

Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions

2,4-dinitrotoluene

ECHA/RAC/RES-O-000007105-81-01/F

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

Agreed

3 June 2022

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS
ON 2,4-DINITROTOLUENE

2 June 2022

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

3 June 2022

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

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s): 2,4-dinitrotoluene

EC No.: 204-450-0

CAS No.: 121-14-2

This document presents the opinions agreed by SEAC and the Committee's justification for its opinion. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <https://echa.europa.eu/restrictions-under-consideration> on **22/09/2021**. Interested parties were invited to submit comments and contributions by **22/03/2022**.

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ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Nathalie PRINTEMPS

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **2 June 2022**.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus**.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: Luisa CAVALIERI

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **3 June 2022**.

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at <https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/66801/term> on **15 June 2022**. Interested parties were invited to submit comments on the draft opinion by **15 August 2022**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. [The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]**]¹.

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and]⁵ 71(1) of the REACH Regulation.] [No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and]³ 71(1)]⁶.

The opinion of SEAC was adopted **by [consensus.] [a simple majority]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion.]⁶.

¹ Delete the unnecessary part(s)

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1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Brief title: Restriction on 2,4-DNT in articles for consumer and professional uses.

Table 1: Proposed restriction entry

Column 1	Column 2
2,4-Dinitrotoluene EC Number: 204-450-0 CAS Number: 121-14-2	<ol style="list-style-type: none">1. Shall not be placed on the market, or used, as a substance in articles for supply to the general public or to professional workers in concentrations ≥ 0.1 % weight by weight.2. Paragraph 1 shall not apply to a substance in articles placed on the market or used in:<ol style="list-style-type: none">a. Explosives,b. Ammunition intended for use, in accordance with national law, by the armed forces or the police.3. Paragraph 1 shall not apply to a use of the substance in articles regulated by:<ol style="list-style-type: none">a. Directive 2009/48/EC on the safety of toys,b. Regulation (EU) 2017/745 on medical devices,c. Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.4. Use and placing on the market of articles already in use in the Union before {EiF} containing 2,4 DNT shall be allowed.5. For the purposes of this entry:<ol style="list-style-type: none">a. professional uses mean use by workers outside industrial installations.b. explosives mean the materials and articles considered to be explosives in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations, with the exception of pyrotechnic articles. Pyrotechnic articles include ammunition.6. The restriction should enter into force after {date 12 months after EiF}.

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1.1. THE OPINION OF RAC

See opinion of RAC.

1.2. THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the restriction proposed by the Dossier Submitter on 2,4-dinitrotoluene, CAS 121-14-2, EC 204-450-0 is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs as demonstrated in the justification supporting this opinion.

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of the proposal

2,4-dinitrotoluene (2,4-DNT) is classified under Regulation (EC) No 1272/2008 (CLP) as a carcinogen category 1B, H350 (may cause cancer)². The substance was therefore included in the candidate list for authorisation (13/01/2010; ED/68/2009³) and into Annex XIV of REACH (Commission Regulation (EU) No 143/2011) on the basis of Art 57(a) of REACH, with a sunset date of 21/08/2015. Following an assessment of the available evidence in accordance with Article 69(2) of the REACH Regulation, the Dossier Submitter considers that there are uses of 2,4-DNT which may lead to a non-adequately controlled risk from the presence of the substance in articles. Whilst there is no information available on current manufacture, import or export of 2,4-DNT in the EU, and ECHA has received no registrations for the substance, the restriction should also prevent potential future uses of the substance in articles.

2,4-DNT is an isomer of the multi-constituent substance DNT (EC: 246-836-1). Two of the isomers of DNT, 2,4-DNT and 2,6-DNT, make up 95 % of DNT whereas four other isomers (2,3-, 2,5-, 3,4-, and 3,5-DNT) account for the remaining 5 %. Currently, there are two active REACH registrations for DNT (one for 1-10 tonnes/year and the other as an intermediate). The main use of DNT (commonly having concentrations of 75-80 % of 2,4-DNT) is in the production of toluene diisocyanate. DNT containing a 50-55 % concentration of 2,4-DNT has been imported for use as a binding agent in the non-ferrous metal industry and in propellants. Other DNT isomers are not specifically targeted by this restriction, but may be in scope if included in articles, e.g. when 2,4-DNT is present in mixtures above a concentration limit of 0.1 % and where the presence of 2,4-DNT is a result of using DNT-mixtures with varying isomer content ratios.

The Dossier Submitter identified current or previous uses of 2,4-DNT in various articles including in refractories, in automotive airbags, in seat belt pre-tensioners, in plastic bottles used in industrial settings for sample taking purposes, as propellants for military and civil small-arms ammunitions, as gelatinising-plasticising agent in explosive compositions, and as a plasticising and waterproofing agent for propellants in gun powders. The latter two uses are considered mixtures as they are not produced as an integral part of an article⁴. Two notifications of a substance in articles (SiA) have been made under Article 7(2) of REACH for 2,4-DNT; for the use as plasticiser in plastic sample bottles used at industrial settings, for which the notifying entity has now ceased, and for the use in propellants for military ammunition articles. Furthermore, the US Environmental Protection Agency lists possible uses of 2,4-DNT in sports equipment and in outdoor toys such as sandboxes. No details of the import, use or manufacture of these articles are available, however.

A search of the SCIP database⁵ for 2,4-DNT indicated that there are articles in the EU containing the substance, e.g. in vehicles, ceramic articles and electronic devices. This information confirms that there are additional articles (probably imported ones) that contain the substance.

In addition to information from animal studies, DNT carcinogenicity has been studied in ammunition production facilities and in the copper mining industry. These studies found an association between cumulative DNT exposure and renal cell cancer. Particularly in miners an

² <https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/6510>.

³ Inclusion of substances of very high concern in the candidate list, Decision by the Executive Director

⁴ See [Guidance on requirements for substances in articles](#) (ECHA 2017).

⁵ In accordance with the Waste Framework Directive, companies supplying articles containing substances on the Candidate List in a concentration above 0.1 % w/w on the EU market shall submit information on these articles to ECHA, from 5 January 2021 onwards. The information provided is then included in the [SCIP database](#).

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association between dermal, but also inhalation, exposure to DNT and renal cancer has been established. Exposure relates predominantly to the handling (and possible inhalation of residuals of) DNT-containing explosive sticks.

2,4-DNT can be released from articles into water, air, and soil at places where they are produced or used. The restriction proposal targets consumer and professional uses in articles where release and exposure of 2,4-DNT cannot be excluded and risk management measures are difficult to implement. For example, 2,4-DNT is applied in plastic sampling bottles used in industrial settings for sample taking where the substance acts as a softener. Possibility of migration and worker exposure of 2,4-DNT from these bottles cannot be excluded. Traces of 2,4-DNT may also be found in refractory products where, again, exposure from the use of the articles cannot be excluded.

Consumer exposure may occur from the use of civilian small arms ammunition such as hunting and sports shooting, if the ammunition propellant contains 2,4-DNT. Shooting of the firearm does not consume all 2,4-DNT used in the ammunition and exposure via inhalation or dermally may occur. Two other examples of consumer uses with exposure potential are in seat belt pre-tensioners, where an explosive charge causes the gas generator to produce a volume of gas and thus pressure, which then acts on a mechanical linkage to pull the seat belt; and in air bags, where deployment releases gas in a similar manner as in pre-tensioners. For uses of 2,4-DNT in vehicle safety systems, groups at risk of exposure include, in addition to the driver, e.g. car repair technicians who may be exposed multiple times when repairing different crashed vehicles or, in case of an accident, the rescue forces. From these uses, both inhalation and dermal exposure may result.

2,4-DNT is considered a non-threshold substance for which no DNEL can be derived. Therefore, the Dossier Submitter is of the view that 2,4-DNT incorporated in articles poses a risk to human health that is not adequately controlled. The use of 2,4-DNT in the production of articles in the EU is subject to authorisation requirements under Title VII of REACH. Authorisation requirements do however not apply to imported articles, and it is thus likely that articles containing 2,4-DNT are produced outside the Union and subsequently imported into the EU.

As part of this restriction proposal, an analysis of risk management options (RMOs) was conducted to identify the most appropriate measures to address the risks identified. The Dossier Submitter concluded that action is required to reduce risks for consumers and professional and industrial workers on a Union-wide level and that the proposed restriction is the most appropriate measure.

