**Working Document of the Working Group on Cosmetic Products**

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**Working Document: Guidance for the implementation of Article 15 of the Cosmetic Products Regulation**

**(replacing the “*CMR exemption procedure February 2020*”)**

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# Introduction and Problem Definition

The purpose of this working document is to replace the existing “CMR Exemption Procedure (February 2020)”[[1]](#footnote-2) guidelines and align it with current regulatory and market developments. It provides updated guidance to ensure compliance with the latest requirements while addressing the evolving landscape of cosmetic products.

## Introduction

Article 15 of Regulation (EC) N° 1223/2009 on cosmetic products (Cosmetic Products Regulation, hereinafter as CPR) establishes that substances which have been classified as carcinogenic, mutagenic or reprotoxic (CMR) in Annex VI to Regulation (EC) 1272/2008 on classification, labelling and packaging of chemical substances and mixtures (CLP Regulation) are prohibited for use in cosmetic products, unless an exemption has been granted. More specifically,

* Pursuant to Article 15(1) of the CPR, the use of a CMR substance of category 2, listed in Part 3 of Annex VI to the CLP Regulation, is prohibited in cosmetic products **unless** it has been evaluated by the SCCS **and** found safe for use in cosmetics.
* Article 15(2) provides that the use of substances classified as CMR substances of category 1A or 1B, listed in Part 3 of Annex VI to the CLP Regulation is prohibited in cosmetics, **except** when the following criterial **cumulatively** fulfilled:
1. *the substance complies with the* ***food safety requirements***
2. *there are* ***no suitable alternatives***
3. *the application has been made for a* ***particular use of the product category with a known exposure****, and*
4. *the substance has been* ***evaluated and found safe by the SCCS*** *considering the cumulative exposure from other sources outside cosmetics.*

As regards the deadline for the implementation of the exemption procedure for CMR 1A/1B substances, Article 15(2) 4th subparagraph of the CPR provides that the Commission shall amend the relevant Annexes to this Regulation within 15 months of the “*inclusion of the substances concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008*”.

## Problem definition

Thus far, the Commission services (DG GROW) have considered that the 15-month timeline for granting an exemption or banning CMRs in cosmetics should be calculated from the **date of entry into force** of the CMR classification, rather than its date of application. Each year, a review is conducted through the Omnibus Act on CMR substances to transpose substances with newly harmonized classifications under the CLP Regulation into the Annexes of the CPR. Specifically, prohibited substances are added to Annex II, while substances that have successfully obtained an exemption from the general ban are listed in Annexes III–VI. With the current process, the application date of the harmonised classification coincides with the application of the prohibition or restriction of such substances under the CPR (i.e., the Omnibus Act on CMRs and the Delegated act for the harmonised classification and labelling of hazardous substances have the same application date).

Nevertheless, recent experience has highlighted certain challenges and limitations in the current system, indicating that it may not be functioning as effectively as intended. For example,

* the complete **lack of transitional periods** for the implementation of the Omnibus Acts, demonstrated that it is practically impossible to withdraw cosmetic products from the market in an effective and efficient manner.
* the submission by industry to the Commission services (DG GROW) of a complete file for a possible exemption[[2]](#footnote-3) is based **only on the RAC opinion**, which proposes a possible classification. Such opinion is not legally binding and may result in a different classification in the CLP. The lack of legal certainty on the possible classification hinders economic operators from a timely submission of an exemption request and jeopardise the process when a dossier submission may be based on a different classification.
* the submission by industry to the Commission services (DG GROW) of a complete file for a possible exemption at **the latest 6 months** from the publication of the RAC opinion, proved to be extremely short for a comprehensive dossier submission and for a proper safety assessment by the Scientific Committee on Consumer Safety (SCCS). For the latter, it should be noted that such safety assessments are considered a priority, which may limit the capacity of the SCCS to address other emerging issues.
* the lack of **specific requirements** and **methodology** to assess the exemption criteria such as the compliance with the food safety requirements and lack of suitable alternatives has resulted in the rejection of exemption requests although substances were assessed and found safe.
* the absence of an **agreed** and **hierarchical approach** to assess all exemption criteria for CMR Cat.1 substances is negatively affecting an effective and efficient exemption process.
* the current **lack of expertise** specifically relevant to the assessment of suitable alternatives or the compliance with the food safety criteria in the Standing Committee on Cosmetics Products, is adversely impacting a smooth and streamlined exemption process.
* the recent introduction of **new hazard classes** under the CLP, in particular ‘endocrine disruption for human health’, necessitate consideration under the CPR using a similar approach as laid down in Article 15.
* the observed **increase of harmonised classifications** of substances as well as of **grouping** of substances that are used in consumer products requires flexibility vis-à-vis timelines and resources.
* the classification of substances that are **constituents of complex substances** (synthetic or natural), requires a new approach for the implementation of Article 15.

The present guidance document aims at clarifying and ensuring that all the requirements for the adoption of Commission measures regulating the use of CMR and ED substances in cosmetics are timely met within the shorter timeframe possible, allowing however, a certain level of flexibility.

# Exemption process

## Establishing a sub-WG for CMR cat. 1 exemption requests

To enhance the efficacy, precision and consistency of handling exemption dossiers under Article 15 of the CPR, it is deemed necessary to establish a **dedicated Sub-Working Group (Sub-WG)**. The creation of this sub-WG is necessary to address the increasing complexity and volume of exemption requests, ensuring that each dossier receives the focused analysis it requires. It will **serve as a technical advisory body to the Standing Committee on Cosmetic Products**, providing detailed scrutiny and expert input on exemption applications, with the aim of supporting the evaluation and decision-making process.

The Sub-WG will consist of representatives from relevant Commission services (DG GROW), Member State experts, and technical advisors from industry with specialized knowledge and expertise in relevant fields including but not limited to toxicology, exposure assessment, regulatory compliance for both cosmetics and food sector, analysis of alternatives, socioeconomic analysis, etc. The Sub-WG will focus specifically on exemption dossiers involving CMR substances of categories 1A and 1B, ensuring an evidence and science-based, proportionate, and efficient evaluation thereby reducing processing times and improving decision-making accuracy.

The primary objectives of the Sub-WG will be to:

* **Conduct in-depth technical assessments** of exemption dossiers submitted by the applicant, ensuring compliance with the exemption criteria -except from the safety assessment performed by the SCCS- set out in Article 15(2) of the Cosmetics Regulation.
* **Harmonize evaluation practices** across dossiers, promoting a consistent and transparent approach in line with the latest scientific and regulatory developments.
* **Facilitate collaboration** and **expertise sharing** among relevant Commission services (DG GROW), regulatory authorities, and external scientific bodies, such as the SCCS.
* **Identify and address technical challenges** in the evaluation process, including assessing food safety compliance and availability of suitable alternatives.

In summary, establishing a sub-WG for exemption dossiers is a proactive step towards enhancing the regulatory process. Among the expected outcomes are:

* a more **robust and transparent** assessment process for exemption dossiers.
* **streamlined decision-making** by addressing technical complexities early in the process.
* **improved alignment** with the goals of consumer safety, public health, and regulatory efficiency.

This Sub-WG will play a crucial role in supporting the Commission’s work in evaluating exemption applications, thereby helping to safeguard consumer safety while maintaining regulatory coherence and operational efficiency.

## A stepwise approach for the evaluation of exemption criteria

### Substances classified as CMR of Category 2

For CMR substances of Category 2, Article 15(1) of the CPR establishes a single criterion for allowing their use in cosmetic products as a way of derogation from the generic bans. CMR Cat.2 substances are prohibited in cosmetic products **unless they have been evaluated by the SCCS and found safe for use in cosmetics**.

### Substances classified as CMR of Category 1

For CMR substances of Category 1, Article 15(2) provides that the use of such substances is prohibited in cosmetics, **except** when the following criterial **cumulatively** fulfilled:

1. *the substance complies with the* ***food safety requirements***
2. *there are* ***no suitable alternatives***
3. *the application has been made for a* ***particular use of the product category with a known exposure****, and*
4. *the substance has been* ***evaluated and found safe*** *by the SCCS considering the cumulative exposure from other sources outside cosmetics.*

The absence of a defined hierarchy for fulfilling the cumulative criteria in Article 15(2) of the CPR presents several challenges. For example, without a specified order, different stakeholders might interpret and prioritize the criteria differently, leading to inconsistencies in the derogation process. This can result in varied application of the regulation across different cases contributing to uncertainty and inconsistency. In addition, assessing all criteria simultaneously can complicate the evaluation process. Evaluators must balance multiple elements—such as food safety compliance, the availability of suitable alternatives, specific exposure scenarios, and overall safety—without clear guidance on which should be addressed first. This can be resource-intensive, requiring significant time and effort from regulatory personnel to assess each aspect comprehensively and reach a conclusion. Moreover, the absence of a clear sequence can lead to inefficiencies, as the applicant might spend resources on fulfilling all criteria simultaneously without knowing which are more critical. This uncertainty and lack of predictability can discourage engagement and hinder compliance with regulatory expectations.

