BACKGROUND NOTE

CALL FOR EVIDENCE AND INFORMATION ON OCTOCRILENE

Introduction and scope

France has conducted a REACH substance evaluation on octocrilene (EC 228-250-8) and, in 2022-2023, determined that further regulatory measures are necessary with respect to environmental releases of octocrilene.

In July 2023, ANSES (French Agency for Food, Environmental and Occupational Health & Safety) launched a public consultation on a Regulatory Management Option Analysis[1] (RMOA) concluding that the most efficient regulatory approach to address environmental risks is to introduce a new restriction entry in Annex XVII to the REACH regulation.

Indeed, as shown in the RMOA, one of the conclusions of the Substance Evaluation was the need to pursue investigation through an RMOA for environmental risks. Despite the impossibility to conclude on endocrine properties, waiting for the LAGDA[2] test currently under the evaluation process, not adequately controlled risks have been identified regarding:

- The specific use of formulation of plastisol for the sediment compartment and groundwater.

- The specific use of octocrilene as UV filter in cosmetic ingredients. Risks are not adequately controlled using a tonnage approach or consumption approach covering releases from bathing and washing of people wearing sunscreens.

France intends to submit a restriction proposal on octocrilene according to REACH Article 69(4).

The call for evidence is launched to gather information on uses of octocrilene, associated releases and impacts to the environment of this substance, alternatives and costs, as well as surveillance data.

The elements that need to be considered during the preparation of a restriction proposal are set out in Annex XV to REACH and further elaboration can be found in ECHA Guidance documents[3].

The information submitted in this call for evidence will be used to assess the risk(s), the socio-economic impacts of restriction option(s), the feasibility of alternatives, as well as the need to investigate potential derogations. However, derogations cannot be investigated without adequate information on risks and socio-economic information, including information on alternatives. If a derogation is not proposed in the initial restriction proposal then it will be incumbent on relevant stakeholders to provide a full justification based on comprehensive information on risks, socio-economic elements and alternatives, during the restriction opinion-making process.

[1] Available at: https://www.consultations-publiques.developpement-durable.gouv.fr/projet-de-rmoa-analyse-de-la-meilleure-option-de-a2895.html
[2] Larval Amphibian Growth and Development Assay
[3] https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions

In areas where no specific information is available, realistic worst-case assumptions are typically used.

The call for evidence will start on 15 November 2023 and ends on 10 January 2024 (23:59 –Helsinki time).

Specific information requests

This call for evidence is intended to gather information or comments on octocrilene, as well as substances, mixtures and articles containing octocrilene, as outlined in the below questions.

Please note that questions 2-7 are divided according to product group (sunscreens, cosmetic products other than sunscreens, and plastisols). If you don't have information on some of the product groups, you can leave these blank.

Any statement, figure or information provided via this call for evidence should be supported with a robust justification, and reference and calculation whenever relevant. Where information is submitted in this call for evidence, but no reference to sources or calculations are made to justify such information, the comments are unlikely to be taken into account.

1. Manufacture and import of the substance

Please provide information (preferably for the whole EEA, but if not available then company- or country-specific information is also welcome) regarding:

a) Number, size and location of manufacturers of octocrilene,
b) Number, size and location of importers of octocrilene,
c) Associated tonnage (if possible, please differentiate between manufacture and imports and provide the information for each company),
d) Market trends in terms of tonnage (please differentiate between manufacture and imports).

2. Uses of octocrilene in <u>sunscreens</u>

a) Please describe the properties of use of octocrilene for the production of sunscreens i.e. is it a contaminant or a chemical used for a specific property (if so, describe the technical function of octocrilene)?
b) Please describe the production process. For which production stages and how is octocrilene used?
c) Please provide information, preferably for the whole EEA (but if not available then company- or country-specific information is also welcome), regarding (please specify the unit):
    1. Used volumes of octocrilene for sunscreen production,
    2. Market price of octocrilene.
d) Regarding sunscreens containing octocrilene, please provide information on:
    1. A description of the end product (mixture/article):
        i. type of product, if relevant (e.g. sunscreen milk, sunscreen cream, sunscreen oil, sunscreen sticks, etc.),
        ii. concentration of octocrilene in the sunscreens.

