

Consultations on potential candidates for substitution and on derogations conditions

You may submit your information via the web form below.

By submitting any information through the webform you confirm that you hold all necessary rights regarding the information provided, including but not limited to copyright where applicable, and therefore that you are entitled to submit the said information for the purposes listed herein and for its use by ECHA, including its Committees. By submitting this information, you also agree that the non-confidential information provided will be published on ECHA's website.

Any confidential information should be provided as attachments and will be made available to ECHA, including its Committees, the European Commission, and the Member State Competent Authorities for the Regulation (EU) No 528/2012 (Biocidal Products Regulation, BPR). Note that any information (including information claimed confidential) submitted to ECHA is subject to Regulation (EC) No 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information and to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents. Therefore, you are asked to provide a justification for each claim for confidentiality submitted to ECHA.

ECHA accepts no responsibility or liability regarding the information (including attachments) submitted via the webform.

Compulsory fields are marked with an asterisk ()*

Substance name: Iodine

EC Number: 231-442-4

CAS Number: 7553-56-2

Which conditions of Article 5(1) are met: 5(1)(d)

Which conditions of Article 10(1) are met: 10(1)(a), 10(1)(e)

I. Personal Information

First Name *

Family Name *

Email *

Email Verification *

Country *

Note: Your name and contact details will not be disclosed to the public.

II. Organisation

Are you submitting information *

On behalf of a Member State Competent Authority

As an Individual

On behalf of an organisation or institution

Type of organisation/institution

Name of organisation / institution*

Federation of European Aquaculture Producers (FEAP)

Country where the organisation or institution is legally established*

Belgium

I do not wish the name of my organisation/institution to be published on the ECHA website.

Note: If you claim the name of organisation/institution confidential, please ensure that it is not mentioned in the following comments, attachments and file names. Also, the type of your organisation/institution cannot be claimed and will always be disclosed.

i III. Information

Comment regarding the following Product Type-Intended use combination(s)*:

Note: Please tick the PT-Use combinations to which your comments are applicable. The submitted information in a given submission, both on available alternatives and derogations, should always be applicable to all the PT-Use combinations selected in the webform. If you want to submit different information for different PT-Use combinations, please make separate submissions.

PT3 - Use 1: Teat disinfection - animal husbandry (Pre-milking disinfection of teats, Post-milking disinfection of teats, Pre and post-milking disinfection of teats]

PT3 - Use 2: Skin disinfectant - animal husbandry [Veterinary hygiene, corporeal hygiene/navel hygiene of newborn animals]

PT3 - Use 3: Fish egg disinfection

PT3 - Use 4: Disinfection of hard surfaces [Surface disinfection in animal houses, Surface disinfection of equipment, Disinfection of fish farm equipment, Surface disinfection of external milk cluster, Surface disinfection of vehicles for animal transport, Disinfection of boots and wheels]

A. Availability of suitable alternatives

Information on alternatives*

I wish to provide information on alternatives to the substance

I do not wish to provide information on alternatives to the substance

Notes:

1. Any confidential argumentation needs to be submitted separately as an attachment.

2. For substances meeting the exclusion criteria of Article 5(1) BPR the availability of suitable alternatives is a key consideration for deciding on the approval of the substance. Therefore, if you wish to provide information on derogation conditions according Article 5(2) BPR in Part B of this webform please also provide information on alternatives in this section A and explain how this is linked with your argumentation related to the derogation conditions.

1. Alternative identity and properties (non-confidential information)*

The European fish farming sector is unaware of any other biocidal substance that could replace iodine in disinfecting live fish eggs and ensuring that pathogenic agents are not transferred between incubators and facilities. Iodine forms part of routine fish hatchery hygiene protocols in Europe and globally.

2. Technical feasibility (non-confidential information)*

Non applicable.

3. Economic feasibility (non-confidential information)*

Non applicable.

4. Hazards and risks of the alternative (non-confidential information)*

Non applicable.

5. Availability (non-confidential information)*

Non applicable.

6. Other comments (non-confidential information)

If you selected "Other" in the PT-Use combination selection field above, please provide here a detailed description of the PT-Use(s)

Non applicable.