A good approach to effectively and efficiently assess compliance with Article 15(2) criteria is to follow a **stepwise, hierarchical evaluation** to avoid unnecessary effort and resources if early criteria are not met. When evaluating exemption requests under Article 15(2) of the CPR, it is crucial to follow a precisely structured and stepwise approach to ensure the process is both **effective** and **efficient**. The four exemption criteria must all be **cumulatively met** for a derogation to be granted. Therefore, if **any single criterion is not fulfilled**, the request must be **declined**, and no further assessment is necessary.

To streamline the evaluation process and optimize resources, the criteria should be assessed in a logical sequence—beginning with those that are easiest to verify and have the potential to eliminate non-qualifying applications early. This approach ensures that **only well-supported requests move to the more complex stages** of the assessment. The following sections outline a step-by-step strategy to guide the applicant through this critical assessment, explaining the rationale and method for evaluating each criterion.

**Step 0: Initial screening – compliance check:**

The **initial screening** is the first step in the process of evaluating an application for an exemption under Article 15(2) of the CPR. This step ensures that only complete and well-documented applications move forward for detailed assessment. It is a **critical gatekeeping stage** designed to save time and resources by filtering out incomplete or insufficiently substantiated requests early on (see Annex 1).

**Step 1: Assessment of the food safety compliance (Criterion a)**

Assess whether the substance meets food safety standards if it **naturally occurs in food** or is **intentionally added** during food manufacturing, preparation, or treatment. This ensures that substances used in cosmetics are at least as safe as those present in food products.

The food safety requirement is often easier to determine because it relies on **existing data** and **Regulations**. If a substance does not meet this criterion, further evaluation is unnecessary, and the application can be rejected at this stage.

This step includes checking compliance with Regulation (EC) No 178/2002 on general food safety requirements and referring to EFSA assessments (European Food Safety Authority) or equivalent scientific opinions to determine whether the substance is deemed safe for use in food. Moreover, it will cross-check with food industry data to confirm compliance with food safety standards (see section 4 and Annex 2).

**Step 2: Assessment of suitable alternatives (Criterion b)**

Determine whether **viable alternatives** exist for the substance in the specific product category. **If alternatives are available that are technically feasible, safer, and meet consumer needs, the exemption request should be declined**.

Assessing the availability of alternatives early in the process ensures that resources are not spent evaluating the safety of substances for which **viable substitutes exist**. If suitable alternatives are identified, there is no justification for granting an exemption (see section 5 and Annex 3).

**Step 3: Assessment of the particular use and product category (Criterion c)**

Evaluate whether the application is for a **particular use within a specific product category** and supported by **known exposure data**. This ensures that the safety evaluation is based on realistic and well-defined exposure scenarios.

Accurate exposure data is essential for a **meaningful safety evaluation**. If exposure is uncertain or exaggerated, the safety assessment will lack reliability. Ensuring that this criterion is met provides a solid foundation for the final safety assessment (see section 6 and Annex 4).

**Step 4: Safety assessment by the SCCS (Criterion d)**

Evaluation of the **overall safety** of the substance for the specific use in cosmetics is performed by the Scientific Committee on Consumer Safety (SCCS) taking into account the (i) **cumulative exposure from other sources** (e.g., food, environmental exposure, etc.) and (ii) **special consideration for vulnerable population groups** (e.g., children, pregnant women, and individuals with compromised health, etc.).

The safety assessment is the **most resource-intensive step**, requiring detailed scientific analysis and input from the SCCS. Ensuring that the previous criteria are met before this step helps avoid unnecessary safety evaluations for substances that will not qualify (see section 7).

This sequential approach allows for a logical and thorough evaluation, ensuring that each criterion is addressed in a manner that supports compliance with the regulation. If at any step a criterion is not met, it may not be necessary to proceed with the subsequent steps, thus maintaining efficiency.

# Timelines

This working document provides an approach for the implementation of Article 15 of the CPR while maintaining its fundamental principles, namely the general ban on CMR substances with a limited possibility for exemptions for CMR of category 1 and 2 substances.

As described under the problem definition section, the timelines for the risk management of CMR substances under the CPR are not clear. The current approach clarifies the process for requesting and granting an exemption where a request for derogation is submitted. This is important for businesses, and especially SMEs, so that they are well informed about when, how and under which conditions they can seek an exemption.

## Timelines of the ATP to the CLP Regulation

Prior to presenting the timelines for the CMR exemption dossier under the CPR, it is important to clarify the process and timelines for publishing RAC opinions and adopting the corresponding Adaptation to Technical Progress (ATP) under the new framework agreed at CARACAL level.

In general, the RAC secretariat aims publishing the RAC opinions adopted in each plenary before the next plenary meeting (there are four RAC plenary meetings each year: March, June, September and December). Generally, the timeline for preparing and publishing RAC opinions and ATPs is as follows, **assuming that year N is the year where an ATP is adopted:**

* RAC Opinions **adopted** in the December’s plenary meeting of **year N-2** andthose adopted in the March-September plenary meetings of **year N-1** are all **published** by Q4 of **year N-1**.
* The ATP that will include the RAC Opinions published in **year N-1** is **adopted** at the end of **year N** (i.e., by Q4 of year N) and **published[[3]](#footnote-4)** in the Official Journal of the EU in **Q1** of **year N+1.**
* This ATP **enters into force 20 days** after its **publication** in the Official Journal of the EU and is applicable **the first day of the month** following **18 months** after the **date of entry into force** (i.e., in **Q3** of **year N+2**).

|  |  |  |
| --- | --- | --- |
| **Event** | **Timeline** | **Example** |
| **Adoption of December RAC Opinions** | Q4 of year N-2 | Q4 2023 |
| **Adoption of March-September RAC Opinions** | By Q3 of year N-1 | By Q3 of 2024 |
| **Publication of RAC Opinions** *(adopted in December of year N-2 and March-September of year N-1*) | year N-1 | By Q4 of 2024 |
| **Adoption of ATP** | **year N** | By Q4 of **2025** |
| **Publication of ATP** | year N + 1 | Q1 2026 |
| **Entry into Force of ATP**  | (year N + 1) + 20 days after publication | Q1 2026 |
| **Application Date of ATP** | (year N + 1) + 20 days after publication + 18 months = **Q3 of year N + 2** | Q3 2027 |

**Timeline for the 2024-2025 RAC plenaries and associated ATPs**

To further understand the new framework, below is the detailed timeline for the RAC plenaries scheduled for 2025, along with the corresponding publication, entry into force, and application dates for the ATPs.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **RAC Plenary and RAC Opinion adoption** | **Publication of RAC Opinions** | **ATP Adoption Year** | **ATP publication Year** | **ATP Entry into Force** | **ATP Application** |
| RAC67 (December **2022**) | Q1 2023 | **By Q4 2024** | **Q1 2025** | **Q1 2025** | **Q3 2026** |
| RAC68 (March **2023**) | Q2 2023 |
| RAC69 (June **2023**) | Q3 2023 |
| RAC70 (September **2023**) | Q4 2023 |
| RAC71 (December **2023**) | Q1 2024 | **By Q4 2025** | **Q1 2026** | **Q1 2026** | **Q3 2027** |
| RAC72 (March **2024**) | Q2 2024 |
| RAC73 (June **2024**) | Q3 2024 |
| RAC74 (September **2024**) | Q4 2024 |
| RAC75 (December **2024**) | Q1 2025 | **By Q4 2026** | **Q1 2027** | **Q1 2027** | **Q3 2028** |
| RAC76 (March **2025**) | Q2 2025 |
| RAC77 (June **2025**) | Q3 2025 |
| RAC78 (September **2025**) | Q4 2025 |
| RAC79 (December **2025**) | Q1 2026 | **By Q4 2027** | **Q1 2028** | **Q1 2028** | **Q3 2029** |
| RAC80 (March **2026**) | Q2 2026 |
| RAC81 (June **2026**) | Q3 2026 |
| RAC82 (September **2026**) | Q4 2026 |
| …. |  |  |  |  |  |

In some cases, certain opinions are deemed **sensitive** or require **additional proof-reading** and **legal scrutiny**. This additional review can lead to delays in the publication of the RAC opinions with subsequent delays in the other steps of the process including their listing in the ATP.

## Timeline for the CPR exemption process

The timeline for the derogation process of **CMR Category 1** and **2 substances** is currently guided by the provisions of **Article 15** of the CPR. However, the timelines and procedures differ significantly for Category 1 and 2 substances.

For **CMR Category 1 substances**, **Article 15(2)** of the CPR stipulates a clear and binding timeline. The Commission is required to amend the Annexes to the CPR within **15 months of the inclusion of the substances** in **Part 3 of Annex VI** of the **CLP Regulation (Regulation (EC) No 1272/2008)**. This amendment process follows the **regulatory procedure with scrutiny**, as described in **Article 32(3) of the CPR**. This strict timeline ensures timely regulatory action for substances that present the highest potential risk, as they are classified as proven carcinogenic, mutagenic, or toxic to reproduction (CMR) in Category 1.

