

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/RES-O-000007148-71-01/F

9 September 2022

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

2 June 2022

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

9 September 2022

ECHA/SEAC/RES-O-000007148-71-01/F

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 adopted by RAC and 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 **9 September 2022**.

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation

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

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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

RAC has formulated its opinion on the proposed restriction based on an evaluation of the identified risk and to the identified options to reduce that risk. The assessment was based on the Annex XV report and information submitted by interested parties as well as other available information as recorded in the Background Document.

RAC 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 risk in terms of the effectiveness in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion.

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.

In addition, SEAC concluded that a 36-month derogation period for uses of 2,4-DNT in Micro Gas Generators (MGGs) and spare parts in the car industry is justified.

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of the proposal

The proposed restriction prevents the placing on the market (including import) and use of articles containing 2,4-DNT where these present a risk to human health. It targets both consumer and professional users.

2,4-dinitrotoluene (2,4-DNT) is classified under Regulation (EC) No 1272/2008 (CLP) as a carcinogen category 1B, H350 (may cause cancer)¹. The substance was included in the candidate list for authorisation (13/01/2010; ED/68/2009²) 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 August 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 risk that is not adequately controlled in articles. Whilst there is no information available on current manufacture, import or export of 2,4-DNT in the EU, and the substance is not registered under REACH, the restriction would also prevent any potential future uses of the substance in articles.

2,4-DNT is an isomer of the multi-constituent substance dinitrotoluene (DNT; EC: 246-836-1). Two of the isomers of DNT (2,4-DNT and 2,6-DNT), make up 95 %, 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 (75-80 % of 2,4-DNT) is in the production of toluene diisocyanate. DNT containing 50-55 % 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.

The Dossier Submitter identified current or previous uses of 2,4-DNT in various articles including:

- refractories,
- automotive airbags,
- seat belt pre-tensioners,
- plastic bottles for industrial sample taking,
- propellants for military and civil small-arms ammunitions,
- gelatinising-plasticising agents in explosive compositions,
- 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 article³.

Two substance in articles (SiA) notifications have been made under Article 7(2) of REACH for 2,4-DNT; for the use as a 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. Furthermore, the US Environmental Protection Agency lists possible uses of 2,4-DNT in sports equipment and in outdoor toys such as sandboxes. However, no details of the import, use or manufacture of these articles are available.

A search of the SCIP (Substances of Concern In articles and complex Products) database

¹ <https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/6510>.

² Inclusion of substances of very high concern in the candidate list, Decision by the Executive Director

³ See [Guidance on requirements for substances in articles](#) (ECHA 2017).

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identified articles in the EU containing 2,4-DNT, 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, the carcinogenicity of DNT has been studied in ammunition production facilities and in copper mining. These studies found an association between cumulative DNT exposure and renal cell cancer. An association between dermal, but also inhalation, DNT exposure and renal cancer has been established, particularly in miners. Exposure relates predominantly to 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 locations where they are produced or used. The restriction proposal targets consumer and professional uses of 2,4-DNT in articles where release and exposure cannot be excluded and risk management measures are difficult to implement. For example, 2,4-DNT is used as a plasticiser in sampling bottles used at industrial settings. The 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 2,4-DNT in civilian small arms ammunition (such as that used for hunting and sports shooting). Not all 2,4-DNT present in ammunition is consumed during use resulting in inhalation or dermal exposure. Two other examples of consumer uses with exposure potential are in vehicle safety systems i.e., seat belt pretensioners (where an explosive charge causes a gas generator to produce pressure, which then acts on a mechanical linkage to tighten the seat belt) and in air bags (where deployment releases gas in a similar manner as in pretensioners). 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 emergency services. From these uses, both inhalation and dermal exposure may result.

2,4-DNT is considered a non-threshold substance for which no Derived No Effect Level can be derived. Therefore, the Dossier Submitter concluded 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. However, this does not apply to imported articles, and it is likely that articles containing 2,4-DNT are produced outside the Union and imported.