7. Conclusion on suitability and availability of the alternative and summary (non-confidential information) *

Provide a non-confidential version of the conclusion on the overall suitability and availability of the alternative and a summary of the key arguments of your submission.

There is no such alternative.

References

B. Derogation conditions according to Article 5(2) of the BPR

Information on derogation conditions*

- I wish to provide information on derogation conditions according to Article 5(2) of the BPR for the substance
- I do not wish to provide information on derogation conditions according to Article 5(2) of the BPR for the substance

Note: Any confidential argumentation needs to be submitted separately as an attachment.

1. Derogation according to Article 5(2)(a) of the BPR

For the selected intended PT-Use(s), please provide detailed non-confidential justifications whether the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst-case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment. Specify how this is linked with the availability of alternatives for such PT-use(s), making reference to the information you have provided under section "A - Availability of suitable alternatives" of this webform. Detailed descriptions and justifications must be provided for each selected PT-uses.

Iodine in fish farming is used in contained systems and with appropriate workers protection measures that exclude contact with humans and its release into the environment without appropriate treatment. Iodophores have the advantage of providing a neutral pH, being non-irritant and are relatively non-toxic. The neutral pH is important for minimising toxicity and ensuring efficacy.

2. Derogation according to Article 5(2)(b) of the BPR

For the selected intended PT-Use(s), please provide detailed non-confidential justifications whether the active substance is essential to prevent or control a serious danger to human health, animal health or the environment. Specify how this is linked with the availability of alternatives for such PT-use(s), making reference to the information you have provided under section "A - Availability of suitable alternatives" of this

webform. Detailed descriptions and justifications must be provided for each selected PT-uses.

Animal Health (WOAH) recommends using iodophores for fish egg disinfection.
See https://www.woah.org/en/what-we-do/standards/codes-and-manuals/aquatic-code-online-access/?id=169&L=1&htmlfile=chapitre_disinfection_eggs.htm

3. Derogation according to Article 5(2)(c) of the BPR

For the selected intended PT-Use(s), please provide detailed non-confidential justifications whether not approving the active substance would have a disproportionate negative impact on society when compared with the risks to human health, animal health or the environment arising from the use of the substance.

Describe the nature and the level of the impacts on society for the concerned use(s). Specify how this is linked with the availability of alternatives for such PT-Use(s), making reference to the information you have provided under section "A - Availability of suitable alternatives" of this webform. Detailed use descriptions, quantification or qualification of the impacts on human health and the environment and justifications must be provided for each use of the active substance and of the alternatives.

health, animal health or the environment arising from the use of the substance.
If the use of iodine for egg disinfection in EU Member States is banned, fish hatcheries will incur in higher risk of infections and would even have to stop exporting to third countries. This would tremendously harm European fish hatcheries and the whole aquaculture

i IV. Attachments

Non-confidential information

Please attach any additional non-confidential information below. ECHA will make this information publicly available.

Add attachment

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Maximum file size is 10 MB Maximum file size is 10 MB

Please note that documents should be submitted in word or pdf format. If you would like to submit more than one document, please create a zip archive where you include all files and upload the zip file as attachment.

Confidential information

Please attach any confidential information below, if applicable. Confidential information will only be used by ECHA, including its Committees, by the Member State competent authorities for biocidal active substances and products and by the European Commission. Therefore, any confidential information cannot benefit from stakeholder involvement. If you upload a confidential attachment, please indicate "CONFIDENTIAL" in the header of each page of the document and include in the document your justifications for confidentiality. This will facilitate ECHA's work if it receives requests for access to documents.

Justification for confidentiality:

I have the following reasons enumerated in Article 4(1) or (2) of [Regulation \(EC\) No 1049/2001](#) regarding public access to documents why the information submitted as confidential cannot be disclosed to persons requesting access to documents (please explain below in the commenting field those reasons; a reason could be that the protection of your commercial interests, including intellectual property, would be undermined).

Add attachment

Browse

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The European Chemicals Agency will ensure on its part that your personal data is processed as required by [Regulation \(EC\) No 45/2001](#) on the protection of personal data.

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