In contrast, for **CMR Category 2 substances**, **Article 15(1)** of the CPR does **not** specify a precise timeline for regulatory action. It states: ‘*The use in cosmetic products of substances classified as CMR substances of Category 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited. However, a substance classified in Category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products. To these ends, the Commission shall adopt the necessary measures in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation.’[emphasis added]*

The reference to **‘*these ends*’** in the English version of the CPR covers **two distinct measures**:

1. The **prohibition** of CMR Category 2 substances in cosmetics, and
2. The **exemption process** that allows the use of a Category 2 substance if the **SCCS** has evaluated it and found it safe for use in cosmetics.

Despite the legal distinction between Category 1 and 2 substances in the CPR, the **Omnibus Acts on CMRs** have applied a **15-month timeline** for amending the Annexes of the CPR, regardless of the classification category. This 15-month period was calculated from the **date of entry into force** of the relevant ATPunder the CLP Regulation. While this approach ensures a degree of consistency, it introduces a **discrepancy between the timeframes** given to economic operators for compliance with the CLP and CPR:

* Under the **CLP Regulation**, the date of entry into force **informs** economic operators that they have 18 months to prepare, while **compliance** is **required** from the **date of application** of the respective ATP.
* Under the **CPR**, the Omnibus Acts amend the Annexes to the CPR **within 15 months of the ATP’s entry into force**, while the legislation does **not** provide any timeframe for economic operators to **prepare** for its application. It should be also noted that the economic operators for cosmetic products are further downstream of the economic operators affected by CLP (i.e., raw material providers, manufacturers, etc.) and depend on the latter to acquire updated information on the materials they use in cosmetic products prior to making any changes in their products. This **creates a misalignment that can lead to legal uncertainty and operational challenges for stakeholders**, even if the application date of the Omnibus Acts is designed to align with that of the ATP.

To resolve this issue, it would be more coherent and practical to align the **15-month timeline** for regulatory action under the CPR with the **date of application** of the ATP under the CLP Regulation. This approach would provide:

1. **consistency in timelines** across both regulations,
2. **legal clarity** for economic operators, and
3. **predictability** for planning **compliance** and **implementation** strategies for both **economic operators** and **surveillance authorities**.

Such alignment would ensure a smooth implementation of Article 15, reduce the compliance burden on industry stakeholders, guaranteeing that the regulatory process remains efficient and effective, without compromising consumer safety. In practice, the timeline for the CPR should be:

|  |  |  |
| --- | --- | --- |
| **Event** | **Timeline** | **Example** |
|  |  | **Old approach** | **New approach** |
| **Publication of RAC Opinions** *(adopted in December of year N-2 and March-September of year N-1*) | year N-1 | Q1-Q4 of 2024 | Q1-Q4 of 2024 |
| **Adoption of ATP** | **By end of year N** | By Q4 of **2025** | By Q4 of **2025** |
| **Publication of ATP** | year N + 1 | Q1 of 2026 | Q1 of 2026 |
| **Entry into Force of ATP**  | (year N + 1) + 20 days after publication | Q1 of 2026 | Q1 of 2026 |
| **Application Date of ATP** | (year N + 1) + 20 days after publication + 18 months = **Q3 of year N + 2** | Q3 2027 | Q3 2027 |
| **Application Date of CPR amendments** |  | **Q3 2027**(Q1 of 2026 + 15 months = Q3 of year N + 2) | **Q4 2028**(Q3 of 2027 + 15 months = Q4 of year N + 3) |

As a hypothetical example and considering the worst-case scenario where a RAC opinion is published in November 2023, the respective ATP would be adopted by December 2024 and published in February 2025, entering into force 20 days after its publication in the OJ (i.e., March 2025). The application date of that ATP would be September 2026 (i.e., March 2025 + 18 months). Considering the above, the measures, adopted via the new approach to apply Article 15 of the CPR, would have an application date of December 2027 (i.e., September 2026 + 15 months).

## Timelines: step-by-step approach

The derogation process for **CMR** substances of **category 1** and **2** follows a structured timeline driven by the **CPR**. The process is split into two main phases:

* *Phase 1: Applicant Submission Period*
* *Phase 2: Regulatory Evaluation Process and Decision*

The **15-month timeline** starts from the **date of application of the respective Adaptation to Technical Progress (ATP)** under the **CLP Regulation**. During this time, applicants can submit derogation requests, and regulators must assess these requests and publish their final decision.

### Phase 1: Applicant Submission Period

**Step 1: Publication of the RAC Opinion (Day 0)**

The derogation process begins with the **publication of the RAC Opinion**, which proposes the classification of a substance as a **CMR Category 1** or **2**. This publication triggers a **9-month period** for the applicant to submit a derogation request.

* **Submission Deadline:** ***9 months*** after the RAC Opinion publication.
* **Documentation Required:**
	+ For **CMR Category 1 substances**, the applicant must provide documentation covering **all four** derogation criteria outlined in **Article 15(2)** of the CPR.
	+ For **CMR Category 2 substances**, only the **SCCS safety evaluation** is required as per **Article 15(1)**.

**Step 2: Initial Screening and Compliance Check**

Upon submission, the Commission services (DG GROW) perform an initial **compliance check** to ensure the dossier meets the regulatory requirements (See Annex 1) within one month from the submission:

* **Duration:** ***1 month***
* **Outcome:** If the dossier is **incomplete**, the clock is paused for **up to *2 months***, allowing the applicant to submit missing information. Failure to provide the required data results in rejection, and the substance will be included in **Annex II** (prohibited substances).

### Phase 2: Regulatory Evaluation Process

**Step 3: Sequential Evaluation of Criteria**

If the dossier submission fulfils the compliance check, the evaluation of the derogation request, against the criteria outlined in Article 15(2) of the CPR, starts within 2 weeks.

1. **Food safety compliance check (Criterion a)**
* **Duration:** ***1 month***
* **Objective:** the Sub-WG will be requested to assess whether the substance complies with food safety standards, based on EFSA opinions and relevant regulations (see Annex 2).
* **Outcome:** If it fails this criterion, the application would be rejected.
1. **Assessment of suitable alternatives (Criterion b)**
* **Duration:** ***2 months***
* **Objective:** the Sub-WG will be requested to determine if suitable alternatives exist for the specific product category (see Annex 3).
* **Outcome:** If suitable alternatives are found, the application would be rejected.
1. **Exposure and product-specific use evaluation (Criterion c)**
* **Duration:** ***1 month***
* **Objective:** the Sub-WG will be requested to verify that the exposure data is realistic and well-defined for the proposed use (see Annex 4).
* **Outcome:** If it fails this criterion, the application would be rejected.
1. **SCCS Safety Assessment (Criterion d)**

If the Sub-WG concludes positively on the ‘Exposure and product-specific use evaluation’, the Commission services (DG GROW) will proceed with a mandate to the SCCS within ***2 weeks***.

* **Duration:** the SCCS assessment must be conducted within ***12 months*** (9 months for the Preliminary SCCS opinion + 3 months for the adoption of the final opinion)
* **Objective:** The SCCS performs a detailed safety assessment, considering cumulative exposure and vulnerable population groups.
* **Clock Stops:** If additional data are requested by the SCCS, the clock pauses until the information is provided, but no later than ***3 months***. Failure to provide the required data results in rejection of the exemption dossier, and the substance will be included in **Annex II** (prohibited substances).

**Step 4: Final decision**

* **Duration:**  ***≈ 13 months*** after the publication of the SCCS opinion
* Considering the outcome of the exemption process, the Commission services (DG GROW) communicate to the Cosmetics Products Working Group (CPWG) a draft Regulation within ***1 month*** from the publication of the final SCCS opinion.
* Member of the CPWG have ***2 weeks*** to submit comments.
* The Commission services (DG GROW) initiate the interservice consultation that should be completed within ***2 months***.
* The draft Regulation is notified to WTO (TBT notification) for ***2 months***.
* The draft Regulation is put on a vote at the Standing Committee on Cosmetic Products at the next meeting and no later than ***4 months*** from the conclusions of the WTO notification.
* The draft Regulation undergoes scrutiny be the Council and the European Parliament for ***3 months***.
* The Commission services (DG GROW) to submit the draft Regulation for Adoption within ***1 month*** from the completion of the scrutiny period.

Using the previous hypothetical scenario:

* RAC Opinion publication: ***Nov 2023***
* Deadline (i.e., 9 months) for submitting derogation dossier: ***Aug 2024***
* Compliance check (1 month): ***Sep 2024***
* Additional info/clarification request (2 months): ***Nov 2024***
* Evaluation of food safety requirements (1 month): ***Dec 2024***
* Evaluation of suitable alternatives (2 months): ***Feb 2025***
* Evaluation of specific use/product types (1 month): ***Mar 2025***
* Safety assessment by the SCCS (15 month-including additional info/clarification request): ***June 2026***
* Preparation of draft Regulation (1 month): ***July 2026***
* Launch of interservice consultation (2 months): ***Sept 2026***
* Submission to WTO (2 months): ***Nov 2026***
* Vote at the Standing Committee (no more than 4 months after the previous step): ***Mar 2027***
* Submission to EP/Council (1 month): ***Apr 2027***
* Scrutiny period (3 months): ***Jul 2027***
* Adoption by COM (1 month): ***Aug 2027***

As explained previously, the RAC Opinion published in Nov 2023 would be included in the ATP published in February 2025 with an application date of September 2026. Considering the 15 months for the CPR measures, the deadline for the Omnibus Act would be December 2027. Following the most conservative approach in each step above, the new process should be completed in August 2027, which is before the deadline of December 2027 (i.e., considering the 15 months from the application date of the ATP).