The scope of the proposed restriction covers articles placed on the EU market that contain 2,4-DNT (seat belt tensioners, plastic sample bottles, ammunition, refractory materials, and others). Specific derogations are proposed. The restriction is assumed to impose very low costs as alternatives to 2,4-DNT are assumed to exist for the identified uses. The Dossier Submitter reasons that otherwise more notifications for uses in articles which historically used the substance, registrations, and applications for authorisation of 2,4-DNT uses would exist.

As there is no known EU production of articles using the substance, there is no need to transition to alternatives or to deplete stocks. If there are any imported articles using the substance, time may be needed for importers to transition to alternative articles that do not contain 2,4-DNT. It is proposed by the Dossier Submitter that 12 months would be a sufficiently long transition time. Moreover, the Dossier Submitter proposes to use the same concentration limit for 2,4-DNT as in Directive 2009/48/EC on the safety of toys.

Given the information at hand, the proposed restriction is assumed to impose very low costs to minimise a potential risk and the Dossier Submitter does not expect wider socio-economic impacts from its implementation. Therefore, the Dossier Submitter considers the proposed measure to be proportionate to the risk identified.

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Standardised laboratory methods for measuring 2,4-DNT in articles (and environmental samples) do exist, suggesting that the restriction is practical and monitorable. The presence of articles on the market that contain 2,4-DNT could be monitored using databases or applications such as the ones used as sources for the preparation of this Annex XV report. The restriction is targeted to the effects or exposures that are of most concern, e.g. those from consumer and professional uses. Given the limited use of the substance, the Dossier Submitter does not expect wider socio-economic impacts from the implementation of the proposed restriction.

2.2. Summary of opinion of SEAC

SEAC has developed its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties, the opinion of RAC, Forum's advice on enforceability as well as other available information recorded in the Background Document.

SEAC supports the view that any necessary action to address the risks associated with 2,4-DNT be implemented on an EU-wide basis to ensure a consistent level of protection of human health and the environment, whilst maintaining the free movement of goods across the Union.

SEAC agrees that the proposed restriction is an effective means to manage the identified risks to consumers and professional users. SEAC concurs with the Dossier Submitter that other risk management options are not as targeted as a restriction under REACH because of limitations in their scope and effectiveness.

Due to the sparse information on uses of 2,4-DNT in the EU, the Dossier Submitter provided a qualitative assessment of the costs and benefits of the restriction, identifying the preventive effect on exposure through imported articles as the major benefit of the proposal. As 2,4-DNT is a non-threshold carcinogen, SEAC agrees with the approach and the conclusions reached by the Dossier Submitter, but notices that the restriction might have been more impactful if the scope had included industrial uses as well.

The Dossier Submitter proposed specific derogations for the use of explosives and ammunition by military and police forces. Given the limited potential for exposure and the need to harmonise with other restrictions concerning the use of ammunition, SEAC sees these derogations to be justified.

Finally, SEAC concluded that the proposed restrictions would be practicable and monitorable.

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

3.1.1. Description of and justification for targeting of the information on hazard(s) and exposure/emissions) (scope)

Summary of proposal:

See RAC opinion.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion:

See RAC opinion.

3.1.2. Description of the risk(s) addressed by the proposed restriction

3.1.3. Information on hazard(s)

Summary of proposal:

See RAC opinion.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

3.1.4. Information on emissions and exposures

Summary of proposal:

See RAC opinion.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

3.1.5. Characterisation of risk(s)

Summary of proposal:

See RAC opinion.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

3.1.6. Uncertainties in the risk characterisation

3.1.7. Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

See RAC opinion.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

3.1.8. Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

See RAC opinion.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

3.2. JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter considers that Union-wide action is needed to address the risks associated with imported articles containing 2,4-DNT and to prevent any future use in EU manufactured articles. This ensures:

- a harmonised high level of protection of human health across the Union; and

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- the free movement of goods within the Union, where relevant.

The Dossier Submitter considers that taking regulatory actions at a national or local level would be neither effective nor efficient since the responsible authorities would have even less access to information about current uses of 2,4-DNT in articles.

SEAC and RAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that any necessary action to address the risks associated with 2,4-DNT exposure should be implemented in all Member States.

Key elements underpinning the SEAC and RAC conclusion(s):

Articles containing 2,4-DNT could be used and placed on the market throughout the European Union. Therefore, exposure could potentially take place in all EU Member States. RAC and SEAC consider that a Union-wide action is needed to address the risks associated with (mostly imported) articles containing 2,4-DNT and to ensure a harmonised high level of protection of human health across the Union.

3.3. JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC and RAC

Summary of proposal:

Based on a generic risk assessment, 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 to do so. The Dossier Submitter assessed various risk management options (RMOs) and identified a restriction under REACH as the most appropriate measure to address the identified risks.

The restriction proposed by the Dossier Submitter is assumed to impose very low costs to reduce a potential risk; given the information at hand, the measure is proportionate to the risk as alternatives to 2,4-DNT appear to exist for the identified uses as the substance is not legally used by EU manufacturers that produce similar articles to the ones in scope of the restriction (otherwise applications for authorisation would have been received by ECHA).

As there is no known EU production of articles using the substance (except for military ammunition, which is already the subject on various defence exemptions), there is no need for EU manufactures to transition to alternatives or for existing stocks to be used up. If there are any imported articles, time may be needed for importers to transition to alternative articles not containing 2,4-DNT. The Dossier Submitter assumes that 12 months would be a sufficiently long transition time. For the restriction, it is proposed to use the same concentration limit (100 mg/kg corresponding to 0.01 %) as in Directive 2009/48/EC on the safety of toys.

The scope of the proposed restriction covers articles placed on the EU market that contain 2,4-DNT (seat belt tensioners, plastic sample bottles, ammunition, refractory materials, and others). Specific derogations proposed by the Dossier Submitter are discussed by SEAC in the section on Scope including derogations.

SEAC and RAC conclusion(s):

SEAC considers that restriction option 2 (RO2), as proposed by the Dossier Submitter, is the

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most appropriate EU wide measure to reduce risk for consumers and professional workers on a Union-wide level from exposure to 2,4-DNT. This option foresees a restriction on the placing on the market and use of articles containing 2,4-DNT for consumers and professional users. The restriction does not cover industrial workers as it is assumed that industrial uses and uses of explosives take place under well controlled conditions. Ammunition for military use and the police are exempted.

SEAC notes that, according to the Dossier Submitter's query of the SCIP database, some (imported) articles containing 2,4-DNT are currently placed on the EU market. The proposed restriction would avoid such imports. Another benefit of the restriction would relate to the prevention of any future uses of the substance in EU manufacturing.

Key elements underpinning the SEAC and RAC conclusion(s):

SEAC notes that the Dossier Submitter assessed several other risk management options to reduce the risk from articles containing 2,4-DNT. These include the following.

Non-REACH risk management options

The Dossier Submitter assessed the following existing EU legislation as potential risk management option:

- Electrical and electronic equipment: under the WEEE Directive 2011/65/EU the use of 2,4-DNT is not currently restricted, even if 2,4-DNT has been identified as being used in such articles (SCIP database). SEAC considers that regulating 2,4-DNT in electrical and electronic equipment under the WEEE Directive would not be enough to reduce the potential exposure to 2,4-DNT from all articles,
- Cosmetics: under Annex II (Prohibited Substances) of the Cosmetics Products Regulation (EC) No 1223/2009, 2,4-DNT is already restricted but the restriction does not cover cosmetic articles.
- Restriction of Hazardous Substances Directive (RoHS): SEAC considers that to prevent the use of 2,4-DNT and to reduce exposure to the substance, the RoHS Directive appears to be less efficient than the proposed restriction.

Other EU-wide regulations were shortly analysed by the Dossier Submitter as potential risk management options:

- Medicinal products for human use: Directive 2001/83/EC;
- Medicinal products for veterinary use: Directive 2001/82/EC;
- Fuels and oil products: Directive 98/70/EC;
- Motor fuels mineral oil products intended for use as fuel in mobile or fixed combustion plants, fuels sold in closed systems (e.g. liquid gas bottles);
- Artist paints: Regulation (EC) No 1272/2008.

