation in a way that would enable migration into the formulation ?

yes

According to the EU Packaging and Packaging Waste Directive (94/62/EC) , the sum of the concentration levels of lead, cadmium, mercury and hexavelent chromium must not exceed 100 ppm.

Does the component comply with the heavy metals requirements of Directive 94/62/EC ?

yes

According to the EU Chemicals Legislation, REACH (Regulation 1907/2006, Article 33), deliberate addition or known presence of Substances of Very High Concern (SVHC) at or above 0,1 % (1000ppm) needs to be indicated for each component.

Does the component contain any SVHC substance > 1000 ppm ?

no

No SVHC > 1000 ppm

Step 3 – Compliance with Food Contact Legislation (1)

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Compliance with EU Food Contact Legislation

The composition of the Raw Material is compliant with the requirements of EU Food Contact Framework Regulation 1935/2004 EC, and in particular with Regulation 10/2011 EC.

Conditions for which compliance is valid (eg. types of food / or simulants , specific conditions)	oil, fresh meat, …

Migration

Type of information available on migration (e.g. test with food, test with simulant, modeling, worst case asumptions, supplier information, …)	Test with food simulant (see attached)

Step 3 – Compliance with Food Contact Legislation (2)

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Presence of 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

Substance XXXX; CAS 1234-05-6

yes

GMP

Component manufactured according to EU Good Manufacturing Practice (EC) No 2023/2006 ?

yes

Step 4 – Add substances of concern to cosmetics safety assessor

Substance XXXX

CAS N° 1234-05-6

Concentration in the component or migrating levelin a relevant simulant: 0.25 %

Reason for reporting :

- [x] banned/ restricted in Annex II / III of the EU Cosmetics Regulation (incl. CMR)
- [ ] Sensitiser Cat 1/Cat 1B
- [x] Sensitiser Cat 1A

Which reference list(s) was used to identify the substances (e.g. CLP regulation, EU Cosmetics Regulation, Cross Industry Guidance Document (Appendix 1), … ?

Cross industry guidance list

CPR Banned Substances

- Annex II of the Cosmetics Regulation bans the presence of +/- 1600 Substances
- Most substances have very low likelihood to be actively used as cosmetic ingredient
  - > 1100 CMR Substances (classified as Carcinogenic, Mutagenic, Reprotoxic)
  - Active drug ingredients, antibiotics
  - Certain natural and synthetic toxins
  - BSE Risk materials
  - Hormones
  - Psychotropic drugs
  - Certain potential cosmetic ingredients

Restricted Substances

- Annex III of the Cosmetics Regulation restricts the max. concentration of +/- 300 substances
- Most substances have very high likelihood to be actively used as cosmetic ingredient
- Easy to control the actively added concentration BUT difficult to manage additional amounts from impurities

Skin Sensitisers

- Skin compatibility is major concern for cosmetics (direct prolonged contact)
- Skin reactions in allergic consumers can be elicited at low concentrations
- Presence of skin allergens may not always be avoidable – but safety can be achieved through concentration/formulation