## Transitional periods

The Commission will decide on *case-by-case* the possibility to allow transitional periods for the implementation of the CMR Omnibus acts. In particular, the Commission may propose a differed application date considering the following elements:

* **Consumer safety/risk to human health**: The primary focus should remain on safeguarding consumer health and safety, therefore, shorter periods for substances with significant safety concerns should be considered.
* **Availability of alternatives and supply chain adjustments**: The current availability of suitable alternatives and the time needed to establish new supply chains should be factored in. Longer periods may be, therefore, justified.
* **Product complexity and reformulation efforts**: The time needed for reformulating products should be considered, especially for complex formulations requiring significant R&D and testing. In that case, longer periods may be allowed.
* **Market dynamics**: Consideration for market demand, existing stock levels, and the economic impact on small and medium enterprises (SMEs) to prevent financial strain should be considered and periods adapted accordingly.
* **Regulatory alignment**: Ensuring timelines are consistent with other regulatory processes to avoid discrepancies and provide legal clarity.

In view of the above, **placing on the market** may range between **6–12 months**, ensuring companies have time to reformulate or discontinue affected products, while **making available on the market** may range between **12–24 months**, allowing distributors and retailers to sell existing stock before the ban fully applies[[4]](#footnote-5).

# Food safety requirements (Criterion a)

## Overview

Compliance with the food safety requirements defined in **Regulation (EC) No 178/2002** (hereafter referred to as the **‘Food Safety Regulation’ or ‘FSR’**) is one of the four essential criteria for allowing an exemption from the generic ban on the use of substances classified as **carcinogenic, mutagenic, or toxic for reproduction (CMR) category 1A** or **1B** in cosmetic products. Fulfilment of this criterion is a prerequisite for the use of such substances under specific conditions.

The **Food Safety Regulation** aims to ensure a high level of protection of human health and consumers' interests in relation to food. It considers, in particular, the diversity of the food supply, including traditional products, while also safeguarding the effective functioning of the internal market. According to this regulation, food encompasses any substance or product, including drink, chewing gum, and any substance intentionally incorporated into food during its manufacture, preparation, or treatment. This also includes water, provided it is intended for human consumption.

Regulation (EC) No 178/2002 has been amended several times. However, **Article 14**, which establishes core food safety requirements, has remained unchanged. This article outlines the fundamental principles that must be followed to determine whether food is safe for human consumption, in particular that:

1. **Food shall not be placed on the market if it is unsafe.**
2. **Food shall be deemed unsafe if it is considered to be:**
	1. Injurious to health; or
	2. Unfit for human consumption.

In determining whether food is **unfit for human consumption**, several factors must be evaluated, including whether the food is **unacceptable for consumption** due to contamination (e.g., by extraneous matter), or through **putrefaction, deterioration, or decay**.

When assessing the safety of a food product, Article 14 specifies additional elements that must be taken into consideration:

* **The normal conditions of use of the food** by the consumer and at each stage of production, processing, and distribution;
* **The information provided to the consumer**, including information on the label or other publicly available sources, regarding how to avoid specific adverse health effects associated with a particular food or category of foods.

The determination of whether food is injurious to health should involve an assessment of:

* **Immediate, short-term, long-term,** and **cumulative toxic effects** on the health of the consumer;
* **Effects on subsequent generations**; and
* **The health sensitivities of specific consumer groups** (e.g., children, pregnant women, elderly individuals, or those with particular medical conditions), especially when the food is intended for such categories.

## Checklist for Compliance with Food Safety Requirements

A checklist (provided in **Annex 2**) is designed to assist the applicant in determining whether a substance complies with food safety requirements. This checklist must be completed by the **applicant that request the derogation** and submitted to the **Commission services (DG GROW)**. The completed checklist will be shared with the members of the dedicated sub-WG and a meeting will be scheduled without delay[[5]](#footnote-6) to present their analysis and initiate discussions.

The experts in the dedicated sub-WG[[6]](#footnote-7) would be requested to assess the information submitted by the applicant, will communicate their views to the Standing Committee on Cosmetic Products that will have to take the final decision on whether this criterion is fulfilled.

The checklist evaluation should consider the following elements:

1. **Is the substance present in food available on the EU market and not considered unsafe due to its presence?**
2. **Is the presence of this substance in food restricted by EU law?**
3. **Would the use of this substance in cosmetics comply with the relevant food-related restrictions?**
4. **If the substance has not yet been used in food, has it been authorized for use in food?**
5. **If the substance has not yet been used in food, would its use at the concentration intended for cosmetics render the food unsafe (either unfit for consumption or injurious to human health)?**

The evaluation process is a crucial step in ensuring the protection of consumer health while maintaining regulatory coherence. The checklist acts as a practical tool to guide the applicant and ensure a comprehensive and consistent assessment of the compliance with food safety requirements for substances that may be used under an exemption in cosmetic products.

# Suitable alternative substances (Criterion b)

## Background

Substituting hazardous chemicals with **safer, more sustainable alternatives** is essential for **protecting human health, preserving the environment,** and **ensuring regulatory compliance**.

For cosmetics, chemicals linked to **carcinogenicity, mutagenicity, reproductive toxicity** and **endocrine disruption** (for human health), necessitate alternative options. Article 15 (2) of the Cosmetic Products Regulation (Regulation 1223/2009, hereinafter referred to as CPR) establishes the exemption criteria for the use of carcinogenic, mutagenic or reprotoxic (CMR) substances of category 1A/1B, allowing their continued use in cosmetics under strict conditions. One of the key requirements for this exemption is that interested parties must demonstrate that ‘[…] *there are no suitable alternative substances available, as documented in an analysis of alternatives*.’

The documentation of the analysis of alternatives serves multiple critical purposes. Firstly, it ensures regulatory compliance with Article 15(2) by proving that all possible substitutes have been evaluated. Secondly, it promotes transparency, allowing regulatory authorities and stakeholders to assess whether a CMR substance is truly indispensable, and thirdly, it supports informed decision-making, ensuring that alternatives are evaluated not only for **technical feasibility** but also for **safety** and **economic viability**.

While some EU legislation (e.g., REACH (EC) No 1907/2006) provide structured approaches for evaluating chemical alternatives, the CPR does not outline a standardized methodology for conducting such an analysis. This regulatory gap means that often businesses rely on **best practices** from other regulatory frameworks (e.g., ECHA’s guidelines on substitution[[7]](#footnote-8), OECD guidance on alternatives assessment[[8]](#footnote-9)). In addition, the lack of **clear criteria** and **harmonized format** for how comprehensive the alternatives assessment should be, create regulatory uncertainty while authorities assess whether the analysis is sufficiently robust, which often leads to inconsistencies in the exemption requests and delaying the overall process.

Given the significance of this analysis, it would be beneficial for:

* 1. Regulators to establish clearer guidelines on how to conduct and document alternatives assessments for cosmetic ingredients, and
	2. Businesses to adopt a transparent, scientifically rigorous methodology, ensuring that technical feasibility, safety, and sustainability of substitutes are fully explored.

## Assessment of the lack of alternatives for CMR substances in cosmetics

The assessment of alternatives should be comprehensive, clear, aligned with regulatory expectations, and structured to effectively communicate the process, findings, and decisions made. Below an overview of a tiered approach for the analysis of alternatives and a dedicated Annex 3.

### Identification of CMR substance

Prior to assessing possible suitable alternatives, information relevant to the identification and use in cosmetics of the CMR substance in question must be provided in the derogation dossier by the applicant. Thes information will be assessed by the respective sub-WG as explained above.

### Defining the substance of concern

In their dossier submission, the applicant must:

1. clearly identify the **chemical name**, **CAS** and/or **EC number**, and where available the **INCI name** of the CMR substance in question.
2. specify its:
	1. **classification** (Carcinogen 1A/1B, Mutagen 1A/1B, Reprotoxic 1A/1B) based on the CLP Regulation (EC No 1272/2008) or
	2. potential classification (Carcinogen 1A/1B, Mutagen 1A/1B, Reprotoxic 1A/1B) based on the respective proposal from the RAC committee
3. provide the **scientific basis** for why the substance is/could be classified as CMR (e.g., reference to the RAC Opinion).
4. indicate whether the substance is already:
	1. Restricted/authorised under the CPR (entry number and Annex)
	2. Restricted or banned under other EU legislation and provide relevant references
	3. restricted or banned under other international markets (e.g., US FDA, Health Canada, China NMPA, etc.) and provide relevant references
5. indicate whether the substance has **previously** been assessed by scientific committees responsible for the safety assessment of cosmetics and provide references (e.g., SCCS Opinion).