SEAC concludes that the scope of these directives is very limited and product-specific and, considering the uncertainties concerning the presence of 2,4-DNT in those articles, none of the above-mentioned EU legislations would be suitable for managing the identified risks and reducing exposure to the substance.

National regulation in Member States

SEAC notes that national authorities would not have direct access to information about current uses of 2,4-DNT in articles, and action on a Member State level could lead to non-harmonised measures. Therefore, regulatory actions taken by individual Member States would neither represent an effective nor an efficient means of risk management.

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SEAC considers that, since exposure may take place in all EU Member States, the existence of regulatory measures at national level will not be sufficient to reduce the risks to human health and environment arising from 2,4-DNT in articles used across the EU.

Risk management options under REACH

Under the REACH regulation, 2,4-DNT is already included in:

- REACH Candidate list for authorisation (13/01/2010; ED/68/2009) implying obligations to notify its presence in articles if the concentration of the substance is >0.1 % and 1 tonne per year (Article 7(2)), and that suppliers must inform their customers on request if an article contains more than 0.1 % by weight of the substance in question (Article 33(b));
- Authorisation Annex XIV of REACH (Commission Regulation (EU) No 143/2011) on the basis of Art. 57(a) Carc 1B. with a foregone sunset date in August 2015. No applications for authorisation were received. SEAC considers that, since Authorisation does not apply to imported articles, given that a relevant part of the concern relates to imported articles, the effectiveness of such a measure is not sufficient.
- Annex XVII entry 28, appendix 2, 2,4-DNT as a substance or a constituent of other substances, or mixtures containing it > 0.1 % are for supply to the general public.

SEAC notes that this restriction proposal has been prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006. This article requires ECHA to prepare an Annex XV restriction dossier, after the sunset date for a substance included on the Authorisation List, in case the risks from the use of the substance in articles are not considered as adequately controlled.

SEAC agrees with the Dossier Submitter that a restriction seems to be the most appropriate means to regulate imported articles containing 2,4-DNT at a EU-wide level. Table 2 summarises the three restriction options presented by the Dossier Submitter.

REACH restriction options

SEAC notes that the Dossier Submitter initially considered three different restriction options and discusses their effectiveness, practicality and monitorability.

- RO1: restriction on placing on the market and use of all articles containing 2,4-DNT addressing the risk to all populations for consumers, professionals and industrial workers. This restriction option would mainly entail impacts to importers of ammunition containing 2,4-DNT and to manufacturers of explosives using DNT, while, according to the Dossier Submitter, impacts to other actors would be low since a limited number of articles are expected to be affected. The efficiency of this restriction might decrease in case Member States would apply for a defence exemption (according to article 2(3) of REACH). SEAC notes that the Dossier Submitter's risk assessment did not cover the whole scope of RO1.
- RO2 (the proposed restriction): restriction on the placing on the market and use of articles containing 2,4-DNT. This restriction option addresses risks to the least protected populations (consumers) as well as the most exposed individuals (professional workers). The restriction does not cover industrial workers as it is assumed that industrial uses and uses of explosives take place under well controlled conditions. Ammunition for military use and the police are exempted. Low socio-economic impacts are expected from this restriction option since only a limited number of articles are affected by the restriction. At the same time, the risk reduction potential of this restriction is potentially lower than that of RO1 as uses in explosives and ammunition for military uses and the police are not restricted under RO2 (although the extent of risks from these uses is not known as they were not assessed by the Dossier Submitter).

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- RO3: restriction on placing on the market and use of articles containing 2,4-DNT of use by the general public would protect the consumers from exposure and risk. This restriction option would have a lower risk reduction potential than RO2 since it would not reduce risks to professional workers using articles containing 2,4-DNT. This restriction option would have low socio-economic impact as a limited number of articles are expected to be affected. Ammunition for military and police use would not be in scope. Uses of explosives are also out of scope as it is assumed that they take place under well controlled conditions.

Table 2: Summary of restriction options considered by the Dossier Submitter

	RO1	RO2	RO3
Consumer uses	✓	✓	✓
Professional users	✓	✓	
Industrial users	✓		
Articles incl. in the scope	all articles containing 2,4-DNT, incl. ammunition and explosives	Consumer and professional articles containing 2,4-DNT, incl. uses in civilian ammunition	consumer articles containing 2,4-DNT, incl. uses in civilian ammunition
Derogations	none, but defence MS exemptions may apply	for explosives and ammunition for military and police uses	for explosives and ammunition for military and police uses
Socio-economic impacts	low, expected to affect only limited number of imported articles	low, expected to affect only limited number of imported articles	low, expected to affect only limited number of imported articles
Risk reduction capacity	high, all articles and uses in scope	medium, articles and uses for consumers and professionals in scope	low, articles and uses for consumers in scope

Since analytical methods exist, all of the above restriction options are considered to be enforceable. In its draft final opinion, RAC concluded that:

- Union-wide action on 2,4-DNT uses in articles is justified;
- The proposed restriction (RO2) is the most appropriate EU wide measure;
- The proposed restriction (RO2) is an effective measure for addressing the identified risks assessed by the DS;
- The proposed restriction is practical and enforceable and monitorable;
- The proposed derogations are justified.

Based on these considerations, SEAC concludes that the restriction proposed by the Dossier Submitter (RO2) is the most suitable restriction option to address the risks assessed by the Dossier Submitter. Covering both consumer and professional uses, this option prevents existing and future uses and exposures from articles containing 2,4-DNT without entailing major impacts to the EU society.

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

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See RAC opinion

RAC conclusion(s):

See RAC opinion

Key elements underpinning the RAC conclusion(s):

See RAC opinion

Justification for the opinion of SEAC

Summary of proposal:

Considering the baseline analysis in section 5.2, the best restriction option appears to be RO2. RO1 would entail higher costs but would lead to a similar risk reduction as industrial uses and uses of explosives are assumed to be well controlled. The following points warrant further consideration:

- Related to the concentration limit, it is proposed to use the same concentration limit as in the notification of substances in articles according to article 7(2) (SiA notifications).
- Related to exemptions, according to the analysis presented in Table 10 in the Background Document, it is proposed to exempt articles covered by Regulation (EU) 2017/745 on medical devices.
- Related to the use in explosives, it is assumed that these are well-regulated and since general safety measures are in place for the handling of explosives, these should limit any exposure to 2,4-DNT. It is therefore proposed to exempt this use from the restriction.
- Following the reasoning in the lead in hunting, sports shooting and fishing restriction proposal, it is proposed to exempt military ammunition from this restriction.
- Related to the transitional period, as there is no EU production of articles, there is no need to transition to alternatives or to deplete stocks. For imported articles, time may be needed for importers to transition to different articles not containing 2,4-DNT. It is assumed that 12 months would be a sufficiently long transitional period.
- In as far as such exposures occur, the proposed restriction would also decrease the exposure of humans via the environment.

SEAC conclusion(s):

SEAC agrees with the scope as proposed by the Dossier Submitter for reducing exposure of consumers and professionals to 2,4-DNT.

In particular, SEAC agrees with the Dossier Submitter that:

- the inclusion in the entry of articles for supply of consumers and for professional uses would reduce risks born by the main vulnerable populations, consisting of consumers and professional workers who could be the most exposed to 2,4-DNT;
- the proposed concentration limit value would prevent future uses and minimise human health exposure from current uses in imported articles;
- a transition period of 12 months appears to provide actors in the supply chain potentially affected by the proposed restriction with sufficient time to comply;
- the exemptions proposed by the Dossier Submitter due to double regulation (toys, medical devices and food contact materials) are warranted;

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- the additional exemptions proposed by the Dossier Submitter concerning explosives and ammunition for military and police use are warranted;
- an exemption for second-hand articles is justified because of enforcement difficulties and economic reasons.

In addition, SEAC notes that RAC considers that further assessment of the risks posed by 2,4-DNT in industrial uses and for professional uses of explosives (both uses that were not risk assessed by the Dossier Submitter) appears to be needed as the available information does not allow a conclusion on whether risks associated with these uses are adequately controlled. SEAC notes that as the Dossier Submitter did not include these uses within their risk assessment it is not possible for RAC or SEAC to propose them to be included within in the scope of the current restriction.

