



Department
for Environment
Food & Rural Affairs

Registration, Evaluation, Authorisation and Restriction of Chemicals (UK REACH): Call for Evidence on amending Annex 14 (the Authorisation List) to include disodium octaborate

June 2022

We are the Department for Environment, Food and Rural Affairs. We're responsible for improving and protecting the environment, growing the green economy, sustaining thriving rural communities and supporting our world-class food, farming and fishing industries.

We work closely with our 33 agencies and arm's length bodies on our ambition to make our air purer, our water cleaner, our land greener and our food more sustainable. Our mission is to restore and enhance the environment for the next generation, and to leave the environment in a better state than we found it.



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Introduction

The authorisation process under UK REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less dangerous substances or technologies where feasible alternatives exist.

The Health and Safety Executive (HSE) provided a recommendation to the Secretary of State on which SVHCs are a priority of inclusion on Annex 14 of UK REACH (the Authorisation List) in December 2021. The Secretary of State, and Welsh and Scottish Ministers must now make a decision on whether they should be added to the Authorisation List. That would mean that prior authorisation would be needed to use them, or place them on the market, after the specified sunset date.

This is a joint Call for Evidence, issued by Defra on behalf of the UK Government, the Welsh Government, and the Scottish Government.

Purpose of this Call for Evidence

Following HSE's recommendation, the Secretary of State must decide whether to add the following substances to the Authorisation List:

- Dicyclohexyl phthalate (DCHP)
- Disodium octaborate

This Call for Evidence is on information relating to disodium octaborate and will be used to inform the Secretary of State's consideration of HSE's recommendation so it is important that we receive as much relevant information as possible.

HSE's recommendation did not propose any exempted uses, or categories of uses, or exemptions for product and process-oriented research and development (PPORD) for the substances.

HSE's recommendation highlighted a number of uncertainties about how disodium octaborate is used in Great Britain, it will take some time for the UK database to become fully populated with information on volume and use of substances registered in GB under UK REACH. In the absence of detailed information on use within GB, HSE's recommendation took account of ECHA data. However, the ECHA data considered the situation across the EU as a whole and not information on GB - specific use. HSE's recommendation also highlighted some gaps relating to the social and economic impacts in GB of adding disodium octaborate to the Authorisation List.

You are invited to provide evidence about the use of the substance, availability of alternatives, impacts on the environment, public health and society as well as any general comments.

Geographical extent

This is a joint Call for Evidence being issued by Defra on behalf of the UK Government, the Welsh Government, and the Scottish Government.

UK REACH regulates the use of chemicals in Great Britain (England, Scotland and Wales). Under the terms of the Northern Ireland Protocol, EU REACH continues to apply in Northern Ireland. We are consulting on potential amendments to the UK REACH Authorisation List.

Audience

This Call for Evidence is aimed at stakeholders such as disodium octaborate manufacturers, importers and downstream users, academics, non-governmental organisations (NGOs) and industry associations. We are interested in all relevant evidence but respondents do not need to address every question if their evidence and/or expertise is only relevant to certain questions. Members of the public are also welcome to submit evidence.

How to respond to the Call for Evidence

You can respond to our Call for Evidence in one of three ways:

- Written responses can be submitted **online** via the Defra Citizen Space consultation hub at:
<https://consult.defra.gov.uk/reach-policy/annex-14-call-for-evidence-disodium-octaborate>
- **Email to:** REACHworkprogramme@defra.gov.uk
- **Post to:** UK REACH Work Programme Team, Defra, Foss House, Kings Pool 1-2, Peasholme Green, York, YO1 7PX.

Responses must be submitted by 12 August 2022

Our preferred method of response to this Call for Evidence is online because it is the easiest way for us to collate, analyse and summarise responses. If you require a different format, please let us know.

Timing and duration of Call for Evidence

The Call for Evidence will commence on 17 June 2022 and will be open to responses for a period of 8 weeks. The Call for Evidence period will end at midnight on 12 August 2022.