### Understand its role in cosmetics

In their dossier submission, the applicant must:

* 1. provide the reported **technical function**(s) of the substance (e.g., UV-filter, colouring, fragrance, emulsification, etc.)
	2. identify the cosmetic **product categories/types** or **body parts** where the substance is used (e.g., sunscreens, rinse-off, oral product, etc.).
	3. describe the **maximum concentration levels** at which the substance is used in different formulations.
	4. describe whether the substance has **no direct functional equivalent**, making it difficult to substitute.
	5. provide information on **how much it is used in cosmetics** available on EU market (e.g., how many unit formulations contain it, market data, share of cosmetics portfolio, etc.).

### Identification of potential alternatives

### Scientific and literature research

In their dossier submission, the applicant must:

1. conduct an extensive literature review to **identify potential substitutes**, using sources such as:
	1. PubMed, ScienceDirect, and Google Scholar for published studies.
	2. ECHA's REACH database for registered safer alternatives.
2. check if the alternative(s) has(ve) undergone a safety assessment by scientific committees responsible for the safety assessment of cosmetics or other scientific committees and provide references.
3. check global regulatory approvals to determine if substitute(s) is(are) accepted, authorised or used in key markets (EU, US, China., etc.).

### Benchmarking from other sectors

In their dossier submission, the applicant must:

1. identify whether the identified alternatives are **used in other sectors** (e.g., pharmaceuticals, detergents, biocides, food, etc.).
2. check whether existing cross-sector **innovations** can be applied in cosmetics.
3. evaluate the **scalability** of alternatives developed for other industries.

### Assessment of alternative substances

In this section several questions must be answered to acquire reliable information and proceed with a decision on whether there is lack of alternatives**. The responsibility for answering these questions falls primarily on the applicant requesting an exemption** under Article 15(2) of the Cosmetic Products Regulation, supported by suppliers, scientific experts and regulatory bodies.

More specifically, cosmetic product manufacturers are considered to lead the alternatives assessment and submit the respective documentation. The raw material suppliers should assist by providing technical and regulatory data on the alternative ingredients, while cosmetic formulators and respective R&D teams should contribute to the evaluation of the formulation challenges and performance. Moreover, the safety assessors should assess health risks and compliance of alternatives, while regulatory affairs experts should ensure alignment with CPR (or other legislation when relevant).

The European Commission services (DG GROW) together with Member State Competent Authorities within the dedicated sub-WG will review the input provided to the questions above, while the Scientific Committee on Consumer Safety (SCCS) may be requested to evaluate safety data for the alternatives.

In the analysis of suitable alternatives, especially when assessing the feasibility and practicality of substituting hazardous substances in products such as cosmetics, the ‘**reformulation efforts’** can be used as a key metric, considering the following:

* **Feasibility and Technical Viability**: Reformulation efforts help determine whether an alternative can be practically incorporated into existing products **without compromising performance** or **quality**. This involves assessing the technical challenges and adjustments needed in the product formulation process.
* **Cost Implications**: Evaluating reformulation efforts includes analysing the cost associated with **developing and testing new formulations**. This can include the cost of research and development, sourcing new ingredients, and potential changes to manufacturing processes.
* **Time to Market**: The time required to reformulate a product and bring it to market is a critical consideration. This assesses how quickly a company can respond to regulatory changes or market demands for safer products.
* **Efficacy and Consumer Acceptance**: Assessing reformulation efforts involves ensuring that the new formulation maintains or improves product efficacy and **consumer satisfaction**. This may include consumer testing and feedback to ensure the reformulated product meets expectations.
* **Regulatory Compliance**: Reformulation is often driven by the need to comply with regulatory requirements. Tracking reformulation efforts helps ensure that alternatives meet **safety standards** and **legal obligations**.
* **Innovation and Competitive Advantage**: Successful reformulation can lead to innovative products that offer a **competitive advantage** in the market. Monitoring these efforts can highlight a company’s commitment to innovation and sustainability.
* **Impact on other sectors**: If the alternative substance is used in other sectors, the increase in demand in cosmetic sector might impact its accessibility and lead to higher costs, which might have an impact on products from other sectors.

Overall, analysing **reformulation efforts** as part of the alternatives assessment process provides a comprehensive view of the practical, economic, and strategic implications of substituting hazardous substances. It helps ensure that any changes made not only comply with safety regulations but also align with business objectives and consumer needs.

#### Technical performance in cosmetic formulations

This next section provides and overview of the elements to be considered, while Annex 3 includes a comprehensive template for this assessment. The applicant must consider the elements below and fill-in the template in Annex 3.

#### Chemical and functional equivalence

* *Does the alternative provide the same* ***stability, efficacy, and sensory properties*** *(e.g., texture, absorption, fragrance, preservation, colour stability, etc.)?*
* *Does the alternative require* ***additional stabilizers, emulsifiers, or preservatives*** *to maintain performance?*

#### Compatibility with other ingredients

* *Does the alternative* ***interact negatively*** *with other ingredients (e.g., pH shifts, phase separation, colour changes)?*
* *Will* ***additional*** *compatibility* ***testing*** *be required?*

#### Impact on shelf-life and product integrity

* *Does the new formulation impact* ***oxidation, microbial growth, or physical stability****?*
* *Does it require the addition of* ***new preservatives or antioxidants****?*

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| ***Significant reformulation efforts occur if:*** |
| * *The alternative compromises stability, efficacy, or sensory properties, requiring additional stabilizers or functional adjustments.*
 |
| * *The alternative causes adverse interactions, such as pH shifts, phase separation, or colour instability, needing extensive compatibility testing.*
 |
| * *The new formulation reduces shelf-life or stability, necessitating additional preservatives or antioxidants.*
 |

#### Regulatory and safety considerations

#### New safety testing requirements

* *Does the alternative require* ***new toxicological assessments*** *(e.g., dermal absorption, genotoxicity/carcinogenicity testing, sensitization, etc.)?*
* *Is additional* ***SCCS review*** *needed for regulatory approval?*

#### Annex compliance and labelling

* *Does the new ingredient* ***fall under Annexes III-VI (restricted/authorised substances)****, requiring concentration adjustments?*
* *Does it trigger* ***new regulatory obligations*** *(e.g., nano-status, endocrine disruptor classification)?*

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| ***Significant reformulation efforts occur if:*** |
| * *The new ingredient* ***requires extensive safety data*** *or additional SCCS assessment, delaying market use.*
 |
| * *The new ingredient triggers* ***new regulatory obligations****, such as listing under Annexes III-VI to CPR, or requires* ***labelling updates*** *and* ***concentration adjustments****.*
 |

#### Manufacturing and supply chain impact

#### Production line adjustments – Cost Considerations

#### ****Capital Expenditure (CapEx)****

* *Will the substitution require* ***investment in new equipment*** *or machinery? If yes, what is the estimated cost?*
* *Are there* ***costs for modifying*** *existing equipment or* ***upgrading*** *production lines (e.g., other temperature settings, safety measures, etc.)?*
* *What are the expected* ***maintenance costs*** *for the new production setup?*

#### ****Operating Expenditure (OpEx):****

* *Does the substitution* ***increase production costs*** *(e.g., additional processing steps, longer production times, specialized labour)?*
* *How does the change impact* ***energy consumption****? Can this increase utility costs?*
* *Will additional* ***training for staff*** *be required, and what are the associated costs?*

####  ****Packaging and Storage Costs:****

* *Does the alternative ingredient require* ***different packaging materials*** *or* ***formats*** *(e.g., airtight, light-resistant)? What are the incremental costs?*
* *Will* ***storage conditions*** *(e.g., refrigeration, humidity control) change, and what is the additional cost per unit?*

#### Raw material sourcing and supply chain stability – Cost Considerations

#### ****Ingredient Procurement Costs:****

* *Is the alternative readily available at* ***commercial scale****, or is it limited to* ***specialized suppliers****?*
* *What is the* ***price difference*** *between the current ingredient and the proposed alternative?*
* *Are there additional costs for* ***testing*** *and* ***validating*** *the quality of the alternative?*
* *Is the alternative available at* ***consistent prices****, or is it subject to* ***price volatility****?*
* *Will the projecting increase in demand of this alternative substance coming also from other sectors will impact the availability of the alternative?*

#### ****Supply Chain Logistics:****

* *Does sourcing the alternative require* ***importing from different regions****, leading to higher shipping, import duties, or customs fees?*
* *Are there increased lead times, and what are the associated holding or shortage costs?*
* *Will switching suppliers require* ***new contracts*** *or* ***minimum order quantities*** *that affect procurement costs?*

#### ****Risk Mitigation Costs:****

* *What is the financial impact of potential* ***supply disruptions*** *(e.g., buffer stock, multiple sourcing strategies)?*
* *Are there costs associated with* ***alternative/backup suppliers*** *or* ***diversifying the supply chain*** *to reduce risks (e.g., supply disruptions, price volatility, quality issues, etc.)?*

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| ***Significant reformulation efforts occur if:*** |
| * *The substitution requires* ***capital investment*** *in* ***new equipment****,* ***process modifications****, or* ***increased operating costs*** *(e.g., energy consumption, specialized labour, or staff training).*
 |
| * *The alternative demands* ***new packaging materials*** *or* ***controlled storage conditions****, significantly increasing costs.*
 |
| * *The alternative is* ***costlier, difficult to source at scale****, or* ***subject to price volatility****, requiring additional quality validation.*
 |
| * *Sourcing the alternative leads to* ***higher shipping costs****, extended lead times, or* ***new import duties*** *and contract requirements.*
 |
| * *Significant costs arise from diversifying suppliers, qualifying alternative/backup sources, or managing* ***potential supply disruptions****.*
 |