Key elements underpinning the SEAC conclusion(s):

Consumer and professional uses

SEAC agrees with the Dossier Submitter that including consumer and professional uses in the scope of the restriction reduces the risk to the most vulnerable populations potentially exposed to articles containing 2,4-DNT.

Professional uses are defined by the Dossier Submitter as uses by workers that take place outside of industrial installations and where fixed risk management measures cannot be used. In the case of 2,4-DNT, the main category of professionals that could be exposed are workers involved in mining, building, construction, maintenance, cleaning activities, hairdressing, beauty and health care services, as well as car repairing activities.

Concentration limit value

SEAC considers that, regardless of the restriction option, a limit value of 0.1% (w/w) of 2,4-DNT seems to be the most practical concentration limit value since it corresponds to the concentration value that is already in place in the notification of substances in articles according to REACH Article 7(2) (SiA notifications).

Based on the available information and RAC's opinion, SEAC considers that the proposed concentration limit is appropriate, i.e. sufficiently low to avoid future uses and effective in protecting human health and the environment; at the same time, it is high enough to be monitored by currently available analytical methods making it a practical, implementable and enforceable measure.

Transitional period

SEAC agrees with the Dossier Submitter's recommendation of a transition period of 12 months after entry into force of the proposed restriction. SEAC highlights that the sunset date for submitting applications for authorisation for 2,4-DNT passed in 2015. Therefore, producers in the EU (if at all existing) have already phased out the substance and stocks should not exist.

SEAC notes that, up to now, no intentional uses of 2,4-DNT in the manufacture of articles have been identified in the EU and currently only imported articles might be placed on the EU market if they are in small volumes and therefore exempt from SiA notifications.

In conclusion, since there seems to be no need for substitution, SEAC considers that a period of 12 months, as proposed by the Dossier Submitter, should be long enough for affected supply chains that rely on imported articles to adapt their operations (if at all needed).

At the same time, as confirmed by RAC's opinion, SEAC considers the proposed transition period short enough to prevent any relevant risk, namely from imported articles. Such transition period would have no or very little negative socio-economic impacts on the supply chain. For imports into the EU, SEAC considers that a transition period is mainly needed to allow current importers to purchase different articles not containing 2,4-DNT.

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Exemptions due to double regulation

SEAC agrees with the exemptions proposed by the Dossier Submitter of toys, medical devices and food contact materials. The reason for this is that these articles are already covered by specific regulations, hence these exemptions would only avoid double regulation:

1. Toys: Directive 2009/48/EC on the safety of toys already prohibits substances classified as carcinogenic 1B (as 2,4-DNT) in toys in concentrations equal to or above 0.1 %, unless a safety assessment has been carried out showing it is safe.
2. Medical devices: aside in some justified cases, Regulation (EU) 2017/745 already prohibits substances classified as carcinogenic 1B in medical devices coming into direct contact with the human body in concentrations equal to or above 0.1 % w/w.
3. Food contact materials: Regulation (EC) No 1935/2004 does not include 2,4-DNT in the list of substances that can be used in food contact materials. Consequently, 2,4-DNT cannot be used in food contact materials. Although strictly speaking it would not be necessary, the Dossier Submitter decided to explicitly exempt these materials to avoid double regulation.

Exemption for explosives

SEAC notes that, in the restriction proposal, the Dossier Submitter aligned its definition of explosives to the one used in the Directive 2014/28/EU on the harmonisation of the laws of the Member States relating to the making available on the market and the supervision of explosives for civilian uses. The definition of explosives in Directive 2014/28/EU is based on that recommended by the United Nations *concerning the transport of dangerous goods and falling within Class 1 of those recommendations*.

However, it was discussed during the opinion making that this definition of explosives would include pyrotechnic articles (fireworks) and ammunition, both uses intended to be restricted by the Dossier Submitter. Therefore, the Dossier Submitter clarified that these types of articles should be within the scope of the proposed restriction and amended the proposed restriction entry in Table 1 accordingly with the reasoning that fireworks and civilian use of ammunition could both lead to consumer or professional exposure.

SEAC notes that, while proposing this exemption on explosives, the Dossier Submitter considers that:

- any exposure to 2,4-DNT as an impurity of TNT or intentionally added, or in TNT recovered from old explosives and ammunition (Technical report, 2010), should be limited;
- if this use of 2,4-DNT existed, it would only concern imported explosives as there is no active registration for 2,4-DNT (albeit there is one for DNT);
- in principle explosives should be well-regulated and safety measures put in place.

SEAC notes that several different directives apply to the manufacture, storage and use of explosives:

- Seveso Directive (2012/18/EU): the classification of TNT as explosive category 1.1 s (P1a explosives) triggers lower tier requirements at 10 tonnes and upper tier requirements at 50 tonnes related to major accident hazards;
- Directive 2014/28/EU on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (recast): to make available on the market and supervise explosives for civil uses, explosives must be designed, manufactured and supplied in such a way as to present

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a minimal risk to the safety of human life and health, and to prevent damage to property and the environment under normal, foreseeable conditions – chemical composition must be taken into account. *This Directive shall not apply to: (a) explosives, including ammunition, intended for use, in accordance with national law, by the armed forces or the police;*

- Industrial Emission Directive (2010/75/EU): Annex I covers the production of explosives and foresees that all appropriate preventive measures have to be taken against pollution, that the best available technologies have to be applied, and that the sites of explosives' production must have a valid permit;
- Waste Framework Directive (2008/98/EC): waste containing 2,4-DNT is considered hazardous waste;
- Chemical Agents Directive (CAD) Council Directive 98/24/EC and Carcinogens and Mutagens Directive (CMD): already foresee workers' protection measures to protect the health and safety of workers using 2,4 DNT and TNT;
- Several other national OELs are in force to protect workers handling explosives.

SEAC notes that no information is available on the use of 2,4-DNT in explosives and the Dossier Submitter did not undertake a specific risk assessment of this use. RAC concluded that further work could be undertaken to determine to extent of risks to professional workers from explosives.

The proposed exemption for ammunition for military and police uses

An exemption for military ammunition was already requested by the Commission and included in the scope of the recent restriction proposal on lead in hunting, sports shooting and fishing. SEAC agrees with the Dossier Submitter that this exemption is justified also in the restriction on 2,4-DNT following the same reasoning as in the lead in ammunition restriction proposal and to be consistent with the Commission's request adopting a harmonised approach between these two restrictions.

SEAC notes that during the consultation one comment indicated that there might be continued use of 2,4-DNT in the production of propellants for manufacturing (military) ammunition and therefore the Dossier Submitter considers that an exemption is warranted.

Exemption for placing on the market and use of second-hand articles

SEAC notes that the use and placing on the market of articles that are already in use will not be affected by the restriction.

SEAC supports the proposed exemption for placing on the market and use of second-hand articles containing 2,4-DNT. SEAC notes that the Forum underlined that, without such exemption, there would be major difficulties for the enforcement of the proposed restriction. For instance, if a car having seatbelt pretensioners and airbags is sold on the second-hand market, the seller as well as the buyer would not be aware of the presence of 2,4-DNT in the car.

In addition to enforcement difficulties, and in the absence of a derogation on second-hand articles, SEAC considers that there would be high costs associated with testing of potential parts containing the substance. These testing costs might entail major economic impacts on the second-hand market that would challenge the proportionality of the proposed restriction.

Finally, SEAC notes that exempting second-hand articles would not significantly impact the risk reduction capacity of the proposal since the substance might have already been released by the article (for instance from the used seatbelt).

Exclusion of industrial uses from the scope

SEAC underlines that the Dossier Submitter did not include industrial uses in the scope assuming that industrial workers are already well protected by risk management measures

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already in place in industrial premises.

SEAC notes that during the consultation (comment #3540), the German Competent Authority questioned why the scope of the restriction proposal was limited to consumers and professional users. They agreed with the Dossier Submitter that professional workers are more comparable to consumers in the use of articles than it is the case with substances and mixtures. Indeed, when consumers and professional workers handle articles, in general, no special measures are taken to protect against substances of concern that may be present in the article. The German Competent Authority explained not to be aware of specific measures taken at industrial workplaces for handling articles containing 2,4-DNT and that containment does not seem plausible in this context.