After the Call for Evidence

Responses to this Call for Evidence will be used to inform the consideration of HSE's recommendation on disodium octaborate by the Secretary of State, and Welsh and

Scottish Ministers. This will help them to decide whether this substance should be added to the Authorisation List, any transitional provisions and if any uses should be exempted.

A summary of responses to this Call for Evidence will be published on the Government website at: www.gov.uk/defra.

The summary will not include your personal name (unless you have asked us to include it) or other personal data such as contact details. The summary may contain the name of your organisation, if you are responding on an organisation's behalf.

Confidentiality and data protection

Information provided in response to this Call for Evidence, including personal data, may be published or disclosed in accordance with the access to information regimes; these are primarily the Environmental Information Regulations 2004 (EIRs), the Freedom of Information Act 2000 (FOIA), the UK General Data Protection Regulation 2016/679 and the Data Protection Act 2018 (DPA). We have obligations, mainly under the EIRs, FOIA and DPA, to disclose information to particular recipients or to the public in certain circumstances.

If you want the information that you provide to be treated as confidential, please be aware that, as a public authority, the Department is bound by the Freedom of Information Act and may therefore be obliged to disclose all or some of the information you provide. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department for Environment Food and Rural Affairs will process your personal data in accordance with the law and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Important: We will take your reasons into account if someone asks for information. Because we must comply with the law, including access to information legislation, we cannot promise that we will always be able to keep details that you provide to us confidential.

Call for Evidence contents

Please complete 'About you' and 'About your organisation' if you are responding on behalf of an organisation. Please select and answer only those remaining sections that you wish to respond to. You do not need to respond to every section to complete your response.

About you

To help us analyse responses we would like to know who you are. Questions in this section provide us with important information as to whether your interest is as a member of the public, academic or on behalf of an organisation.

1. What is your name?
2. What is your email address?
3. Are you responding as an individual or on behalf of an organisation?
4. Where are you based? Please Select:

England

Scotland

Wales

Northern Ireland

Not UK Based

5. Would you like your response to be confidential? (required)

Yes

No

If yes, please tell us which part of your responses you would like to be confidential.

About your organisation

What type of organisation are you responding on behalf of?

Please select:

A government body

Non-governmental organisation (NGO)

Local authority

Charity

Consultancy

Small or micro business (Less than 50 employees)-

Medium business (50 – 249 employees)

Large business (250 or more employees)

Industry association

Other

If you answered Other, please state your organisation type.

If you are responding on behalf of an organisation, what is the name of the organisation?

Background

The Health and Safety Executive (HSE) recommends priority substances for inclusion in the Authorisation List from the UK REACH Candidate List of substances of very high concern (SVHCs). Substances added to the Authorisation List cannot be used or placed on the market in Great Britain without prior authorisation after the specified sunset date. Dicyclohexyl phthalate and Disodium octaborate are both listed on the UK REACH Candidate List.

For further information on these substances and why we are considering adding these substances to the Authorisation List, see [HSE's recommendation](#), including the background document for these substances. This Call for Evidence is focused on addressing uncertainties and data gaps relating to that recommendation, especially in respect of how those substances are used in Great Britain and the social and economic impacts of adding them to the Authorisation List.

HSE held a three month public consultation on their draft recommendation where they sought information and evidence on the technical aspects of their recommendation. We are not intending to re-run or duplicate that exercise.

We are also running a parallel Call for Evidence relating to dicyclohexyl phthalate that is available at:

<https://consult.defra.gov.uk/reach-policy/annex-14-call-for-evidence-dchp>

Questions

Please note that not all questions need to be answered in order to submit a response and we encourage you to only answer the questions that are relevant to you.

Evidence to support any of your answers is welcome in the form of quantitative and qualitative data, case studies, reports, and documents.

Uses

1. What use(s) of the disodium octaborate are you aware of (sectors, types of uses, categories of products, etc.)?
 - a. In general?

