**Response to comments document (RCOM)**

on the Annex XV dossier

proposing restriction

on 2,4-dinitrotoluene

**Non-confidential**

**ECHA/RAC/RES-O-0000007105-81-01/F**

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

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| **Substance name** | **EC number** | **CAS number** |
| 2,4-dinitrotoluene | 204-450-0 | 121-14-2 |

2 June 2022

**General comments and answers to specific information requests**

**Specific information requests:**

1. 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

1. **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

1. **DEROGATION AND TRANSITION PERIOD**

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

1. **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)

1. **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

1. **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

1. **EXPOSURE AND RISKS**

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

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| Ref. | Date/Type/Org. | Comments |
| 3526 | Date:  2021/10/20 17:58  Content:  Scope or restriction option analysis  Hazard or exposure  Information on alternatives  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  ACEA  Org. country:  Belgium  Attachment: | Answer to specific info request 1:  For vehicle pyrotechnics the assumptions on the amount of 2,4-DNT were incorrect. 2,4-DNT is used in Micro Gas Generators (MGG) for bonnet actuators and seat belt pretensioners. No air bag uses were identified. The Dossier Submitter incorrectly identified the amount of 2,4-DNT in a seat belt pretensioner as 50g, whereas the maximum amount is 80mg. |
| Answer to specific info request 2:  Estimated imports from Asia are between 0 – 1 tonne per annum. Estimated imports from North America are between 0 – 1 tonne per annum |
| Answer to specific info request 3:  The maximum Risk Characterisation Ratio (RCR) is 0.0533, based on 5 seatbelt pretensioners being deployed simultaneously in a vehicle accident. This demonstrates that a risk to the occupants does not exist and a derogation for automotive pyrotechnics is justified. As a derogation has already been proposed for explosives, the wording could be amended to: Paragraph 1 shall not apply to a substance in articles placed on the market or used in: a. Explosives, b. Ammunition used for military use. c. Automotive pyrotechnics |
| Answer to specific info request 5:  Alternatives are based on Nitroglycerin (CAS No. 55-63-0). A full composition of the alternative propellant is included in the attached presentation |
| Answer to specific info request 7:  The maximum amount of 2,4-DNT in a seat belt pretensioner is 80mg. For 5 simultaneous seatbelt pretensioner deployments in a cabin, the concentration in the cabin would be 0.48ug/m3, which is significantly below the 9ug/m3 long term DNEL. |
| Dossier submitter response:  Thank you for the comment confirming that 2,4-DNT is used in seatbelt pretensioners at a lower concentration than we had estimated. We noted your assessment of the risk, however, the DNELs were based on a threshold effect and the main concern is from the non-threshold carcinogenic effects. However, to avoid misunderstandings, the illustrative scenario for general public exposure to 2,4-DNT from seat belt pretensioners has been removed from the Dossier. There is still a risk to consumers, but the main risk is likely to be to professional workers repairing vehicles after an accident. In addition, only information related to risk has been submitted and no information relevant to the Impact Assessment has been included. |
| RAC Rapporteurs comments:  Thank you for your comment. RAC acknowledges that some assumptions of the Dossier Submitter on the discarded exposure scenario on risk from seat belt pre-tensioners to consumers were overestimated (Amount of 2,4-DNT in seat-belt pre-tensioners). However, the Background Document pointed out that quantitative assessment was included to illustrate a risk using the available threshold based national OELs and not related to the non-threshold effects. RAC agrees that, from a risk perspective, a derogation is not justified due to plausible worker exposure during car maintenance or disposal. |
| SEAC Rapporteurs comments:  SEAC thanks ACEA for this comment. However, no socio-economic information is provided that could be assessed by SEAC. |