SEAC shares the concerns raised by the German Competent Authority. SEAC notes that the Dossier Submitter did not include these uses within their risk assessments and, therefore, that they cannot be included within the scope of the current proposal. Nevertheless, in agreement with RAC, SEAC considers that the exclusion of workers at industrial setting was not sufficiently justified in the restriction proposal, as it is not specified which OCs and RMMs would be in place, and that further work could be undertaken to determine to extent of risks at industrial sites and to professional workers using explosives posed by 2,4-DNT and explore how these could best be addressed.

3.3.1. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

See RAC opinion.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

3.3.2. Socio-economic impact

Baseline scenario

The following baseline scenario emerges from the information available.

- Regulatory framework: 2,4-DNT is included in the Candidate list, in the Authorisation List (Annex XIV) with a foregone sunset date in 2015 and in Annex XVII of REACH, entry 28 and appendix 2 that restrict the supply of 2,4-DNT to the general public as a substance and in a mixture containing >0.1 % DNT;
- Commercial availability: 2,4-DNT is available commercially as a purified isomer or as a component of technical grade dinitrotoluene (DNT) that is currently manufactured in the EU as a non-isolated intermediate in quantities of 540 000 to 810 000 tonnes per year. The majority of this use is in the manufacture of TDI;
- Existence of self-classifications of 2,4-DNT in the EU: SEAC notes that, although there are no notifications, a number of self-classifications of 2,4-DNT have been made. This implies that the substance might be available and used in the EU at volumes of <1 tonne/year and in uses exempt from the authorisation requirement (e.g., in applications covered by the R&D exemption to authorisation). However, despite an extensive stakeholder consultation, no information hinting at any current use of the substance was made available to the Dossier Submitter.

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- Absence of manufacture of articles containing 2,4-DNT in the EU: SEAC notes that no registrations on the substance, nor applications for authorisation for the use of 2,4-DNT in the production of articles were received in the EU. Therefore, SEAC considers that, at present, there seems to be no direct manufacture of articles containing 2,4-DNT in the EU. Notwithstanding the above, SEAC notes that it cannot be fully excluded that some production exists.
- Presence in the EU market of a few uses of (imported) articles containing 2,4-DNT: SEAC notes that articles containing 2,4-DNT are included in the SCIP database. Since 5 January 2021, companies placing articles onto the EU market that contain SVHC in a concentration above 0.1% w/w have to submit to ECHA, via this database, information on articles throughout their whole lifecycle, including the waste stage. Article categories containing 2,4-DNT indicated in the SCIP database are mainly electronic equipment and parts thereof, but the substance was also notified in corrugated sheets, vehicles (e.g. seat-belt pre-tensioner), military arms and ammunition, iron, steel or aluminium based articles, plastics and articles thereof (e.g. 3-way fluid connector in commercial printing inks toners and related finishing products). As the SCIP database covers the whole service life of articles, it has to be noted that articles containing 2,4-DNT might be new articles or articles at the waste stage (i.e. a legacy use of the substance). SEAC notes that the fact that some notifications in the SCIP database are recent (August 2021) might indicate that these are current uses. SEAC also notes that, in the SCIP database, there is neither information on tonnages nor on the exact part of the articles containing the substance that might or might not lead to potential exposure. Moreover, SEAC notes that authorisation requirements do not apply to imported articles. Therefore, SEAC considers that articles containing 2,4-DNT can be produced outside the Union and subsequently imported into the EU. Such articles might cause a risk to the health of the general population and to professional workers in the EU. However, neither SiA notifications under REACH nor Safety Gate notifications were received in the EU. Hence, at present, only a limited volume of articles (containing under one tonne of 2,4-DNT per year in total) could have been legally placed on the EU market. SEAC notes that it cannot be excluded that, without the restriction, historical uses could potentially be resumed. Even in the absence of applications for authorisation, notifications in the SiA and in the Safety Gate and from the SCIP database, although very unlikely, SEAC considers that it cannot be fully excluded that some uses have been missed;
- Concentrations of 2,4-DNT in most (imported) articles are far below the proposed limit value as otherwise there should be transmission of information to customers according to Art. 33 of REACH;
- Existence of alternatives: it is assumed that EU manufacturers have found technically and economically feasible alternative substances or technologies to replace 2,4-DNT in at least a range of historical uses. Since there seems to be no production and only limited import (if any) of articles containing 2,4-DNT, there should be no need to switch to alternatives, hence neither substitution costs nor expenses to depletion of existing stocks are expected;
- Exposure of consumers, professional workers and industrial workers in the EU is not known but it cannot be excluded.

In the absence of contradictory information, SEAC finds it unlikely that articles containing 2,4-DNT (except for uses in ammunition for which the AeroSpace and Defence Industries Association of Europe (ASD) informed about Defence Exemptions pursuant Art. (2)3 of REACH) are currently produced in the EU, but considers it likely that some (imported) articles are placed on the market and used in the EU, containing an amount of the substance lower than one tonne per year in total. SEAC takes note of RAC's conclusion that, in the absence of a restriction, the use of articles containing 2,4-DNT (a no-threshold carcinogen) might pose a risk to consumers and professional workers that should be addressed.

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SEAC considers that different levels of uncertainty are associated with the various assumptions on the baseline scenario as described above (current and future uses, import, exposure, types of alternatives, etc.). These uncertainties and the associated socio-economic impacts are discussed in more detail below.

Justification for the opinion of SEAC

3.3.2.1. Costs

Summary of proposal:

Overall, the compliance costs accruing to EU actors in various supply chains of articles are expected to be very low. No costs are expected for either manufacturers or importers of the substance or mixture because there is no direct article manufacturing in the EU (as no applications for authorisation were received). There may be some costs for importers of articles, having to re-source different products but this cost is assumed to be negligible.

For consumer uses of 2,4-DNT in articles, it is assumed that there are suitable alternatives available; for professional uses of 2,4-DNT in articles the situation is less clear. An RIVM study on alternatives for phthalate plasticisers lists alternatives for its use in ammunition as a plasticiser and deterrent (burning rate regulators), which could also be considered for the similar use of 2,4-DNT (RIVM, 2013).

The Dossier Submitter is of the view that the potential for loss of employment or changes in price for end users will be negligible. Specifically, the Dossier Submitter argues that EU companies either have found suitable alternatives for the substance use in articles or articles containing 2,4-DNT are imported. In the latter case, substitution or ceasing costs would accrue to non-EU entities and would only represent a welfare cost to the EU if non-EU producers had sufficient market power to pass through any production price increments. Considering the types of articles suspected to contain 2,4-DNT, this seems very unlikely to happen because of market competition. The Dossier Submitter invokes the example of the use in seatbelt pretensioners; the car industry is a highly competitive sector and EU car manufacturers will not agree to a pass through of incremental production costs incurred by their non-EU based suppliers because of a REACH restriction on 2,4-DNT.

In sum, the economic impact of a restriction on 2,4-DNT in articles covered by this proposal would be minimal. The assumptions on the availability of alternatives, loss of employment or changes in consumer prices were tested in a call for evidence but no information was received questioning the assumptions made (<https://echa.europa.eu/previous-calls-for-comments-and-evidence/-/substance-rev/27201/term>).

SEAC conclusion(s):

Based on the assessment carried out by the Dossier Submitter, in the absence of contradicting information, SEAC concludes that, overall, only limited socio-economic costs can be expected from the proposed restriction along the supply chain in the EU.

However, SEAC highlights that more information on the need of substitution and the costs of alternatives could still become available during the consultation on the SEAC opinion. Thus, at a later stage of the opinion development, SEAC's conclusions with regard to the costs may still change.

Key elements underpinning the SEAC conclusion(s):

SEACs conclusion on costs is grounded on the assumption that currently there is no manufacture in the EU, only a few known uses exist, these are related to imports into the

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Union and in any case alternatives exist. However, SEAC notes that uncertainties are associated with these assumptions.

SEAC acknowledges the challenges faced by the Dossier Submitter in gathering quantitative data on costs during the preparation of this restriction proposal.

As quantitative data are not available, SEAC cannot carry out any quantitative assessment of the costs associated with the proposed restriction. Therefore, SEAC agrees with the qualitative approach proposed by the Dossier Submitter.

Costs to European manufacturers

Since, based on the available information, there is no direct manufacturing of articles containing 2,4-DNT in the EU (as no applications for authorisation were received), SEAC considers that no or only limited costs can be expected for any potential European manufacturers of the substance or mixture or articles containing 2,4-DNT.