An analysis of risk management options (RMOs) was conducted to identify the most appropriate measure to address the risks identified. The Dossier Submitter concluded that action is required on a Union-wide level to reduce risks for consumers as well as for professional and industrial workers 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 (e.g., seat belt tensioners, plastic sample bottles, ammunition, refractory materials and others). Specific derogations are proposed. The restriction is assumed to impose very low societal costs as alternatives to 2,4-DNT are assumed to exist for the identified uses. The Dossier Submitter reasons that if this was not the case (i) more notifications for uses in articles would have been submitted and (ii) more Applications for Authorisation for continuing use of 2,4-DNT would have been made.

As there is no known EU production of articles using the substance (as these would have been subject to Applications for Authorisation), there is no need to transition to alternatives or to deplete stocks. However, if there are any imported articles containing 2,4-DNT, time may be needed for importers to transition to alternative articles. The Dossier Submitter proposed that 12 months would be a sufficiently long transition time. Moreover, the Dossier Submitter

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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 identified risk.

Standardised laboratory methods for measuring 2,4-DNT in articles (and environmental samples) exist, suggesting that the restriction is both practical and monitorable. The presence of articles on the market that contain 2,4-DNT could be monitored using the SCIP database. 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

2.2.1. Summary of RAC opinion

The scope of the proposed restriction is clear and sufficiently justified.

RAC notes that 2,4-DNT is included on Annex XIV of REACH (Commission Regulation (EU) No 143/2011), that no applications for authorisation were submitted and that the restriction proposal had been prepared based on Article 69(2) of the REACH Regulation. RAC supports the Dossier Submitter's conclusion that there are uses of 2,4-DNT in articles after the sunset date which may lead to a risk that is not adequately controlled.

Based on the conclusions of ECHA's Member State Committee, 2,4-DNT is a non-threshold carcinogen and is an SVHC. As a non-threshold carcinogen and suspected mutagen, a quantitative risk characterisation (i.e. against a DNEL value) was not considered appropriate by the Dossier Submitter. A qualitative approach to risk assessment and a 'minimisation of exposure' approach to risk management was therefore carried out by the Dossier Submitter. During the development of the RAC opinion it became clear that the substance is still used in the EU in articles, such as automotive pyrotechnic devices (including seat belt pretensioners), electronic equipment, explosives and ammunition. Other uses have been identified in the past.

The extent of current use and the presence of imported articles on the EU market is uncertain but potential import of articles on the EU market may lead to a risk to human health. Consequently, there is a risk which needs to be addressed. RAC agreed that restriction option two (RO2), as proposed by the Dossier Submitter, is an appropriate EU wide measure to reduce the risk for consumers and professionals from exposure to 2,4-DNT. However, from a risk minimisation perspective, RAC noted that RO1, which was a restriction on all uses irrespective of the setting, i.e., including uses at industrial installations and civilian uses of explosives, would increase the risk reduction capacity compared with RO2. RAC noted that the Dossier Submitter had not undertaken a risk assessment for uses of explosives at industrial installations assuming that existing risk management measures were sufficient.

RAC concludes in line with the Dossier Submitter that the exemption proposed for uses in toys, medical devices, and food contact materials is sufficiently justified in order to avoid double regulation. The exemption proposed for the second-hand market acknowledges the practical difficulties in enforcing a restriction on the second-hand market.

RAC highlighted several aspects of the proposed scope that could be misunderstood, specifically related to the definition of explosives and professional uses and suggested alternative definitions. Uses by workers in industrial installations and non-military uses of

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explosives is not within the scope of the proposed restriction as the Dossier Submitter concluded that appropriate and effective OC and RMM can be implemented for these uses, e.g. identified by the OSH legislation. However, the Dossier Submitter did not assess whether such OCs and RMMs are indeed in place. Based on the information available in the Background Document, RAC could not evaluate whether the existing OCs and RMMs in industrial installations and for non-military uses of explosives were sufficient and could, therefore, not rule out the potential for 2,4-DNT to pose a risk in these uses. Additional assessment would be necessary to confirm that risks were controlled in these uses.

The proposed concentration limit and transitional time are considered to be effective to prevent potential risk to humans.