2. Volume of octocrilene-containing sunscreen end products (mixtures/articles) placed on the market (at the EEA member state level, please specify the unit). If possible/relevant, specify volumes by distribution channel (e.g., supermarkets, pharmacies, etc.).
3. Consumer market price of octocrilene-containing end products (mixtures/articles) (at the EEA member state level, please specify the unit and, if possible, the price trend over time).
4. Market data (preferably for the whole EEA, but if not available then company- or country-specific information is also welcome):
    i. number, size and location of producers of octocrilene-containing sunscreens
    ii. market share (market share of each of the producers mentioned in question 2.d.4.i just above and market share of octocrilene-containing sunscreens out of the whole sunscreen market)
    iii. turnover of the producers of octocrilene-containing sunscreens
    iv. any other relevant market information.

3. Alternatives to octocrilene in <u>sunscreens</u>

a) Can octocrilene be substituted and, if so, how? Please identify all existing or emerging alternatives (chemicals or processes) and what would be needed to transition to them in terms of steps (e.g. new equipment, adaptation of current equipment or organization, training, research and development, etc.) and timelines.
b) Could you please provide information on the advantages and disadvantages of those substitutes compared to octocrilene, regarding the following criteria: availability, technical and economic feasibility, efficiency, and hazards/risks? Which alternative(s) is(are) best and why? In case of several potential alternatives, could you please rank them from the most promising to the least promising and justify (against the above-mentioned criteria).
c) Does substitution impact the properties/quality of the end product? If so, in what manner?
d) What would be the cost of substitution for each of the potential alternatives (per tonne, company or product or in total for sunscreen production on the EEA market)? Please also provide the basis for your estimates by differentiating clearly between any one-off investment costs (e.g. new equipment, adaptation of current equipment or organization, training, research and development, etc.) and any changes to operating costs (e.g. the price difference between the alternative and octocrilene).
e) Please also provide information on whether abandoning the use of octocrilene would require reformulation and the costs and timelines required to reformulate.
f) If the substance cannot be substituted at this point of time, are substitutes expected to be available within a foreseeable future? If so, which are these substitutes and when are they expected to be available in sufficient quantities to supply the market?
g) What is/would be the difference in the market price of end-products produced with substitutes of octocrilene? Would any extra-cost of substitution be passed onto consumers or internalised in the production costs?

h) Are you considering abandoning the use of octocrilene, and if so, which timeline are you considering?
i) For the companies which have already substituted octocrilene in their sunscreen products or which have never used it:
    1. which chemicals do you use to fill the same function?
    2. what are the advantages and disadvantages of those compared to octocrilene, regarding availability, efficiency, technical and economic feasibility, and hazards/risks?

4. Uses of octocrilene in <u>cosmetic products (excluding sunscreens)</u>

a) Regarding cosmetic products containing octocrilene other than sunscreens, please provide information on:
    1. A description of the end product (mixture/article):
        i. type of product,
        ii. concentration of octocrilene in the product (mixture/article)
    2. Volume of octocrilene-containing end products/articles placed on the market (preferably for the whole EEA, but if not available then company- or country-specific information is also welcome, please specify the unit). If possible/relevant, specify volumes by distribution channel (e.g., supermarkets, pharmacies, etc.).
    3. Consumer market price of octocrilene-containing end products (at the EEA member state level, please specify the unit and if possible, the price trend over time)
    4. Market data(preferably for the whole EEA, but if not available then company- or country-specific information is also welcome):
        i. number, size and location of producers of octocrilene-containing products
        ii. market share (market share of each of the producers mentioned in question 4.a.4.i just above and market share of octocrilene-containing products out of the whole product group market for each article mentioned in question 4.a.1.i)
        iii. turnover of the producers mentioned in question 4.a.4.i (if possible, for each article mentioned in question 4.a.1.i)
        iv. any other relevant market information
b) For each type of cosmetic product other than sunscreens identified in question 4.a.1.i, please describe the properties of use of octocrilene: i.e. is it a contaminant or a chemical used for a specific property (if so, please describe the technical function of octocrilene)?
c) For each type of cosmetic product other than sunscreens identified in question 4.a.1.i, please describe the production process. For which production stages and how is octocrilene used?
d) For each type of cosmetic product other than sunscreens identified in question 4.a.1.i, please provide information at the EEA member state level regarding (please specify the unit):
    1. Used volumes of octocrilene,
    2. Market price of octocrilene.