#### Market and Consumer Acceptance

#### Impact on Consumer Experience

* *Does the reformulation alter* ***texture, fragrance, foaming properties, absorption rate, or ease of application****?*
* *Will the product require* ***consumer re-education*** *or marketing adjustments?*
* *Will the price of the product likely to increase?*

#### Brand positioning and Claims

* *Does the reformulation impact* ***certifications*** *(e.g., vegan, organic, hypoallergenic, etc.)?*
* *Will it affect* ***functional claims*** *(e.g., ‘long-lasting’, ‘24-hour hydration’, etc.)?*

#### International competitiveness

* *Will the reformulation impact negatively the international trade of the cosmetics, and if yes, to what extent?*

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| --- |
| ***Significant reformulation efforts occur if:*** |
| * *The reformulation* ***alters key sensory attributes*** *(e.g., texture, fragrance, absorption) or requires* ***consumer re-education*** *and* ***marketing changes***
 |
| * *The reformulation affects* ***product certifications*** *(e.g., vegan, organic) or functional* ***claims****, potentially impacting market positioning and consumer trust.*
 |

### Decision on the lack of suitable alternatives

The experts in the sub-WG would be requested to consider the documented analysis of alternatives submitted by the applicant and provide their own score in the same report (see Annex 3). To this end, the same scoring matrix to rank alternatives based on safety, technical performance, cost, and sustainability will be used.

The outcome of the discussions at the sub-WG level will be communicated to the Standing Committee on Cosmetic Products that will have to take the final decision on whether suitable alternatives exist, considering the feasibility of implementation (e.g., cost, time, and resource availability, etc.) and ensuring that the decision aligns with any legal or regulatory requirements.

# Particular use of the product category (Criterion c)

Different product categories and uses have significantly different exposure levels and risks. For example, a CMR substance might be acceptable in a rinse-off product like shampoo but not in a leave-on face cream due to higher exposure duration and absorption. This criterion aims to minimize exposure to CMR substances and ensures that **the derogation is granted only when the risk is well understood and acceptable for a specific product category**. Moreover, it prevents the broad approval of CMR substances across all cosmetics and limits their use to specific, justified cases.

Criterion ‘c’ refers to the requirement that any request for derogation must specify the intended use within a defined product category, along with a clear understanding of how consumers will be exposed to the substance (important for the assessment of criterion ‘d’).

1. The ‘***particular use*’** implies that the derogation request must be specific about the **intended cosmetic use (i.e., function** or **application)** of the substance within a cosmetic product. The use should be clearly defined, such as whether the substance will be used for example in a face cream, shampoo, deodorant, lipstick, or sunscreen, etc. Broad, non-specific applications like ‘for all cosmetic products’ would **not** meet this criterion.
2. The ‘***product category*’** of **cosmetic products must be identified** for which the substance will be used. This is important since product categories in cosmetics have different levels of exposure based on the type and (e.g., rinse-off, leave-on products, etc.).
3. The ‘***known exposure*’** indicates that there must be a clear understanding and quantification of **how and to what extent consumers will be exposed** to the substance. This includes factors such as:
	* the frequency and duration of use (e.g., daily, occasional)
	* the concentration of the substance in the product
	* the amount of product applied (typical quantity per application)
	* the route of exposure (dermal, oral, inhalation), and
	* the target population (general population, vulnerable groups like children or pregnant women, etc.)

Applicants must provide information and justification for **all three elements** of criterion ‘c’ in the derogation request to allow the Sub-WG to assess the fulfilment of that criterion (See Annex 4). Considering that all the elements above are already available in the respective parts of the Product Information Files (PIF), the applicant should be able to submit this information without delay.

In practice, this criterion ensures that the safety assessment and the derogation decision are based on **realistic, specific** and **defined use scenarios**, rather than hypothetical or generalized uses. In addition, it will enable the Scientific Committee on Consumer Safety (SCCS) to conduct a focused safety evaluation that considers the actual exposure risk for consumers. This criterion also helps avoid unnecessary risks by ensuring that the substance’s safety is carefully considered in the specific context of its intended use.

The experts in the dedicated sub-WG would be requested to assess the information submitted by the applicant and communicate their views to the Standing Committee on Cosmetic Products that will have to take the final decision on whether this criterion is fulfilled.

# Safety assessment (Criterion d)

In the case of derogation requests for the use of **CMR category 1A, 1B,** or **2 substances** in cosmetic products, a **rigorous safety assessment process** is conducted by the **Scientific Committee on Consumer Safety (SCCS)**. More specifically, in the case of CMR Cat.2 substances, upon submission of the derogation request, the Commission services (DG GROW) proceeds without delay in mandating the SCCS to perform a safety assessment based on the safety dossier submitted by the applicant. In the case of CMR Cat.1 substances, for the Commission services (DG GROW) to mandate the SCCS, all three of the other derogation criteria must be met.

In both cases, the safety dossier must include comprehensive toxicological data, information on exposure scenarios, and justification for the safety of the substance at the proposed use levels in cosmetic products **following the SCCS Notes of Guidance[[9]](#footnote-10)** and therespective **checklists**[[10]](#footnote-11). In addition, for CMR Cat.1 substances the dossier must include also a **cumulative exposure assessment** from sources **other than cosmetics** and consider the exposure of **vulnerable population groups**.

Upon adoption of the mandate by the SCCS, the scientific committee has **10 months** to deliver a preliminary opinion. The preliminary opinion is publicly available for comments for up to **2 months**. Following the commenting period, the SCCS will finalise their opinion and publish it within **3 months**. Upon request form the SCCS to applicant to provide clarification or submit additional data, the assessment time is paused. This period should not exceed **4 months**.

**On imperative grounds of urgency, the Commission services (DG GROW) may use the urgency procedure to modify and shorten such timelines.**

Based on the SCCS opinion, the Commission services will decide whether to allow the use of the substance in cosmetic products by way of derogation. This process ensures that only substances meeting the highest safety standards are granted an exemption for use in cosmetic products.

# Natural Complex Substances

The Classification, Labelling, and Packaging (CLP) Regulation[[11]](#footnote-12) differentiates between a ‘**substance’** and a ‘**mixture’**. A substance can be ‘**mono-constituent’** or can contain **more than one constituent** (so called a ‘**complex substance’**). **Plant extracts** that are not chemically modified form a distinct subcategory within complex substances.

The ECHA Guidance on ‘Impurities and (degree of) purity in CLP and in the CLH process’ suggests that the definition in Article 2(7) of the CLP Regulation refers to a **substance** as it is placed on the market by a specific company. This highlights that the regulatory interpretation of a substance depends on its market presentation.

**Article 15 of the CPR** establishes a direct link between the harmonised classification of a substance as a carcinogenic, mutagenic, or reprotoxic (CMR) substance in categories 1A, 1B, or 2 and the prohibition or restriction of its use in cosmetic products. However, the CPR although it includes and defines the terms ‘substance’ and a ‘mixture’, it does not include the term ‘complex substance’.

|  |  |
| --- | --- |
| **Substance receiving harmonised classification** | **Prohibition in accordance with Article 15 CPR relates to** |
| Mono-constituent substance (even if it may be a constituent in a complex substance) | Mono-constituent substance |
| Complex substance | Complex substance |
| Plant extract | Plant extract |

Consequently, even if a substance that has received a harmonised classification as a CMR 1A, 1B, or 2 is present as a constituent in a natural complex substance—regardless of its concentration—the prohibition established by Article 15 of the CPR applies solely to the substance itself and not to the natural complex substance in which it is present.

However, the presence of a hazardous classified substance within a natural complex substance used in cosmetic products can still pose a significant risk to human health. To ensure a harmonised approach to addressing this potential risk, the Commission services (DG GROW) would request a formal safety assessment of such substances when they are part of plant extracts used in cosmetics, in accordance with Article 31(1) of the CPR.

Although Article 31 of the CPR does not impose legal deadlines, the safety assessment conducted by the SCCS, followed by the corresponding regulatory action by the Commission, should be treated as a priority. This approach is essential to reassure consumers of the safety of cosmetic products containing plant extracts with CMR-classified substances. Moreover, it would provide businesses with much-needed legal certainty regarding the compliance of such products.

# Endocrine Disruptors

Endocrine disrupting chemicals (EDs) are of synthetic or natural origin and require specific attention since they can alter the functioning of the endocrine system. Endocrine disrupting properties have been an important focus of scientific research, and the accumulated knowledge identifies endocrine disrupting chemicals as a concern to public health.

Substances and mixtures with endocrine disrupting properties pose a concern to public health and the environment. Different studies show that endocrine disruption can lead to certain disorders in humans, among others birth defects, developmental, reproductive or neurodevelopmental disorders, cancer, diabetes and obesity, and that those disorders have a high and increasing incidence in both children and adults.