Alternatives appear to be available. However, due to the lack of data and information, it was not possible for RAC to verify the risk of potential alternatives in all sectors.

RAC agreed that the proposed restriction is practical (both by industry and Member States) and monitorable. The restriction is expected to be enforceable and there are existing analytical methods, although further work on them is needed.

Two comments were received from industry trade associations (automotive and aerospace/defence) in the consultation on the Annex XV report and one from a Member State. These comments included requests for derogations for automotive pyrotechnic articles (e.g. bonnet actuators and seat-belt pre-tensioners) and to support the existing derogation under REACH article 2(3) for explosives and ammunition for military use. RAC concludes in line with the Dossier Submitter that an exemption for military uses is justified but that the exemption for the use of 2,4-DNT in pyrotechnic articles such as seat-belt pretensioners or bonnet actuators in vehicles is not justified from a risk perspective. The comment from the Member State raised concerns about limiting the scope to professional workers and consumers.

The uncertainties do not change the overall conclusion that there is a risk from the presence of 2,4-DNT in articles that is not adequately controlled.

RAC recommends that **the inclusion of the multi-constituent substance DNT and its other isomers (e.g. 2,6-DNT) in the scope of the restriction would increase its risk reduction capacity**, noting that this would require further scientific assessment.

2.2.2. Summary of SEAC opinion

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 concluded that any necessary action to address the risks associated with 2,4-DNT should 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 appropriate as a restriction under REACH because of limitations in their scope and effectiveness.

Given the limited 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

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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 notes that the restriction might have been more impactful if the scope had also included industrial uses .

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 concludes that these derogations are justified.

In the consultation of the SEAC draft opinion, new information was provided on the need for a 36-month derogation period for uses of 2,4-DNT in Micro Gas Generators (MGGs) and an unlimited derogation for legacy uses of 2,4-DNT in the car industry (i.e., for spare parts) to avoid disproportionate impacts. On the basis of the information supporting these derogation requests, SEAC finds that the justification for a time-limited derogation for MGGs appears to be justified. However, an unlimited derogation for uses of 2,4-DNT in spare parts was not justified on the basis of the information provided. Instead, SEAC considers that a 36-month derogation period also for this use will minimise any major economic impact.

Finally, SEAC concluded that the proposed restrictions would be practical 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

Summary of proposal:

The scope of the proposed restriction covers articles placed on the EU market, or used, that contain 2,4-dinitrotoluene (2,4-DNT). 2,4-DNT is classified as carcinogen in category 1B, which is the basis of the identification of the substance as Substance of Very High Concern (SVHC). 2,4-DNT is a non-threshold carcinogen. The substance is an isomer of a multi-constituent substance DNT (EC no. 246-836-1) that has six isomers. The two major forms being 2,4-DNT and 2,6-DNT. 2,6-DNT is also classified as Carc. 1B and Muta. 2 and is often present in smaller quantities than 2,4-DNT. The restriction proposal does not cover other isomers such as 2,6-DNT but the Dossier Submitter considers that if articles contain more than 0.1% of 2,4-DNT then the presence of other isomers will also be reduced as a result of the proposed restriction.

The proposed concentration limit of 0.1 % (w/w) aims to prevent the intentional addition of 2,4-DNT in articles in the EU and ensure that imported articles (unknown quantities in the EU market) meet the same standards. The limit is the same as for the notification of substance in articles (Art. 7(2)) under REACH.

The restriction proposal targets consumer and professional uses in articles (where release of 2,4-DNT cannot be excluded and risk management measures (RMM) are difficult to implement). The Dossier Submitter clarified that professional use is defined as in the REACH legal text, which differentiates between industrial and professional use in definitions 13, 25 and 35 as well as in section 6 of Annex VI and entries 19, 31 and 39 of Annex XVII.

