



Final minutes: Derogation Requests Sub-group Meeting

Revision of EU Ecolabel Criteria for Rinse-off Cosmetics

Friday 25th September 14:00 – 16:30 CEST

Webex meeting platform

Agenda

	Friday 25th September	Schedule
	Connection of participants	13:45 – 14:00
1.	Introduction and structure of the meeting (JRC)	14:00 – 14:10
2.	Substances for which derogation requests were received <ul style="list-style-type: none">• Presentation of background information (JRC)• Discussion of proposed options (all)	14:10 – 16:20
3.	Conclusions and next steps	16:20 – 16:30
4.	Close of meeting	16:30

List of participant organizations

BEUC/EEB

CESIO

Colgate-Palmolive

Danish Competent Body

DG ENV

ECHA

Ecolabel Norway

EEB/SSNC

EFfCI

LAMIRSA

NATRUE AISBL

Novamex

UBA

The sub-group meeting was run in a web meeting format using the WEBEX platform. Ahead of the meeting, the JRC circulated among participants a discussion paper, summarizing the background information of the substances for which a derogation request was submitted. For each substance, a short presentation was given by JRC. Then, the floor was opened for discussion. Participants were asked to comment/ask questions orally. Posting comments in the 'chat room' facility was also allowed.

Surfactants classified as H400 or H412

There was a general agreement on the derogation of surfactants classified as H412, keeping the existing derogation on H412-classified surfactants.

One stakeholder agreed with the derogation and mentioned that the actual derogation in the criterion text should be as specific as possible. A good idea could be to have a general derogation for surfactants classified H412 and then specifically derogate other H412 substances (Sodium Laureth Sulfate and Cocamidopropyl betaine were requested by industries to be derogated).

Several stakeholders expressed agreement with the need to keep the derogation as it exists today in the EU Ecolabel and other labels. One stakeholder stated that it is obvious that soaps and shampoos contain surfactants. The efficiency of the alternatives to H412-classified surfactants are very poor, so the derogation can be accepted, with the condition that these surfactants are readily aerobically and anaerobically biodegradable.

Several stakeholders did not agree with derogating surfactants classified as H400. One stakeholder requested that the industry should provide more specific information and data on what H400 surfactants are used, in which products and in what concentration. The argument of price increase should not be accepted. Another stakeholder stated that this derogation is present in EU Ecolabel for detergents, but it is not essential for cosmetics. Another stakeholder offered to provide information on the use of H400 surfactants.

Ethyl N2-dodecanoyl-L-argininate hydrochloride (LAE)

Many stakeholders stated that this substance is not extensively used in the current cosmetic market. This substance could not be found in existing products in Denmark, Sweden and Germany. A screening of a database of 3000 cosmetics returned only three entries using LAE. The need of this derogation was questioned.

One stakeholder explained that this substance is not abundant in the existing markets because it has been recently developed, and it is hard to enter the market due to the negative image of preservatives. However, the substance has been approved as a food additive and cosmetic ingredient in several countries. One stakeholder offered to provide comparative information of the toxicity and the environmental fate (biodegradability) of available alternatives.

Sodium fluoride

Several stakeholders agreed with the need of this derogation on the condition that it must be specific for the use of sodium fluoride in toothpaste. This derogation is included in other labels (Nordic Swan). One stakeholder added that it should be specified which property of the substance is derogated; in this case it is H301.

One stakeholder suggested to derogate not only sodium fluoride, but also any of the allowed fluoride sources as per CPR Annex III. The suggestion was to apply the derogation not only for toothpaste, but for oral care products in general (also including mouth-rinse products as an example). Fluoride sources allowed in oral care products include Sodium Monofluorophosphate, Tin Fluoride and Olafleur. These substances can act as sources of fluoride and help the cavity protection. They are included in the cosmetics regulation with a maximum concentration of active fluoride. The stakeholder offered to provide detailed information on the specific hazard classes of these substances. A brief summary of the hazard classes of these compounds has been provided: *“Sodium Monofluorophosphate MFP, max 0.15% in oral care products (classified H302,H312,H315,H319); Stannous Fluoride (refer 35 Annex III CPR, max 0.15% in oral care products; classified H302,H314,H412)”*.