To take account of those potentially harmful substances, Commission Delegated Regulation (EU) 2023/707[[12]](#footnote-13) amended Regulation (EC) No 1272/2008 by adding, in its Part 3 of Annex I, new hazard categories for endocrine disruptors, including for human health:

* **Category 1** - known or presumed endocrine disruptors for human health (ED HH 1); and
* **Category 2** - suspected endocrine disruptors for human health (ED HH 2).

The CLP Regulation defines ‘endocrine disruptor’ as a *‘substance or a mixture that alters one or more functions of the endocrine system and consequently causes adverse effects in an intact organism, its progeny, populations or subpopulations’*.

The CPR does not lay down specific provisions for the risk management of EDs, nevertheless, the negative effects on human health of EDs necessitate establishing an appropriate risk management system to restrict the use of such hazardous chemicals in cosmetic products. To this end, the appropriate approach would be the application of Article 31 of the CPR in view of potential risk to human health. Paragraph 1 of Article 31 allows the Commission to take measures designed to amend Articles II to VI if there is potential risk to human health, arising from the use of substances in cosmetic products, which need to be addresses on Union-wide basis. The Commission measures are conditioned to the SCCS opinion.

The process of banning or restricting the use of substances in cosmetic products that have received a harmonised classification under the CLP as ED HH of category 1 or 2 is as follows:

* **Step 1**: RAC publishes its opinion proposing an ED HH of category 1 or 2 classification for a certain substance.
* **Step 2**: The applicant that is interested in acquiring a derogation from the generic prohibition, must submit a formal **letter of intention** to the Commission services (DG GROW) **no later than 6 months** from the publication of the RAC Opinion. In that letter, the applicant must provide information on the use of that substance in cosmetic products and their interest in defending its use in cosmetics. The Commission services (DG GROW) will inform the members of the Cosmetic Products Working Group without delay.
* **Step 3**: The Commission services (DG GROW) considering the substance’s classification, and the information submitted by applicant, will include that substance in a work programme aimed at prioritising possible future regulatory actions, giving priority to substances of higher concern that are used significantly in cosmetic products.
* **Step 4**: The Commission services (DG GROW), following the working plan timelines, will prepare and publish a **call for data** with duration of **12 months** to allow all interested parties to submit information, data and scientific evidence regarding the safety of the relevant substance in cosmetic products.
* **Step 5**. The Commission prepares a mandate to the SCCS based on the input from the call for data. Upon adoption of the mandate by the SCCS, the scientific committee has **10 months** to deliver a preliminary opinion. The preliminary opinion is publicly available for comments for up to **2 months**. Following the commenting period, the SCCS will finalise their opinion and publish it within **3 months**. Upon request form the SCCS to applicant to provide clarification or submit additional data, the assessment time is paused. This period should not exceed **4 months**.

**On imperative grounds of urgency, the Commission services (DG GROW) may use the urgency procedure to modify and shorten such timelines.**

* **Step 6.** Based on the conclusions of the SCCS, the Commission services (DG GROW) prepare a draft implementing Regulation amending the annexes to the CPR based on its Article 31(1) (Regulatory process with scrutiny)

ANNEX 1: Checklist for initial screening – feasibility check

This checklist helps ensure the application meets the minimum formal requirements before moving to the detailed assessment phase. Each item should be marked as **Yes**, **No**, or **Not Applicable (N/A)**.

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Answer** | **Comments** |
| **1. General Information on the Application** |
| 1.1 Is the application form fully completed? | ☐ Yes ☐ No ☐ N/A |  |
| 1.2 Is the request submitted within the 9-month deadline after the RAC opinion publication? | ☐ Yes ☐ No ☐ N/A |  |
| 1.3 Is the identity of the applicant (manufacturer or responsible person acting alone or in consortium represented by a business association or another representative) clearly indicated? | ☐ Yes ☐ No ☐ N/A |  |
| **2. Substance Identification** |
| 2.1 Is the chemical identity clearly described? (e.g., name, CAS number, chemical structure) | ☐ Yes ☐ No ☐ N/A |  |
| 2.2 What is the proposed classification by RAC? | ☐ Carcinogenic☐ Mutagenic ☐ Reprotoxic |  |
| **3. Completeness of Documentation** |
| 3.1 Is there a comprehensive explanation of how each exemption criterion is met? | ☐ Yes ☐ No ☐ N/A |  |
| 3.2 Are toxicological studies and exposure data included? | ☐ Yes ☐ No ☐ N/A |  |
| 3.3 Is there a documented analysis supported by scientific evidence (where applicable), for the following criteria? |  |
| 1. *compliance with the food safety requirements*
 | ☐ Yes ☐ No ☐ N/A |  |
| 1. *suitable alternatives*
 | ☐ Yes ☐ No ☐ N/A |  |
| 1. *particular use of the product category with a known exposure*
 | ☐ Yes ☐ No ☐ N/A |  |
| 1. *safety dossier*
 | ☐ Yes ☐ No ☐ N/A |  |
| **4. Food Safety Criterion (Criterion a)** |
| 4.1Does the applicant provide a complete checklist for assessing compliance with the food safety requirements? | ☐ Yes ☐ No ☐ N/A |  |
| 4.2 Is there existing EFSA (European Food Safety Authority) data or equivalent documentation? | ☐ Yes ☐ No ☐ N/A |  |
| **5. Availability of Suitable Alternatives (Criterion b)** |
| 5.1 Has the applicant performed an Analysis of Alternatives? | ☐ Yes ☐ No ☐ N/A |  |
| 5.2 Are there alternatives identified? | ☐ Yes ☐ No ☐ N/A |  |
| **6. Specific Use and Known Exposure (Criterion c)** |
| 6.1 Is the application for a particular use in a specific product category? | ☐ Yes ☐ No ☐ N/A |  |
| 6.2 Are exposure estimates provided? | ☐ Yes ☐ No ☐ N/A |  |
| 6.3 Is the target population defined (e.g., general public, vulnerable groups)? | ☐ Yes ☐ No ☐ N/A |  |
| **7. Safety for Use in Cosmetic Products (Criterion d)** |
| 7.1 Does the applicant submit a safety assessment, considering also the requirement of cumulative exposure from other sources? | ☐ Yes ☐ No ☐ N/A |  |
| 7.2 Are vulnerable population groups specifically considered? | ☐ Yes ☐ No ☐ N/A |  |
| **8. Administrative and Procedural Requirements** |
| 8.1 Has the applicant confirmed their awareness of the submission timeline and procedures? | ☐ Yes ☐ No ☐ N/A |  |
| 8.2 Is there a signed declaration of compliance with Article 18 of the CPR? | ☐ Yes ☐ No ☐ N/A |  |

**Outcome of the Screening**

* **Proceed to Detailed Assessment** ☐
* **Request Additional Information** ☐
* **Reject the Application** ☐

**Comments on Decision:**

|  |
| --- |
|  |

ANNEX 2: Checklist for assessing compliance with food safety requirements

This checklist is intended to guide applicants through the regulatory requirements and ensure a thorough and consistent assessment process. It helps ensure the safety of consumers and aligns with the broader regulatory framework for cosmetic products.

|  |  |  |  |
| --- | --- | --- | --- |
| **No** | **Question** | **Answer** | **Comments** |
| **1** | Is the substance present in food products available on the EU market?If yes, please provide examples. | ☐ Yes ☐ No ☐ N/A |  |
| **2** | What are the food categories and typical concentrations where the substance is present?  |  |  |
| **3** | If the substance is present in food products (in EU), is it considered safe by EU food safety standards, i.e., not deemed injurious to health or unfit for consumption? | ☐ Yes ☐ No ☐ N/A |  |
| **4** | Would its use in food in a concentration planned for cosmetics make the food unsafe (unfit for human consumption or injurious to human health)? | ☐ Yes ☐ No ☐ N/A |  |
| **5** | Has the substance been authorized or restricted for use in food under EU law?If yes, please specify (the details of authorisation and/or restriction, legal basis, etc.). | ☐ Yes ☐ No ☐ N/A |  |
| **6** | Has the substance been evaluated by EFSA?If yes, please specify. | ☐ Yes ☐ No ☐ N/A |  |
| **7** | Is the substance present in food products available outside the EU market?If yes, please specify. | ☐ Yes ☐ No ☐ N/A |  |
| **8** | If the substance is present in food products (outside EU), is it regulated in the respective jurisdictions?If yes, please specify. | ☐ Yes ☐ No ☐ N/A |  |
| **9** | Has the substance been evaluated by scientific committees outside EU?If yes, please specify. | ☐ Yes ☐ No ☐ N/A |  |

|  |
| --- |
| Additional explanation if needed: |

ANNEX 3: Questionnaire and scoring system for assessing suitable alternatives

The scoring system below aims to quantify the **impact of reformulation efforts** by assigning a score to each key factor (technical, regulatory, manufacturing, and consumer acceptance). The total score indicates whether the reformulation is **minor**, **moderate**, or **significant**.