The Dossier Submitter further clarified that professional workers that use substances outside of a controlled workplace setting could be considered similar to consumers in their capacity to implement risk management measures (i.e., to have limited capacity). Professional uses are carried out in the context of commercial activities and are assumed to take place by multiple actors each at small scale e.g., local garage, small cleaning businesses. Professional workers are more likely to have limited knowledge of the risks of substances and difficulties in ensuring appropriate risk management and preventing the exposure of consumers for whom they are providing a service. It is unlikely that an occupational exposure limit (OEL) would be helpful as the only possible RMM is likely to be personal protective equipment/respiratory protective equipment (PPE/RPE) or mobile extraction, either of which are not considered particularly efficient in reducing exposure. Such RMMs would also not prevent exposure to the environment. In addition, self-employed people are also not covered. Therefore, the scope of the restriction assessed by the Dossier Submitter is related to consumer and professional uses.

Thus, the restriction proposal does not cover uses by workers inside industrial installations.

Two specific exemptions are proposed: ammunition intended for use, in accordance with national law, by the armed forces or the police and explosives as it is assumed by the Dossier Submitter that these uses will be well controlled.

Since the term explosive may encompass different types of articles, the Dossier Submitter clarified that, for the purposes of this restriction, the term explosive means, by analogy to 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, "*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*".

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Moreover, articles covered by regulation on medical devices, toys and food contact materials are proposed to be exempted to avoid double regulation.

A transitional period of 12 months after entry into force is proposed. There are no expected existing stocks except for the production of military ammunition and the transitional period is proposed to allow importers to transition to different articles not containing 2,4-DNT.

RAC conclusion(s):

- RAC concludes that the purpose of the restriction is clear.
- RAC agrees that limitation of the substance scope to 2,4-DNT is justified as this is the substance identified as an SVHC and listed on Annex XIV of REACH. Nevertheless, given the findings on the use of 2,4-DNT in the EU, RAC notes that the risk reduction capacity of the restriction may in the future be improved by the expansion of the scope to cover the multi-constituent substance DNT and all its isomers.
- RAC agrees with the proposed concentration limit of 0.1.
- RAC agrees that the targeting of professional users and the general population is appropriate to address the risks to human health outside industrial installations. RAC agrees that potential exposure from the use of the substance in articles inside industrial installations, where RMM can be implemented, can be minimised. However, RAC notes that, whilst these uses would be within the scope of OSH legislation on carcinogens, the Dossier Submitter did not assess whether appropriate OCs and RMMs are implemented.
- RAC considered that the definition of explosive proposed (based on UN recommendation class 1) is not sufficient to define the explosives that should be excluded from the scope of the restriction. Specifically, it should be made clear that explosive are those defined in Directive 2014/28/EU and that pyrotechnic articles (which should not be excluded from the scope of the restriction) are those defined in Articles 3 (1) to (4) in Directive 2013/29/EU.
- RAC concludes that civilian use of explosives may lead to uncontrolled exposure of workers when handling the explosive and to fumes containing the substance. RAC notes that no risk assessment on explosives was performed by the Dossier Submitter.

Key elements underpinning the RAC conclusion:

Scope

The scope of the proposed restriction is limited to 2,4-DNT, which is on Annex XIV of REACH and whose sunset date has passed. The Dossier Submitter concludes that the risks arising from the use of 2,4-DNT in articles is not adequately controlled. The restriction proposal ban the placing on the market (including import) and use of articles containing 2,4-DNT where these uses are concluded to present a risk to human health .

The concentration limit of 0.1 % w/w for 2,4-DNT in articles, proposed by the Dossier Submitter, based on the concentration limit applied for substance in Article (SiA) notification and information requirements under REACH is considered to be appropriate.

The restriction proposal covers both the placing on the market and 'use' of the substance in articles as defined in the REACH regulation. Use means "any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation".

2,4-DNT has been identified as an SVHC on the basis of its carcinogenic properties. So, the targeting of the risk assessment to human health concerns is justified due to the potential for

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dermal, inhalation or oral exposure arising in professional and consumer exposure scenarios.