Substances of concern to the Cosmetic Safety Assessor

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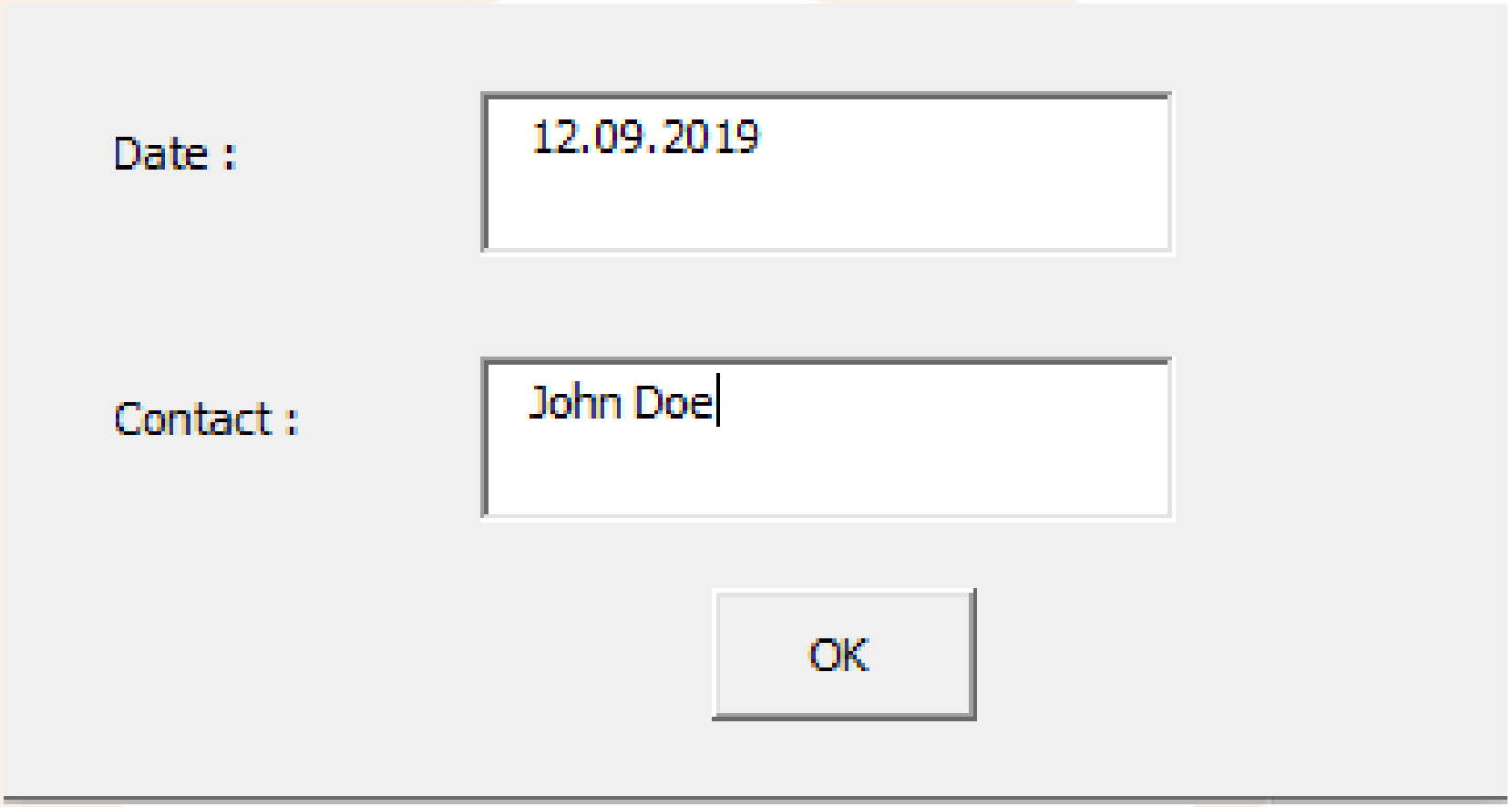
- Cosmetic companies can manage direct addition but **need to know impurities from raw materials and packaging !!!**
- Otherwise risk with regard to regulatory compliance and public perception

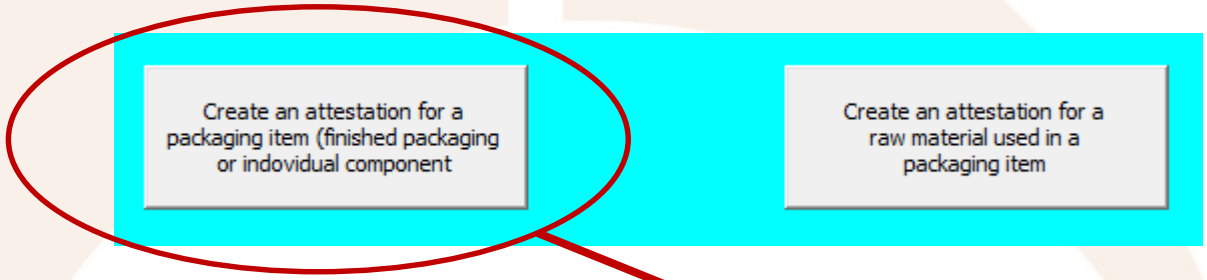
Step 5 – Additional Information

Please provide any additional relevant information on the packaging Rawmaterial that may help the Cosmetic Product Safety Assessor to evaluate its safety when used with the cosmetic formulation.In particular, provide Documents of Compliance (DoC) as well as references/summaries of migration evaluation (OML, SML) in relation to the components or its raw material :