Substitution and reformulation costs

SEAC notes that neither during the stakeholder consultations carried out by the Dossier Submitter for the preparation of the Annex XV Dossier nor in the consultation on the restriction proposal, industry raised any major compliance issue.

In the absence of any contradictory evidence, SEAC interprets this fact as an indication that technically and economically feasible alternative substances or technologies are already in use or that they exist and can be easily used after the entry into force of the restriction. Moreover, SEAC considers that the absence of comments on compliance costs in the consultations confirms that currently there are no or only limited uses of articles containing 2,4-DNT in the EU. As a consequence, SEAC considers that it is not likely that the industry will face major challenges to substitute 2,4-DNT in any relevant uses. Therefore, SEAC considers that the proposed restriction is expected to entail no or very limited reformulation and substitution costs, including expenditures for R&D, new investments and possible increased operational costs, for European manufacturers.

Wider impacts on non-EU manufacturers

SEAC notes that the proposed restriction might induce some substitution costs to non-EU manufacturers. This could entail some minor costs in the EU, possibly to importers to purchase articles without 2,4-DNT and to EU consumers if the non-EU manufacturers would pass these costs to them.

Costs to importers

Given that articles containing 2,4-DNT are currently imported into the EEA, SEAC considers that some costs for importers of articles containing 2,4-DNT (such as ammunitions) can be expected since importers will have to purchase alternative 2,4-DNT-free articles.

Impacts on European consumers

SEAC notes that no information on the possible impacts on consumers was included by the Dossier Submitter in the Background Document. However, based on the fact that no information was made available that would challenge the assumptions made by the Dossier Submitter regarding the baseline scenario, SEAC considers that, as a consequence of the proposed restriction, no significant loss of consumers' surplus has to be expected in terms of availability, quality and prices.

SEAC's conclusion on the impacts on consumers is grounded on the following arguments:

- availability and quality of 2,4 DNT-free articles: only very few articles containing 2,4-DNT (if at all) are currently placed on the EU market hence articles of the same quality containing alternative substances are available and most likely already dominate the market;

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- prices of 2,4 DNT-free articles: European and non-European companies will need to keep their market shares and market position in front of their competitors. SEAC considers that major increases of consumers prices of 2,4-DNT-free articles are unlikely. SEAC notes that, in general, if articles containing 2,4-DNT are produced outside the EU, as a possible reaction to the restriction, some non-EU manufacturers might decide to substitute 2,4-DNT in their products by more expensive alternatives. In this case, the resulting costs could trickle down to EU consumers. However, due to price competition on the market, SEAC considers that it is unlikely that the industry will include any additional substitution, reformulation and testing costs in the final prices of these articles.

Social impacts

Based on the information available at this stage, SEAC considers that no or only negligible loss of employment of European workers can be expected from the proposed restriction since it appears that alternatives exist and that currently manufacture of articles containing 2,4-DNT is not taking place within the EU.

Enforcement costs

SEAC considers that the generic value of €55,600 of annual average cost per restriction proposed by ECHA is likely to be a good indicative estimation of the costs for enforcing the proposed restriction. SEAC notes that enforcing the proposed restriction is not expected by the Forum to cost more than the enforcement of other REACH restrictions.

Testing costs

SEAC notes that laboratory methods for measuring 2,4-DNT in articles (and environmental samples) exist, suggesting that the restriction is practical and monitorable.

According to USEPA, standard analytical detection methods include gas chromatography (GC) and high-performance liquid chromatography (HPLC).

SEAC notes that mainly imported articles are likely to be tested both by importers and by enforcement authorities.

SEAC underlines that the estimation of testing costs would require information of the number of tests that have to be performed, and information on costs related to sampling and sample preparation carried out by the laboratory. SEAC notes that such information is not included in the Annex XV Dossier.

However, SEAC considers that the drafted baseline provides some indication of the limited magnitude of the costs associated to testing and sampling.

SEAC notes the Forum's conclusion that costs of enforcement would depend on the sampling and testing procedures, and on their availability within the EEA.

3.3.2.2. Benefits

Summary of proposal:

The Dossier Submitter considers that the available epidemiological studies support the hypothesis that occupational exposure to DNT may cause cancer, since excess cancer mortality observed among DNT-exposed workers is consistent with findings from experimental studies of DNT-exposed animals. These studies associate an excess of hepatobiliary cancer and both urothelial cancer and renal cell cancer with jobs in which workers were supposedly exposed to purified 2,4-DNT and miners supposedly exposed to technical grade DNT, respectively.

Whilst the Dossier Submitter notes that the willingness-to-pay for avoiding cancer is

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substantial, no quantitative assessment of the benefit expected from this restriction could be undertaken.⁶ This is for three reasons. First, considering the assumptions made in the costs assessment, there are unlikely to be (m)any workers or consumers exposed. Second, typical exposures to 2,4-DNT from various articles are not known. Third, there is no known dose-response function that would link exposure to 2,4-DNT to the associated types of cancer.

The Dossier Submitter considers therefore that the benefit of the proposed restriction is due to its preventive value, as it would prevent future uses of the substance in articles, and thus avoid regrettable substitution and potential risks to workers and consumers in the EU.

SEAC conclusion(s):

SEAC considers that the main benefits of the proposed restriction would derive from preventing potential future uses and imports of articles containing 2,4-DNT and to avoid regrettable substitution. This would entail benefits both in terms of prevented impacts to human health and to the environment.

Key elements underpinning the SEAC conclusion(s):

SEAC based its conclusion on the fact that, even if there is no or only limited manufacture, placing on the market and use of articles containing 2,4-DNT in the EU, impacts to human health and to the environment cannot be completely excluded.

Human health benefits

SEAC notes that 2,4-DNT is a non-threshold substance classified under Regulation (EC) No 1272/2008 (CLP) as a Carcinogen category 1B, H350 (may cause cancer), Reprotoxic. 2 H361f and Mutagen 2 H341. SEAC notes that no threshold could be established for carcinogenicity and mutagenicity, while for reprotoxicity a threshold applies. The substance was therefore included in the Candidate list for authorisation in 2010 and into Annex XIV of REACH on the basis of Art. 57(a) of REACH with a foregone sunset date in 2015.

Based on the properties of the substance, SEAC considers that the main benefit of this restriction in terms of human health is the prevention of risk of hepatobiliary, urothelial and renal cell cancers to professional workers or consumers.

SEAC notes that the Dossier Submitter carried out a qualitative assessment of the benefits of the proposed restriction. SEAC agrees with the adoption of this approach based on the three arguments made by the Dossier Submitter that likely only few professional workers or consumers are exposed to 2,4-DNT, exposures from various articles are not known and a clear dose-response function has not been identified for the cancer types caused by exposure to 2,4-DNT. In any case, SEAC agrees with the Dossier Submitter that the willingness-to-pay for avoiding cancer is substantial.

SEAC highlights that, as in all other restrictions, the benefits of the proposed restriction strictly depend on whether the chosen alternative substances or technologies are safer for human health and the environment. According to the EU RAR (2008), the most probable route of human exposure to 2,4-DNT is inhalation and dermal contact for workers involved in the production and use of 2,4-DNT containing explosives.

SEAC notes that, even if, according to the EU RAR (2008), there is no valid human epidemiological study available, two studies (Seidler et al., 2014, Brüning et al., 1999) support the hypothesis that occupational exposure to DNT may be carcinogenic. Excess cancer mortality observed among DNT exposed workers is similar to the findings from experimental studies of DNT exposed animals.

⁶ See SEAC's [Reference willingness-to-pay values for monetising chemicals health impacts](#).

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In addition, SEAC notes that during a call for evidence⁷ held between January and March 2021, two comments were received providing some information on the occupational exposure to 2,4-DNT from production and handling of explosives between 1990 and 2021.

According to RAC, the proposed restriction is an appropriate instrument for the minimisation of potential risks related to 2,4-DNT; hence, SEAC considers that benefits can be expected from the proposed restriction in terms of morbidity and mortality risk that could be avoided.

Benefits to the environment

While the main endpoints of 2,4-DNT concern human health and the main goal of the restriction proposal is the reduction of human health risks, SEAC notes that, in addition, 2,4-DNT is classified as Aquatic Acute 1 H400 and Aquatic Chronic 1 H410 and thus there could be some benefits for prevented impacts to the environment.