- b. By your business? (*only for businesses*)
2. What function does disodium octaborate perform in that use?
3. Can you specify the volume and/or value of each of the use(s)?
- a. Overall in GB?
- b. By your business? (*only for businesses*)
4. Can you provide evidence of disodium octaborate being present in a finished article (please state)?
- Yes
- No
- a. If yes, at what concentration?
- b. If yes, what is the article?
5. Can you provide evidence of disodium octaborate being required to produce goods that are necessary for living (for example food and medicines)?
- Yes
- No
- a. Which goods?
- b. How is disodium octaborate used?

Availability of alternatives

6. Can you provide evidence of any alternative substances, processes or technologies currently available for the use(s) of the substance?
- a. If so, what are the alternatives?
- b. Are they considered safer?
- c. Why/Why not?
7. Are you planning to substitute the use of disodium octaborate with an alternative substance, process or technology? If so, by when? (*only for businesses*)
8. Can you provide evidence that there are uses for which there are no alternatives (substances, processes or technologies)?
9. Can you provide evidence of any research, development or innovation efforts attempting to develop alternative substances, processes or technologies? If so, how long do you expect that the development / testing will take?
- a. In GB or countries outside of GB?
- b. By your business? (*only for businesses*)

Market and Supply Chain

10. Please specify the sector in which disodium octaborate is used and describe the supply chain, including your business' role in the supply chain?
 - a. What is the value/volume of the substance sold in GB?
11. Can you provide data on the turnover of the sectors concerned and the number of people employed in GB?
12. Can you estimate the relative proportion of SMEs in the concerned sectors (in terms of number of businesses and employment) in GB?
13. Is the use of the substance connected to specific geographic locations in GB?
 - a. If so, where does the use of the substance take place?

Competitiveness

14. Do you have any evidence on the time and/or cost of substitution for disodium octaborate? This includes (if relevant) the need for changes in the production process, need for new product testing, qualification and certification.
 - a. For your business?
 - b. In your sector?
15. What is the expected impact of substitution on the costs of your business's inputs or final products?
16. Can you provide evidence of the impact that including disodium octaborate on the UK REACH Authorisation List would have? This includes changes in the competitive position with respect to non-GB competitors in the GB market and in international markets.
 - a. To the concerned sectors?
 - b. To your business? (*only for businesses*)
 - c. To your supply chain?
 - d. To society?

Other impacts of inclusion in the Authorisation List (innovation and business opportunities)

17. If the substance is included in the Authorisation List, would it create business opportunities (e.g. gaining new markets or higher market share, development of alternative substances / products / production techniques)? Please provide evidence of what these would be:
 - a. In your sector?
 - b. For your business? (*only for businesses*)

18. Can you provide evidence on any potential effects that adding disodium octaborate to the Authorisation List would have on businesses' capacity to innovate (e.g., the capacity to produce more efficiently, to a higher quality, to a larger scale of products and services, or the capacity to bring R&D to the market)?
19. Can you provide evidence of whether the economy, society or the environment would be better or worse off (all factors considered) if the substance is included in the Authorisation List?

Sustainability and social impact

20. Can you provide evidence of whether the use of any potential alternative substances, processes or technologies would have any impact on sustainability and/or climate change (considering the whole life cycle: manufacture of the substance / energy/ production / consumption / waste / recycling)? If so, what are these alternatives and what impact does the evidence suggest they would have?
21. Can you provide evidence that adding this substance to the Authorisation List would have a particular impact on certain groups in the population (e.g. people from certain age groups, people with certain disabilities or health problems, people of a particular race or sex)? If so, what impact does the evidence suggest there would be?

Application for authorisation (*only for industry actors*)

22. If the substance is included in the Authorisation List, would you consider applying for an authorisation?
23. Are you aware of whether your suppliers/downstream users would consider applying for an authorisation?

Regulatory options

24. Can you provide evidence that other regulatory options could better address the concerns for human health and/or the environment for which the substance is recommended for inclusion in the Authorisation List?
25. What are these regulatory options and why would they better address the concerns?

Other remarks

26. Please take this opportunity to provide additional comments/information on disodium octaborate?
We are particularly interested in any possible social and/or economic impacts of adding disodium octaborate to the Authorisation List.