5. Alternatives to octocrilene in cosmetic products (excluding sunscreens)

If relevant, please provide a differentiated answer to the following questions for each type of cosmetic product other than sunscreens identified in question 4.a.1.i on uses.

a) Can octocrilene be substituted and, if so, how? Please identify all existing or emerging alternatives (chemicals or processes) and what would be needed to transition to them in terms of steps (e.g. new equipment, adaptation of current equipment or organization, training, research and development, etc.) and timelines.
b) Could you please provide information on the advantages and disadvantages of those substitutes compared to octocrilene, regarding the following criteria: availability, efficiency, technical and economic feasibility, and hazards/risks? Which alternative(s) is(are) best and why? In case of several potential alternatives, could you please rank them from the most promising to the least promising and justify (against the above-mentioned criteria).
c) Does substitution impact the properties/quality of the end product? If so, in what manner?
d) What would be the cost of substitution for each of the potential alternatives (per tonne, company or product or in total for each type of cosmetic product on the EEA market)?
   Please also provide the basis for your estimates by differentiating clearly between any one-off investment costs (e.g. new equipment, adaptation of current equipment or organization, training, research and development, etc.) and any changes to operating costs (e.g. the price difference between the alternative and octocrilene).
e) Please also provide information on the number of products that would require reformulation and the costs and timelines required to reformulate.
f) If the substance cannot be substituted at this point of time, are substitutes expected to be available within a foreseeable future? If so, which are these substitutes and when are they expected to be available in sufficient quantities to supply the market?
g) What is/would be the difference in the market price of end products produced with substitutes of octocrilene? Would any extra-cost of substitution be passed onto consumers or internalised in the production costs?
h) Are you considering abandoning the use of octocrilene, and if so, which timeline are you considering?
i) For the companies which have already substituted octocrilene in their cosmetic products other than sunscreens or which have never used it:
    1. which chemical/ingredient do you use to fill the same function?
    2. what are the advantages and disadvantages of those compared to octocrilene, regarding availability, efficiency, technical and economic feasibility, and hazards/risks?

6. Uses of octocrilene in plastisol

a) What are the end-uses/applications of plastisol?
b) Please describe the properties of use and technical functions of octocrilene for the production of plastisol.

c) Please describe the production process. For which production stages and how is octocrilene used? Please provide information at the EEA member state level (but if not available then company- or country-specific information is also welcome) regarding (please specify the unit and, if relevant, please differentiate between each application of plastisol):
    1. Used volumes of octocrilene for plastisol production
    2. Market price of octocrilene
d) Regarding plastisol containing octocrilene, please provide information on:
    1. Volume of plastisol containing octocrilene mixtures placed on the market (at the EEA member state level, please specify the unit)
    2. Volume of end products/articles containing plastisol placed on the market (at the EEA member state level, please specify the unit)
    3. Market price of octocrilene-containing end products (at the EEA member state level, please specify the unit and, if possible, the price trend over time)
    4. Market data:
        i. number, size and location of producers of octocrilene-containing plastisol
        ii. market share (market share of each of the producers mentioned in question 6.d.4.i just above and market share of octocrilene-containing products out of the whole sunscreen market)
        iii. turnover of the producers of octocrilene-containing plastisol
        iv. any other relevant market information.

7. Alternatives to octocrilene in <u>plastisol</u>

a) Can octocrilene be substituted and, if so, how? Please identify all existing or emerging alternatives (chemicals or processes) and what would be needed to transition to them in terms of steps (e.g. new equipment, adaptation of current equipment or organization, training, research and development, etc.) and timelines.
b) Could you please provide information on the advantages and disadvantages of those substitutes compared to octocrilene, regarding the following criteria: availability, efficiency, technical and economic feasibility, and hazards/risks? Which alternative(s) is(are) best and why? In case of several potential alternatives, could you please rank them from the most promising to the least promising and justify (against the above-mentioned criteria).
c) Does substitution impact the properties/quality of the end product? If so, in what manner?
d) What would be the cost of substitution for each of the potential alternatives (per tonne, company or product or in total for plastisol production on the EEA market)?
e) Please also provide the basis for your estimates by differentiating clearly between any one-off investment costs (e.g. new equipment, adaptation of current equipment or organization, training, research and development, etc.) and any changes to operating costs (e.g. the price difference between the alternative and octocrilene).
f) Please also provide information on whether abandoning the use of octocrilene would require reformulation and the costs and timelines required to reformulate.
g) If the substance cannot be substituted at this point of time, are substitutes expected to be available within a foreseeable future? If so, which are these

substitutes and when are they expected to be available in sufficient quantities to supply the market?

h) What is/would be the difference in the market price of end products produced with substitutes of octocrilene? Would any extra-cost of substitution be passed onto consumers or internalised in the production costs?
i) Are you considering abandoning the use of octocrilene, and if so, which timeline are you considering?
j) For the companies which have already substituted octocrilene in their plastisol production or which have never used it:
    1. which chemical/ingredient do you use to fill the same function?
    2. what are the advantages and disadvantages of those compared to octocrilene, regarding availability, efficiency, technical and economic feasibility, and hazards/risks?