The substance has been detected in groundwater near sources such as munitions sites where the substance is used. Moreover, it is reported in the Background Document that, as a result of its moderate solubility, 2,4-DNT can be transferred to plants via root uptake from soil and it is expected to accumulate readily in plant materials (EPA, 2008). In fact, 2,4-DNT and its metabolites have been extracted from plant material in studies where different plant species have been exposed to 2,4-DNT.

In conclusion, SEAC notes that the presence of 2,4-DNT in the environment and, as a consequence, exposure of the general population via the environment cannot be excluded.

3.3.2.3. Other impacts

Summary of proposal:

The Dossier Submitter has identified no other social, wider economic and distributional impacts.

SEAC conclusion(s):

Based on the available information, SEAC considers that no additional social, wider economic and distributional impacts have to be expected from the implementation of the proposed restriction.

Key elements underpinning the SEAC conclusion(s):

No information was provided by the Dossier Submitter or in the consultation of the Annex XV report on wider socio-economic or other impacts.

3.3.2.4. Overall proportionality

Summary of proposal:

The Dossier Submitter considers that the restriction is assumed to impose very low costs to reduce a potential risk; given the information at hand, the Dossier Submitter considers that the measure is proportionate to the risk.

SEAC conclusion(s):

SEAC considers that the restriction is targeted to reduce the potential risks of consumers and professional workers in uses that are of most concern, while entailing very low costs. Based

⁷ <https://echa.europa.eu/previous-calls-for-comments-and-evidence/-/substance-rev/27201/term>

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on the available information, RAC and SEAC consider the proposed restriction to be proportionate to the risk.

Given the uncertainties on the baseline, SEAC cannot exclude that consultation on the SEAD draft opinion might provide more information and possibly challenge the assumptions made by the Dossier Submitter on costs and benefits of the proposed restriction and, thus, SEAC conclusions on the overall proportionality of the proposed restriction.

Key elements underpinning the SEAC conclusion(s):

The conclusion of SEAC on proportionality is based on the following reasoning.

On the benefit side, the proposed restriction has the potential to prevent negative impacts on human health and the environment from future exposures to 2,4-DNT:

- Benefits to human health will come from avoided morbidity and mortality risk (and related costs of illness) from hepatobiliary, renal and urothelial cancer associated to the consumer and worker exposure the 2,4-DNT for which no safe level can be established;
- Further benefits will come from avoided impacts to the environment and possible avoidance of the associated costs of remediation.

On the cost side, the costs associated with the implementation of the proposed restriction are expected to be minimal for EU actors because:

- Substitution costs borne by EU entities are expected to be minimal since most probably there is no need to substitute 2,4-DNT in articles, given that:
 - Manufacture of articles containing 2,4-DNT is unlikely to take place within the EU;
 - Only few uses in articles were clearly identified to occur in the EU (SCIP 2021).
- the costs associated with monitoring, enforcement and testing activities (to be carried out both by industry and by National Enforcement Authorities) are not expected to be significant;
- the main costs are expected to be for importers, but even there it might be reasoned that these costs are likely to be minor as available alternatives are already placed on the EU market.

Therefore, SEAC considers that the proposed restriction appears to be proportionate to the risk.

Table 3: Summary of impacts of the proposed restriction

Benefits	Costs
<p><u>Benefits for human health</u> and related socio-economic benefits:</p> <ul style="list-style-type: none"> • Risk reduction due to reduced exposure to 2,4-DNT • Avoidance of adverse health effects of hepatobiliary, urothelial and renal cell cancers • Avoidance/reduction of costs of illness <p><u>Benefits for the environment</u> and related socio-economic benefits:</p> <ul style="list-style-type: none"> • Avoided contamination of the environment 	<ul style="list-style-type: none"> • Minor costs of substitution (if at all) • Some minor costs for importers • Some testing cost for industry • Enforcement cost for National Enforcement Authorities

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- | | |
|---|--|
| <ul style="list-style-type: none">• Avoided cost of soil remediation, namely the top-soil layer, in case remediation would be carried out | |
|---|--|

3.3.2.5. Uncertainties in the proportionality section

SEAC considers the following elements to be the most relevant uncertainties concerning the above-mentioned baseline and consequently potentially affecting SEAC assessment of proportionality:

- Current production and associated need of substitution: in case (highly unlikely) that articles containing 2,4-DNT are currently manufactured in the EU, producers will need to switch to alternatives, and they will have to bear substitution costs. However, manufacture of articles containing 2,4-DNT in the EU is not expected to exist since theoretically production should not occur since the use of the substance must be authorised;
- Alternatives: if safer alternatives exist for each use, even if there would be substitution costs, these costs can be expected to be lower than the benefits of the proposed restriction deriving from switching to less hazardous alternatives;
- Current and future uses: in case not all existing (or potential future) uses have been identified, other than those of the SCIP, there might be some extra costs, probably only for importers. At the same time the benefits of the proposed restriction would be higher too. The same would occur if, in the EU, the volumes of articles containing 2,4-DNT already identified in the SCIP (mainly imported) would be higher. In both these cases, SEAC conclusion on proportionality would not be challenged;
- Current and future exposure: in case European consumers and professionals are currently (and potentially in the future) exposed to 2,4-DNT from articles more than expected, the benefits of the proposed restriction would be higher.

Overall, SEAC considers that, even if the different uncertainties associated to these elements might have implications on the assessment of costs and benefits, the level of such uncertainties are not of such a magnitude that would challenge SEAC's conclusions on the proportionality of the proposed restriction.

3.3.3. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter considers that the proposed restriction is practical because it is implementable, enforceable and manageable. The restriction is implementable as companies can test for a concentration limit in an article or make it a condition of the contract for purchase not to have the substance present in the article. It is assumed that for any imported articles covered in this proposal containing the substance there are alternatives. In addition, the proposed restriction gives sufficient time to the impacted supply chains to transition.

The measure is enforceable as authorities can set up efficient supervision mechanisms to monitor industry's compliance with the proposed restriction. Testing and sampling methods exist for several matrices, including water, air, and solid waste, explosive etc. The Dossier Submitter assumes that, if and where lacking today, suitable methods can be developed to fully enforce the restriction. In addition, the Dossier Submitter believes that the restriction is manageable by industry and authorities.

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RAC and SEAC conclusion(s):

Although not all aspects on the implementability and the enforceability have been fully elaborated, RAC and SEAC consider that the proposed restriction to be practical, implementable, manageable and enforceable. This is in line with the Forum advice.

Key elements underpinning the RAC and SEAC conclusion(s):

Manageability

RAC and SEAC agree with the Dossier Submitter that the restriction is manageable both by industry and National Enforcement Authorities (NEAs). For the EU industry, in fact, since there seems to be no manufacture in Europe, most probably the industry is already complying with the proposed restriction therefore there should be no issues with manageability. For the manageability by Public Authorities, see the paragraph on enforceability.

Implementability

SEAC notes that manufacturers, as well as retailers of articles, will need to seek confirmation from their suppliers about the content of 2,4-DNT in the articles they purchase. In addition, NEAs may request information about the product composition from the suppliers of the consumer products.

According to the information currently available, RAC and SEAC consider that the proposed restriction is implementable within the timeframe of 12 months for the actors involved.

This RAC's and SEAC's conclusion is based on the following elements:

- the concentration of 2,4-DNT in articles:
 - can be tested by companies all along the supply chain by using already existing analytical methods;
 - in most articles is already below the proposed limit value – hence it can be expected that the industry is able to respect such limit.
- considering that the sunset date to apply for an authorisation for 2,4-DNT was august 2015, alternative technologies, techniques and substances that are commercially available, economically feasible and most probably already used by the EU industry actors.

On this basis, since no information challenging this conclusion was received, RAC and SEAC consider that the proposed restriction appears to be implementable. More information on this point might come from the industry during the consultation on the SEAC draft opinion.

Enforceability

RAC and SEAC agree with the Dossier Submitter and the Forum that the proposed restriction is expected to be enforceable by National Enforcement Authorities and that the EU Member States can set up efficient supervision mechanisms for the proposed restriction. RAC and SEAC consider that:

- specific testing and sampling analytical methods for different matrices seem to exist for the detection and measurement of 2,4-DNT concentration in articles (and mixtures). Since substance in article (SiA) notifications have already been reported, information requirements are already foreseen under REACH and some methods are described in scientific literature for several matrices (including water, air, solid waste,

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explosives etc⁸). It is expected that suitable methods can be further developed to enforce the restriction.