Each criterion is scored from **0 to 3** based on the level of impact:

|  |  |  |
| --- | --- | --- |
| **Score** | **Impact Level** | **Description** |
| **0** | None/Minimal Impact | No changes or only minor adjustments needed. |
| **1** | Low Impact | Some changes required, manageable within normal processes. |
| **2** | Moderate Impact | Noticeable changes affecting formulation, regulatory compliance, or production, requiring additional resources or testing. |
| **3** | High/Significant Impact | Major changes across multiple areas (formulation, manufacturing, compliance), requiring extensive resources and time. |

**Scoring Categories:**

*Technical and formulation complexity*

1. **Functionality** – Does the alternative provide the same technical function?
2. **Stability & Compatibility** – Does it affect product stability or compatibility with other ingredients?
3. **Product Performance** – Will the consumer experience be affected (e.g., texture, fragrance, absorption)?

**Scoring Example:**

* 0 = No functional difference, fully compatible
* 1 = Minor adjustments required for stability or texture
* 2 = Moderate incompatibility, requires new stabilizers or preservatives
* 3 = Significant reformulation required due to performance loss

*Regulatory & Safety Impact*

1. **Regulatory Status** – Is the alternative approved under the Cosmetics Regulation? Does it require SCCS review?
2. **Safety Testing** – Will it require new toxicological studies or additional data?
3. **Compliance with Annexes** – Does it trigger restrictions under Annex III-VI or labelling updates?

**Scoring Example:**

* 0 = Already approved with no additional safety requirements
* 1 = Minor updates to documentation, no new testing needed
* 2 = Requires some new toxicological studies or labelling changes
* 3 = Extensive safety testing and regulatory approval required

*Manufacturing & Supply Chain Impact*

1. **Production Adjustments** – Will new equipment or production processes be necessary?
2. **Raw Material Availability** – Is the alternative available at an industrial scale?
3. **Cost of Reformulation** – Will reformulation increase production costs significantly?

**Scoring Example:**

* 0 = No changes to production or procurement
* 1 = Minor adjustments to processes, raw material easily available
* 2 = Moderate supply chain risk or process adjustments required
* 3 = High cost and significant changes to production, limited availability

*Consumer & Market Impact*

1. **Consumer Perception** – Will the reformulation affect how consumers perceive the product (e.g., efficacy, claims)?
2. **Product Claims & Certifications** – Will it require changes to product claims or certification status (e.g., vegan, organic)?

**Scoring Example:**

* 0 = No change to consumer experience or claims
* 1 = Minor impact on product claims or certifications
* 2 = Moderate changes to marketing strategy or consumer perception
* 3 = Significant rebranding or loss of key certifications

## **Total score and impact levels**

Table 1: Impact level and interpretation.

|  |  |  |
| --- | --- | --- |
| **Total Score** | **Impact Level** | **Interpretation** |
| **0 – 9** | Minor Impact | Reformulation is straightforward, manageable within normal processes. |
| **10 – 18** | Moderate Impact | Requires noticeable changes and additional testing or adjustments but is feasible. |
| **19 – 33** | Significant Impact | Major effort required across multiple areas; significant time and resources needed for reformulation. |

Table 2: Significant reformulation effort - Evaluation template.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Criteria** | **Score (0–3) by Applicant** | **Explanation / Comments** | **Score (0–3) by Regulators** | **Explanation / Comments** |
| **A. Technical & Formulation Impact** |
| 1. Functionality |  |  |  |  |
| 2. Stability & Compatibility |  |  |  |  |
| 3. Product Performance |  |  |  |  |
| **B. Regulatory & Safety Impact** |
| 4. Regulatory Status |  |  |  |  |
| 5. Safety Testing |  |  |  |  |
| 6. Compliance with Annexes |  |  |  |  |
| **C. Manufacturing & Supply Chain Impact** |
| 7. Production Adjustments |  |  |  |  |
| 8. Raw Material Availability |  |  |  |  |
| 9. Cost of Reformulation |  |  |  |  |
| **D. Consumer & Market Impact** |
| 10. Consumer Perception |  |  |  |  |
| 11. Product Claims & Certifications |  |  |  |  |
| **Total Score** |  |  |  |  |
| **Impact Level** |  |  |  |  |

***Instructions:*** *Score each criterion from 0 to 3 based on the level of impact (0 = No impact, 1 = Low impact, 2 = Moderate impact, 3 = Significant impact). Provide a brief explanation for each score in the ‘Explanation / Comments’ column (e.g., ‘Requires new safety testing’ or ‘Ingredient readily available’). Sum the total score to determine the overall impact level. Use the total score to guide decision-making on whether the reformulation effort is manageable or requires significant resources.*

|  |
| --- |
| Additional Comments: |

ANNEX 4: Questionnaire and checklist for particular use and product category

**Applicant Questionnaire**

|  |  |
| --- | --- |
| **Section/Question** | **Response** |
| **1. Intended Use** |
| 1.1 What is the specific function of the substance in the product? |  |
| 1.2 What type of cosmetic product will the substance be used in? |  |
| 1.3 Is this request for a broad range of products or a specific product category? | ☐ Broad range of products☐ Specific product category |
| **2. Product Category** |
| 2.1 Is the product a leave-on or rinse-off product? | ☐ Leave-on☐ Rinse-off |
| 2.2 Specify the product category according to established classifications or relevant notification in the CPNP (e.g., make-up products, skin cleansing, etc.) |  |
| **3. Consumer Exposure** |
| 3.1 How often will the product be used? |  |
| 3.2 What is the expected duration of use per application? |  |
| 3.3 What is the concentration of the substance in the final product? |  |
| 3.4 How much product is typically applied per use? |  |
| 3.5 What is the primary route of exposure? (Check all that apply) | ☐ Dermal ☐ Oral ☐ Inhalation |
| 3.6 How will the product be applied? (e.g., topical, aerosol spray) |  |
| 3.7 Who is the target population for this product? |  |
| 3.8 Are there vulnerable groups that might be exposed to this substance via the use of the specific product type? (If yes, specify) | ☐ Yes ☐ No (Details: \_\_\_\_\_\_\_\_\_\_) |
| **4. Supporting Documents** |
| Please attach supporting documents (e.g., exposure assessments, scientific studies). | ☐ Attachment(s) included☐ No attachment |

**Questionnaire for Regulators**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Checklist Item** | **Yes** | **No** | **N/A** | **Comments** |
| 1. Is the intended cosmetic use of the substance clearly defined? |  |  |  |  |
| 2. Has the specific product category been identified? |  |  |  |  |
| 3. Is the request limited to a particular product category and not broad or unspecified? |  |  |  |  |
| 4. Has the leave-on/rinse-off classification been indicated? |  |  |  |  |
| 5. Is the frequency and duration of use clearly described? |  |  |  |  |
| 6. Is the concentration of the substance in the product specified and justified? |  |  |  |  |
| 7. Is the amount of product applied per use provided? |  |  |  |  |
| 8. Has the route of exposure been identified (dermal, oral, inhalation)? |  |  |  |  |
| 9. Is the target population specified, including vulnerable groups? |  |  |  |  |
| 10. Are all relevant supporting documents attached? |  |  |  |  |

|  |
| --- |
| Additional Comments: |

1. <https://ec.europa.eu/docsroom/documents/39989> [↑](#footnote-ref-2)
2. An application dossier for an SCCS assessment and evidence for the other three criteria of Article 15(2) for CMR cat.1A/1B or only an SCCS application dossier from CMR cat.2. [↑](#footnote-ref-3)
3. Delegated acts generally require a 2-month scrutiny period by the European Parliament and the Council after their adoption by the European Commission, thus the publication in year N+1. [↑](#footnote-ref-4)
4. It is to be noted that the same approach already applies to all other substances regulated under the CPR, even if the SCCS cannot exclude CMR concerns. [↑](#footnote-ref-5)
5. Such discussion could take place in the context of the CPWG meetings, but also at *ad hoc* level to facilitate the process. [↑](#footnote-ref-6)
6. Consultation of DG SANTE is not excluded. [↑](#footnote-ref-7)
7. <https://echa.europa.eu/substitution-to-safer-chemicals> [↑](#footnote-ref-8)
8. <https://www.oecd.org/en/publications/guidance-on-key-considerations-for-the-identification-and-selection-of-safer-chemical-alternatives_a1309425-en.html> [↑](#footnote-ref-9)
9. <https://health.ec.europa.eu/latest-updates/sccs-notes-guidance-testing-cosmetic-ingredients-and-their-safety-evaluation-12th-revision-2023-05-16_en> in case of nano considerations, the respective guidance document should be used as well: <https://health.ec.europa.eu/publications/sccs-guidance-safety-assessment-nanomaterials-cosmetics-2nd-revision_en> [↑](#footnote-ref-10)
10. <https://health.ec.europa.eu/publications/checklists-applicants-submitting-dossiers-cosmetic-ingredients-be-evaluated-sccs_en> [↑](#footnote-ref-11)
11. Regulation (EU) 2024/2865 of the European Parliament and of the Council of 23 October 2024 amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures; ELI: <http://data.europa.eu/eli/reg/2024/2865/oj>; entered into force on 10 December 2024. [↑](#footnote-ref-12)
12. Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures; ELI: <http://data.europa.eu/eli/reg_del/2023/707/oj> [↑](#footnote-ref-13)