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| 3540 | Date:  2022/02/07 09:25  Content:  Scope or restriction option analysis  Type:  MemberState  Country:  Germany | General Comments:  In the view of the German CA it seems in general reasonable to restrict the use of 2,4-DNT in articles. Even more so, as it mainly affects imports, because no authorization has been granted within the EU.  However, we wonder why the scope of the restriction proposal is limited to consumers and professional users, only. We agree that professional workers are more comparable to consumers in the use of articles than it is the case with substances and mixtures. When handling articles, no special measures are usually taken to protect against SVHCs that may be present in the article. However, also for industrial workplaces we are not aware of specific measures taken when handling (explicitly not manufacturing/producing) articles. Containment does not seem plausible in this context.  As a minor comment, please check the wording in section 4.2. A distinction is made here between occupational and professional uses, which in our view does not make sense as profes-sional uses are a part of occupational uses. |
| Dossier submitter response:  Thank you for the comments, the editorial has been made accordingly. Related to industrial uses, the use of articles in industrial settings is likely to be better controlled. |
| RAC Rapporteurs comments:  Thank you for your comment. RAC agreed that the effectiveness and practicability, including enforceability of the restriction would be further increase by including all users in the scope of the restriction. However, RAC notes that no risk assessment was made by the dossier submitter at industrial workplace in the restriction proposal. |
| SEAC Rapporteurs comments:  Thank you for your comment. It has been reported in the draft opinion. |

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| 3541 | Date:  2022/03/22 14:18  Content:  Request for exemption  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Mariachiara.Detragiache@asd-europe.org  Org. country:  Belgium | General Comments:  AeroSpace and Defence Industries Association of Europe (ASD) is the voice of European Aeronautics, Space, Defence and Security Industries. ASD welcomes the opportunity to comment on the restriction proposal for 2,4-DNT. ASD is aware of existing Defence Exemptions according to Art. 2 (3) of the REACH regulation that allow for the continued use of 2,4-DNT in the production of propellant which is later used in the production of (military) ammunition. This exemption enables continued industrial use of 2,4-DNT as an alternative to the user making an application for an authorisation. Therefore, the following statement on page 2 last paragraph of the Annex XV report: “As there is no EU production of articles, there is no need to transition to alternatives or stocks” is incorrect. Equally, the statement on page 6 section 1.2.1 is incorrect: “There is no current manufacture or import of 2,4-DNT in the EU as ECHA has not received any applications for authorization for this substance…”. However, this misperception due to lack of information will be of no consequence for our industry provided the proposed derogations for explosives and ammunition used for military use are implemented as worded on page 4 of the Annex XV report. Furthermore, defence ammunition has a life cycle in excess of 20 years, and ammunition currently in MS Defence Agency stock may be requested on a loan basis by other MS Defence Agencies within the life of the ammunition. As such, the proposed 12 month transition period for the 2,4-DNT restriction would be insufficient for defence purposes if it were not for the derogation. ASD therefore maintains that the proposed derogation is still of upmost relevance for the defence industry in the EU. ASD supports the proposed wording of the derogation shown on Page 4 of the Report. We are not aware that ECHA currently pursues a different wording for the restriction or has shifted to the first restriction option with no derogation (as shown on page 29) that would have a more severe impact on the defence industry and uses. If the latter is the case, ASD urges ECHA to undertake detailed conversations with the defence industry and MS defence agencies prior to implementing a different wording. As a side note, ASD would like to highlight that the European Defence Industry disagrees with the statement ‘Propellants are usually regarded as substances/mixtures within the context of the REACH Regulation‘ in the Annex XV report. |
| Dossier submitter response:  Thank you for the comments. We have updated the background report for the information on defence exemptions and the relevant statements that depended on this information. However, there is an exemption for military ammunition proposed and this seems to deal with the issues raised in the consultation response. We note the disagreement on consideration of propellants as substances/mixtures but, as no further explanation is given, this is not further considered. |
| RAC Rapporteurs comments:  Thank you for your comment. RAC support the exemption for the use of 2,4-DNT in explosive or ammunition by the armed force and the police. |
| SEAC Rapporteurs comments:  Thank you for your comment. Derogation for explosives and ammunition for military uses are already included in the restriction proposal. |