Step 6 – Date and Contact



Scenario of Finished Packaging Item



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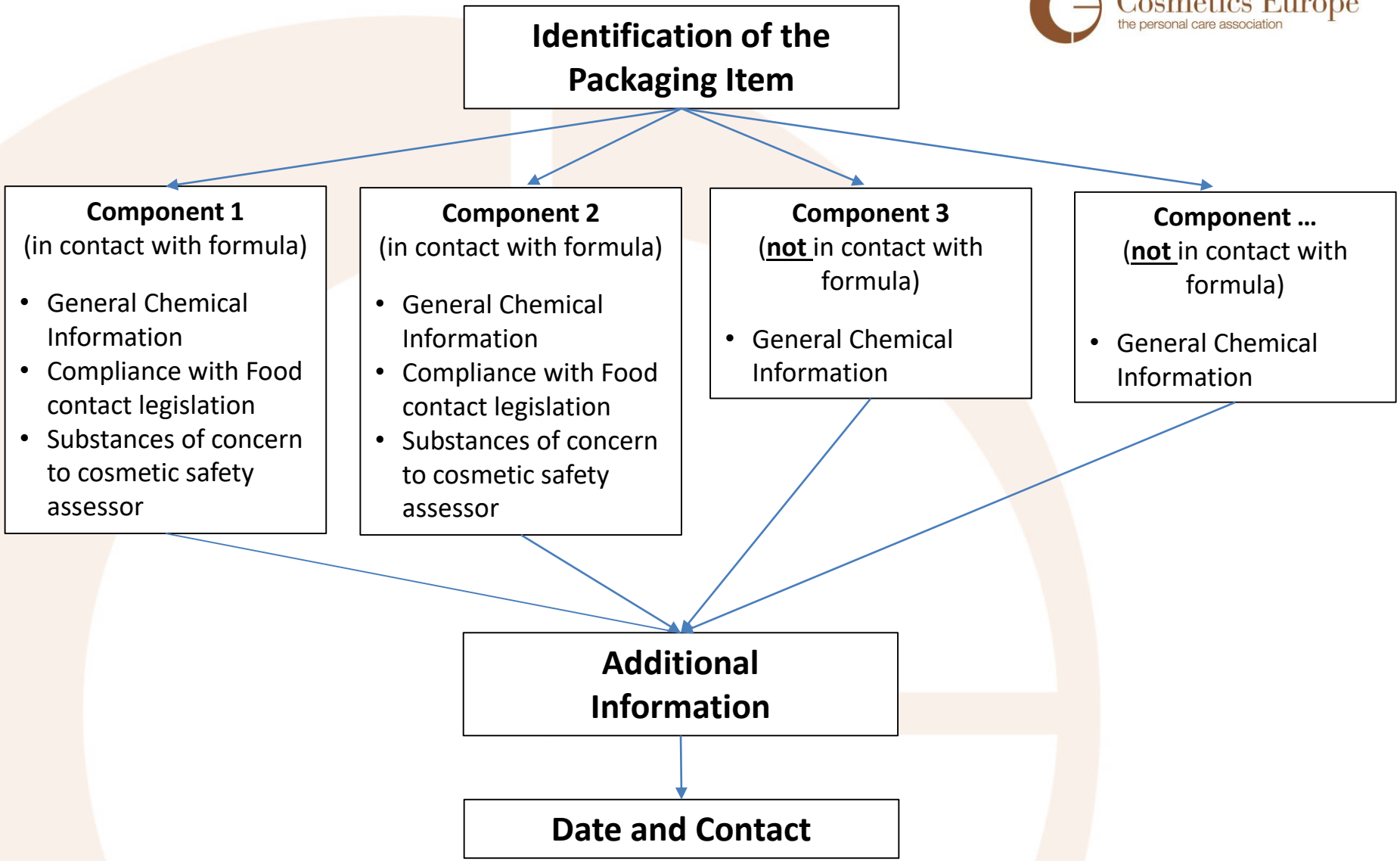

Information ultimately available for the safety assessor (1)

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- Description of packaging and its components, incl. their chemical nature and weight

- For each component :
  - identity and concentration of SVHC substances > 0,1 %
  - Heavy metals > 100 ppm
  - Identification if component is in ‘migrateable’ contact with the formulation

Information ultimately available for the safety assessor (2)

- For each component in 'migrateable contact':
  - Statement on compliance with Food Contact Legislation (incl. applicable foods/simulants) OR
  - Reason of non compliance. (If linked to a specific substance : Identification and concentration*)
  - Identification and concentration * of SML substances
  - Identification and concentration* of substances of specific concern to the cosmetic safety assessor (banned/restricted under Cosmetics Regulation & skin sensitisers)

* If above reporting threshold

Information ultimately available for the safety assessor (2)

- For each component in 'migrateable contact':
  - Statement on compliance with Food Contact Legislation (incl. applicable foods/simulants) OR
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Challenges

Learnings from trials 2016/2018

- Guidelines can work in principle
- Difficult to obtain information from suppliers, especially further up in the supply chain
  - → Lack of knowledge of regulatory obligations of the final customer (Cosmetics Regulation)
  - → Lack of knowledge of cross industry initiative
  - → Misunerstandings on the scope/functioning of the guidelines
  - → Unwillingness to change established practice for a trial

Need better roll-out of guidelines, in particular by supplier associations.

Practical Issues

- Reporting levels for CMR substances 1 ppm too low
  - → *aligned to 10 ppm with other substances of concern due to changed approach of Commission on CMR in cosmetics*
- Expection by clients that final cosmetic packaging must be fully food contact compliant
  - → *clarified that formal food compliance is not mandatory. The guidance approach can also be applied for non-compliant packaging. However, in this case more information may need to be provided on the reasons of non-compliance*
- Many final cosmetic packaging respect food contact legislation composition, but do not do specific migration tests
  - → *Clarified that relevant information on food contact compliance can be passed on regarding raw materials/compounded raw materials*

Practical Issues

- Impossible to systematically analyse for 2000 substances of concern to cosmetic safety assessor (CPR Annex II, Annex III and CLP sensitisers)
  - *Requires common sense approach*
  - *Most of the substances of concern would never reasonably expected to occur in packaging*
  - *Expert team reviewed the lists and identified +/- 400 substances whose presence in food contact packaging cannot be realistically excluded*

Future Challenges

- Implement guidance into daily practice along all steps in the supply chain
- Expectation management of competent authorities
- Update and further refine list of reportable substances of concern
- Potential identification of Endocrine Disruptors as substances of concern to cosmetic safety assessors
- Evolve the approach to accomodate recycled materials

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Thank you for your attention !