- the concentration limit of 0.1 % w/w of 2,4-DNT is a pragmatic choice that can be enforced for all the articles in the scope of the restriction since it is the same already applied for SiA notification and information requirements under REACH;
- the quantification limit is assumed to be below the proposed concentration limit as no information is available to challenge this conclusion;
- inspections on placing on the market of articles are carried out on a regular basis by the National Enforcement Authorities to monitor compliance by the industry;
- 2nd hand articles benefits from a derogation also due to the difficulties that their enforcement would cause to National Enforcement Authorities.

SEAC notes that the Forum advice underlines some (minor) potential improvements concerning the enforceability of the restriction on 2,4-DNT as proposed by the Dossier Submitter. In fact, the Forum considers that the restriction proposal would benefit from additional explanation about testing and sampling methods, by underlying that:

- testing and sampling methods are not explicitly mentioned in the Annex XV Dossier;
- it is not specified if testing and sampling methods are according to ISO/CEN;
- how sampling and analysis would be conducted in some specific articles (such as airbags in cars, ammunition and other complex articles).

The Forum advice also suggests that:

- unusual proceedings might be needed for the many different matrixes of the articles in which 2,4-DNT could be found;
- enforcement actions may require liaison with Customs authorities and the identification of the imported articles that might be more suspected of containing 2,4-DNT.

RAC and SEAC note that none of the points for clarification raised by the Forum is challenging the enforceability of the restriction proposal. In line with the Forum, RAC and SEAC consider that the exemption for second-hand articles will highly contribute to the enforceability of the proposed restriction.

Based on the Forum advice, while waiting for further information that might come from the consultation on the SEAC draft opinion, RAC and SEAC conclude that the enforcement of the proposed restriction will be practicable, provided that analytical methods are available or developed.

3.3.3.1. Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter considers that the efficacy of the restriction can be monitored through the EU Safety Gate (former Rapid Alert System for Non-Food Products (RAPEX)) system at

⁸ [Hazardous Substances Data Bank \(HSDB\): 1144 - PubChem \(nih.gov\)](#)

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EU level. National control campaigns may be launched as a mean to monitor the compliance, e.g. coordinated by Forum.

RAC and SEAC conclusion(s):

RAC and SEAC conclude that compliance with the restriction appears to be monitorable in general, although additional practical advice may need to be issued to enforcement authorities for complex articles.

In particular, the SCIP database and the EU safety Gate may be used to monitor the efficacy of the restriction provided that regular national control campaigns are performed (e.g. on complex articles such as seatbelt pre-tensioners and airbags, ammunition or other complex articles).

RAC and SEAC agree that time trend monitoring could be performed with samples from the environment, from animals, plants or from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring.

Key elements underpinning the RAC and SEAC conclusion(s):

RAC and SEAC consider that the presence of articles on the EU market and any violation of the compliance to the proposed restriction could be monitored at EU level by using, for instance:

- the SCIP database or other database that were used for the preparation of the proposed restriction;
- notifications gathered via the EU Safety Gate system (the rapid alert system for dangerous non-food products, former RAPEX), provided that regular national control campaigns are performed on complex articles potentially containing 2,4-DNT;
- monitoring campaigns at national level;
- customs' controls on imported articles.

RAC and SEAC note that measuring 2,4-DNT in complex articles with the current laboratory methods might be challenging.

3.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

3.4.1. RAC

Summary of proposal:

See RAC opinion

RAC conclusion(s):

See RAC opinion

Key elements underpinning the RAC conclusion(s):

See RAC opinion

3.4.2. SEAC

Summary of proposal:

The Dossier Submitter identifies the extent of the use of the substance as the main uncertainty of the proposal. However, the identified key uncertainty cuts in both direction since if there are less/more uses, then the benefit of preventing exposure from such uses will be lower/higher but also the costs of replacing the substance by alternative substances or technologies will be lower/higher.

SEAC conclusion(s):

In the absence of contradicting information, SEAC considers the following to be the most relevant sources of uncertainty of SEAC assessment of the proposed restriction:

- Volumes of articles (mainly imported) containing 2,4-DNT present in the EU;
- Alternatives: for which uses and to which extent alternatives exist and are less hazardous than 2,4-DNT;
- Current and future production: whether currently or in the future articles containing 2,4-DNT are manufactured in the EU;
- Current uses: whether all current uses (other than those of the SCIP) have been identified during the preparation of the proposed restriction;
- Future uses: whether and to what extent, in the absence of the proposed restriction, 2,4-DNT would be used in the future;
- Current exposure: whether and to what extent European consumers and professionals are currently exposed to 2,4-DNT from articles;
- Future exposure: whether and to what extent, in the absence of the proposed restriction, European consumers and professionals will be exposed to 2,4-DNT from articles in the future.

Overall, SEAC considers that, even if the uncertainties on these elements might have implications on SEAC assessment of costs and benefits, the level of such uncertainties are not of such a magnitude that they would challenge SEAC's conclusions on the proposed restriction.

Key elements underpinning the SEAC conclusion(s):

The level of potential uncertainties associated to each of above-mentioned elements of the current situation and on how the situation would evolve without any regulatory measures, as well as their socio-economic implications under different scenarios are described below.

Current and future production

SEAC notes that the Dossier Submitter assumes that currently articles containing 2,4-DNT are not produced in the EU. The assumption on absence of current production is supported by the fact that no application for authorisation were submitted for 2,4-DNT before the sunset date. However, it can't be completely excluded that some unauthorised production is taking place in the EU, but SEAC considers this possibility as highly unlikely.

Moreover, it can't be completely excluded that, in the absence of the proposed restriction, there might be some future production of articles containing 2,4-DNT in the EU.

Current and future uses

SEAC notes that, based on the information from the SCIP database, currently some types of articles containing 2,4-DNT are used in the EEA. Furthermore, given the existence of some notifications and self-classifications, it cannot be completely excluded that some other uses

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at volumes below one ton per year have not been missed during the preparation of this restriction proposal. This possibility could imply, on one hand, costs for the industry to substitute 2,4-DNT and, on the other hand, higher benefits of the proposed restriction. The stakeholder consultations might provide further information.

The same can be said for potential future uses that would be avoided by the proposed restriction.

Taking into account the available information gathered during the stakeholder consultation carried out for the preparation of the Background Document, SEAC considers that the assumptions made by the Dossier Submitter on uses seem to be associated to a low level of uncertainty. Therefore, SEAC concludes that such uncertainty is of small magnitude and does not affect SEAC conclusions.

Current and future exposure

SEAC notes that the Dossier Submitter assumes that European consumers and professionals can potentially be exposed from articles containing 2,4-DNT. SEAC considers that, if ever the current or potential future level of exposures to 2,4-DNT of EU consumers and professionals are higher, the benefits of the proposed restriction would be higher too.

Identity, costs and risks of the alternative substances

If unable to use 2,4-DNT due to the proposed restriction, some companies might have to shift to 2,4-DNT-free alternatives. SEAC notes that, in this case, the proposed restriction would imply benefits to human health and the environment only if alternative substitutes are safer than 2,4-DNT, which seems to be the case.

On the side of costs, SEAC notes that the magnitude of costs of the proposed restriction would depend on the extent to which the affected industry (if any) would switch to more expensive alternative techniques, technologies or substances instead of 2,4-DNT.

Concentration of 2,4-DNT in imported articles

The information in the SCIP database, even in the absence of Safety Gate notifications, suggests that, at present, there is some import of articles containing 2,4-DNT. SEAC notes that the concentration of 2,4-DNT in articles is not known but expected to be low.

In general, SEAC notes that, if the concentration of 2,4-DNT in articles were higher than expected, the concentration limit value of the proposed restriction would be able to reduce risk even more.

Cause and effect relationship between exposure to 2,4-DNT and health effects

Only a qualitative risk assessment from the exposure to 2,4-DNT was carried out by the Dossier Submitter. While this is a point to keep in mind, SEAC considers that it is not of a particular concern in this case.

4. REFERENCES

See Background Document