Titanium dioxide

In general, stakeholders agreed on granting this derogation, on the condition that the substance is used in sunscreens only and not in an inhalable form (e.g. sprays), as it summarises this comment posted in the chat: *“We agree on this derogations but only for sunscreens and if is not use in spray. The problem with titanium dioxide is inhalation and its effects on the lungs. That is why the ban on the use of titanium dioxide in powder and spray is important”*.

One stakeholder stated that TiO₂ is allowed for use in sunscreens in Nordic Swan, as the alternatives have a worse environmental profile. However it was asked if industry requested derogation of TiO₂ used in other products than sunscreens, since TiO₂ is also used in other cosmetics (e.g. decorative eye powder). The JRC explained that the industry did not request the derogation of TiO₂ in decorative cosmetics.

One stakeholder stated that UV filters are generally tricky to deal with in ecolabels, because most of them are problematic in one way or another. It was suggested to compare alternative substances.

With respect to the use of TiO₂ as a colourant, one stakeholder stated the absence of other alternatives for creams.

One stakeholder mentioned that while investigating the need of a derogation for TiO₂ used as a colourant in paints, it emerged that TiO₂ is typically used together with thrimetylopropane (TMP) for dispersion purposes, and it was asked whether the derogation of TMP would be relevant also for cosmetic products. The JRC asked the industry to provide data on the use of TMP as well as on the use of TiO₂ in products other than sunscreens, e.g. hand creams.

Sodium Laureth Sulfate (SLES) and Cocamidopropyl betaine (CAPB)

It was discussed the specific derogation for SLES and CAPB, that are two surfactants with H412 classification.

One stakeholder mentioned that in the case of CAPB, the final substance is not a sensitizer, although it contains traces of an intermediate raw material which is a sensitizer. Another stakeholder posted in the chat: “CAPB is also registered and self-classified as Skin Sens.” <https://echa.europa.eu/registration-dossier/-/registered-dossier/25362/2/1>. It was clarified that the compound is not a sensitizer. However, if the impurity during manufacture is not removed, then the compound is skin sensitizing..

One stakeholder mentioned that in Nordic Swan the derogation focuses on the impurity (dimethylaminopropylamine) and not on CAPB. Another stakeholder stated that given the classification as H412, this derogation would be included in the general derogation for surfactants.

The JRC clarifies the definition of impurity which is a substance whose concentration in the final formulation is less than 0.01% weight by weight for rinse-off products, and less than 0.001% weight by weight for leave-on products, regardless if the substance is added to the formulation or comes within the raw material from which the substance is derived.

Additional point: criterion 3 (a) (iii)

The JRC explained that many comments were received on the limit specified in the formula contained in criterion 3 (a) (iii):

$$100 \cdot c [H410] + 10 \cdot c [H411] + c [H412] \leq X\%$$

where c is the fraction of the product, measured in percentage by weight, made up of the classified substance.”

Some comments received by the JRC prior to the meeting expressed that a limit of X=2.5% would be unattainable, whereas other comments mentioned that a limit of X=25% would be too weak for the credibility of the label. Therefore, the JRC asked for the views of the stakeholders participating in the sub-meeting.

One stakeholder stated that if the criterion 3 (a) (iii) is to be applied on top of criterion 3 (a) (i), then existing data show that a limit of X=2.5% is achievable. The JRC confirmed that all criteria are cumulative, therefore criterion 3 (a) (iii) is to be applied on top of criterion 3 (a) (i).

One stakeholder mentioned that the limit in Nordic Swan is 2.5%, but surfactants classified as H412 are exempted from the inclusion in the calculation. Another stakeholder specified that in Blue Angel this formula is not written in the same way as the EU Ecolabel does, although the result is the same. The formula represents a theoretical calculation of the CLP classification of the final product, since cosmetic products are not generally classified.

One stakeholder stated that the concern for the achievability of a limit of 2.5% is real only if H412 surfactants are not exempted from the calculation.

Close of the meeting

The JRC thanked all participants and reminded that further data and comments should be submitted to the JRC by **Wednesday 30th September cob** at the latest.