8. Exposure assessment, emissions and analytical methods

a) Please provide information about environmental monitoring and surveillance of octocrilene**:**
    1. **In all media** (wastewater treatment plant, freshwater and marine water compartments, sediment, soils, groundwater).
    2. Please distinguish between the European level and the non-European level, specify the objective of the data collection, material and methods (test item, analysis method, detection limit, quantification limit), spatio-temporal information.
b) Has octocrilene been detected in fishery and aquaculture products (mussels, oysters, shellfish, farmed fish, etc.)? If yes, please indicate the species and the concentration measured for each species. Please indicate the basis of your answer (studies, monitoring/surveillance data) and provide any associated data, in particular spatialized data.
c) Has the presence of octocrilene had an impact on the production of these products (excess mortality, withdrawal from sale, etc.)?
d) Please provide all data regarding the presence of octocrilene in wildlife animals: source of data, concentration value, material and methods, and ADME (Adsorption Distribution Metabolisation Extraction) information.
e) Please provide information on the degradation process for octocrilene in environment media (representative of the media exposed by uses).
f) Does the presence of octocrilene have or has it had an impact on the use of the water resource: prohibition of use for drinking water, prohibition of swimming, etc.? Please indicate the basis of your answer (e.g. studies or monitoring data) and provide any associated data, in particular spatialized data.
g) Please provide information regarding data on analytical methods available to quantify or detect octocrilene in mixtures, articles and in the environment (for all media, if available), with information on the limit of detection (LoD) and limit of quantification (LoQ).
h) Please also indicate any challenges related to the detection of octocrilene in mixtures, articles or the environment (e.g. matrix complexity, analytical methods' limit of detection).

9. Socio-economic impacts

Please provide information on the socio-economic impacts of a possible restriction (such as a ban of the use of octocrilene in the use, production and placing on the market of mixtures/articles referred to in questions 2, 4 and 6 or setting a concentration limit of octocrilene in these mixtures/articles), i.e. quantitative or qualitative information on potential advantages and disadvantages, including:

a) Costs and benefits to affected actors, e.g. producers, professionals, consumers or alternative providers. This may include substitution costs (if not already provided above in the questions on alternatives), profit losses, employment impacts or cost savings.
b) Key economic parameters for the sectors using octocrilene at EEA level, such as (unless already provided in the previous questions):
    1. number of affected companies
    2. profits
    3. potential gain/loss of market share
    4. turnover
    5. number of people employed in the EU or abroad, if relevant
    6. current share of products containing octocrilene.
c) Any other information enabling an assessment of potential impacts related to the markets of end products relying on octocrilene at EEA level.

10. Open comments

Please provide any other information considered relevant. Moreover, please provide any additional information on other potential uses / products not covered in the above questions.

Who should participate to the call for evidence?

This call for evidence is intended for interested parties such as private companies (manufacturers, suppliers, recyclers, downstream users, distributors, importers etc.), sector associations, laboratories, scientific organisations, NGOs and other stakeholders or Member State Authorities holding relevant information. Both EU/EEA and non-EU stakeholders are encouraged to participate.

Information can be submitted confidentially and will be treated as such.

https://echa.europa.eu/calls-for-comments-and-evidence

For any clarifications please contact: stephane.jomini@anses.fr

How to submit a comment in the call for evidence

When you are ready to make your comments, click on the appropriate link in the "How to submit your contribution" field. Please be aware that it is not possible to save your submission and come back to it, so you should already have your comments prepared in an attachment or saved in some other format in advance.

The web form contains five main parts:

- Section I: Personal information
- Section II: Organisation
- Section III: Non-confidential comments - both general comments and information on specific issues (see below). Your responses can be entered directly into the form or through section 4 as an attachment. However, please do not submit the same comments via both means.
- Section IV: Non-confidential attachments can be added here.
- Section V: Confidential attachments can be added here. Confidential information will only be available to the ECHA Secretariat, the Committees and Member State Competent Authorities. However, if ECHA receives an Access to Documents request, we may come back to you for justifications why the information is confidential. You can also add this information already in the relevant part of the webform.

Once you have finished your submission press the "Submit to ECHA" button and your comments will be submitted. You will receive a submission number via e-mail and you should refer to this in any communication with ECHA on this issue.

It is not possible for you to retrieve your submission so you may want to take a screen shot, or printed copy for your future reference.