CONSULTATION

ECHA PROPOSES RESTRICTION ON 2,4 DNT

Summary

2,4-dinitrotoluene (2,4-DNT) is classified as a carcinogen category 1B (associated with renal cell cancer), was included in the candidate list for authorisation and into Annex XIV of REACH with a sunset date of 21/08/2015. ECHA considers that there are uses of 2,4-DNT in articles (such as refractories, in automotive airbags, in seat belt pre-tensioners, in plastic bottles used in industrial settings for sample taking purposes, and in propellants for military and civil small-arms ammunitions). Consumer and professional exposure may occur from the uses identified and due to the non-threshold effects of 2,4 DNT these exposures my pose a risk that is not adequately controlled. The Dossier Submitter concluded that action is required to reduce risks for consumers and professional workers on a Union-wide level and that the proposed restriction is the most appropriate measure. The restriction is assumed to impose very low costs to reduce a potential risk and alternatives to 2,4-DNT exists for the identified uses; given the information at hand, it is assumed that the measure is proportionate to the risk assuming a 12 month transition time.

The consultation on this proposed restriction will start on 22 September 2021 and ends on 22 March 2022.

When responding to the consultation, stakeholders should ensure that they are referring to the most recent version of the Annex XV report and any annexes (i.e. those published alongside the consultation).

Respondents are also encouraged to take into account when certain aspects of the proposal are planned to be discussed in the committee's plenary meetings (see table below) and time their submissions accordingly (multiple submissions are possible throughout the consultation).

	Committee	
Plenary meeting of the Committee (timing)	**Risk Assessment Committee (RAC)**	**Socio-Economic Assessment Committee (SEAC)**
1 (2.5 months after PC starts)	Verify the proposed scope. Conclude on hazard and hold preliminary discussion on exposure/risk.	Verify the proposed scope. Conclude on costs of the proposed restriction and hold preliminary discussions on its benefits.
2 (5.5 months after PC starts)	Conclude on exposure/risk and hold preliminary discussion derogations.	Conclude on benefits and hold preliminary discussions on proportionality and derogations.
3 (8.5 months after PC starts)	Finalise the derogations. Finalise the opinion plus justification text and adopt the final opinion.	Conclude on proportionality and derogations. Finalise the opinion plus justification text and agree the draft opinion.

4	Not relevant.	Conclude on issues raised during the SEAC draft opinion consultation. Adopt the final opinion.

Information on the hazards of the substance(s) and the costs of the proposal would make the most impact if submitted by month two and exposure/risk, benefits and derogations by month four of the consultation. This early submission would also allow the information to be considered at the appropriate time. This timing takes into account that stakeholders have access to the dossier much earlier than in the past, as it is published two weeks after submission or more than six weeks in advance of the start of the consultation.

It is possible to submit more than one consultation response during the six month period so please take this into account when deciding when to submit information.

How to submit a comment in the consultation on the proposed restriction

Firstly, please read the consultation guidance that describes the relevant information that should be submitted. It is available here: https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c.

When you are ready to make your comments, click on the appropriate link on the ECHA website. 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:

- Introduction: containing some general information on the restriction and a link to this note and the PC guidance.
- Section 1: Personal information
- Section 2: Organisational information
- Section 3: Non-confidential comments on the proposal - 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. General comments can be on any aspect of the Annex XV restriction proposal, including on issues related to socio-economic analysis.
- Section 4: Non-confidential attachments can be added here.
- Section 5: 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 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.

Specific information requests

In addition to the general comments, outlined above, the consultation includes several specific questions to gather information that is considered to be particularly relevant to the evaluation of the proposal, as follows:

- The Dossier Submitter has assessed the risks and socio-economic impacts of the proposed restriction based on the available information on uses of 2,4-DNT in articles. Please provide (i) information on any **other sectors or uses** that may be affected by the proposed restriction that were not already assessed by the Dossier Submitter or (ii) **additional information** to refine the existing assessment of sectors or uses presented by the Dossier Submitter.
    - Quantities of 2,4-DNT per use; technical function of 2,4-DNT in the use; releases to the environment, consumer, professional or industrial worker exposure from the use;
    - Identity, hazard and risk of alternatives.
    - Information on the impacts of the proposed restriction (costs and benefits to society, including industry and SMEs). Please refer to Annex XVI of REACH for an overview of the elements that should be included in an impact assessment

PRODUCTION, USE AND IMPORT OF ARTICLES CONTAINING 2,4-DNT

Are you aware of any present or future manufacture in the EU, use or import of articles containing 2,4-DNT?

In particular, could you please provide the following information:

On the **USE or IMPORT** of articles containing 2,4-DNT, please provide:

- Description of the current and expected future uses/imports in the EU
- Types of uses (professional worker uses or consumer uses)
- Quantities used or imported
- whether uses will remain stable, increase or decrease in the future in the absence of the proposed restriction?
- Uses that would no longer exist in the EU anymore once the proposed restriction becomes effective

DEROGATION AND TRANSITION PERIOD

- Please provide any information available onthe suitability of the length of the transition period proposed by the Dossier Submitter

COSTS for the EU manufacturers, importers and consumers in case the proposed restriction on articles containing 2,4-DNT

Please provide any information available on

- Expected costs for substituting 2,4-DNT for EU manufacturers
- Expected costs for substituting 2,4-DNT for EU importers

- Expected consumer surplus losses (lower quality, lower availability, higher prices)

ALTERNATIVES TO 2,4-DNT

The Dossier Submitter assumes the existence of alternatives to 2,4-DNT in Annex XV report and explains that alternatives must already be in use in the EU because there seems to be no manufacture nor uses of articles containing 2,4-DNT.

Please provide any available information on alternatives to 2,4-DNT:

- Existing alternatives
- Technical and economic feasibility of the existing alternative substances or technologies,
- for which uses alternatives are not available and/or the performance of alternatives are not considered adequate
- information on any challenge expected for switching to these alternatives
- risk profiles of the existing alternatives compared to 2,4-DNT

TESTING AND SAMPLING METHODS

The Dossier Submitter assumes the existence of methods to test and sample articles containing 2,4-DNT and explains that such methods already exist in the EU.

Please provide any available on:

- Existing testing and sampling methods (standardised, media, etc)
- economic costs associated to the existing methods

EXPOSURE AND RISKS

Please provide any data regarding the potential risks and related environmental or human health impacts

The final opinions of both Committees are scheduled to be available by September 2022. ECHA will send the joint opinion of the Committees to the European Commission, which will take the decision whether to include the proposed restriction in Annex XVII of the REACH Regulation.

The Dossier Submitter and the Rapporteurs will all respond to the issues raised in the consultation and these responses will be published with the launch of the consultation on the SEAC draft opinion in month nine of the process.