2,4-DNT is an isomer of the multi-constituent substance DNT (CAS no. 246-83-1). Two of the isomers of DNT: 2,4-DNT and 2,6-DNT make up 95% of DNT. Isomers of 2,4-DNT such as 2,6-DNT share common physicochemical properties and carcinogenic potential and would usually occur together with 2,4-DNT. 2,6-DNT has been considered to be approximately 10 times more potent than 2,4-DNT as a hepatocarcinogen. It has even been suggested that 2,4-DNT is a promoter and that 2,6-DNT is a complete hepatocarcinogen (ACGIH, 2001). RAC agrees that potential cumulative risk to the various isomers could be relevant as at least 2,4-DNT and 2,6-DNT share common carcinogenic and mutagenic properties. The exclusion of DNT from the scope of the restriction (which is targeted only to the presence of 2,4-DNT) may lead to an underestimation of risk from articles.

The scope of the restriction assessed by the Dossier Submitter is only related to consumer and professional uses. The restriction proposal does not cover the use of 2,4-DNT in articles used in industrial installations where the Dossier Submitter assumed that release and exposure can be excluded or where RMM can be implemented.

The Dossier Submitter noted that the REACH legal text differentiates between industrial and professional use in definitions 13, 25 and 35, as well as section 6 of Annex VI. In Annex XVII of the REACH regulation, the terms "industrial installation" and activity of a "professional outside industrial installations" are used. However, as noted in Appendix R.12.3 of the ECHA guidance document R.12, there is currently no definitive way to differentiate between the two categories of use. The current R.12 IR/CSR guidance notes that the terms "*industrial*" and "*professional*" are used to:

- To define the level of occupational health and safety management systems applied in companies. It is recommended to understand the concept "professional" as a characteristic to distinguish between use: i) at industrial sites and ii) uses outside industrial sites (but not consumers or general public). This will lead to different life cycle stages in terms of use description."

R.12 Guidance also highlights that some cases could potentially be considered as either industrial or professional uses. As an example, car 'repair and finishing', that is relevant in the case of 2,4-DNT, is identified as a borderline case between industrial and professional use.

In addition, RAC notes that the term "industrial site" may be preferred to the term "industrial installation" as industrial sites may not contain industrial installations.

RAC notes that workers at industrial settings are covered by EU OSH legislation (i.e., Chemical Agents Directive and the Carcinogens, Mutagens or Reprotoxic Substances at Work Directive). In addition, RAC agrees with the Dossier Submitter that the risk can be minimised at industrial sites where OCs and RMMs can be implemented. However, the Dossier Submitter did not assess whether such OCs and RMMs are indeed in place. There is one active registrant for the use of DNT in the formulation of mixtures as a plasticiser in explosives. However, a threshold-based DNEL was derived in the CSR, which may not be appropriate to ensure that the OCs and RMMs recommended or implemented are sufficient to control the risks to workers when handling explosive articles containing 2,4-DNT. There is also no information in the CSR on potential exposure assessment and risk characterisation. In addition, a response in the consultation (#3541) indicated that there are several defence exemptions that currently allow for the continued use of 2,4-DNT in the production of propellants for (military) ammunition. However, RAC notes that no risk assessment for these uses was made by the Dossier Submitter. The effectiveness, practicality (including enforceability) of the restriction would be further increased by including all uses in the scope of the restriction (restriction option 1 in the Background Document). A comment from a Member State supporting a restriction on the use of 2,4-DNT in articles at industrial settings was submitted in the consultation on the

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Annex XV report.

An exemption is proposed for explosive articles. The definition of "explosive" proposed by the Dossier Submitter is based on the definition in 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.

In this Directive explosives are defined as the materials and articles considered to be explosives in the UN recommendations on the transport of dangerous goods and falling within class 1 of those recommendations. The UN recommendation (Volume I, 21th revised edition, 2019) states that class 1 comprises:

(a) Explosive substances (a substance which is not itself an explosive but which can form an explosive atmosphere of gas, vapour or dust is not included in Class 1), except those that are too dangerous to transport or those where the predominant hazard is appropriate to another class;

(b) Explosive articles, except devices containing explosive substances in such quantity or of such a character that their inadvertent or accidental ignition or initiation during transport shall not cause any effect external to the device either by projection, fire, smoke, heat or loud noise (see 2.1.3.6); and

(c) Substances and articles not mentioned under (a) and (b) which are manufactured with a view to producing a practical explosive or pyrotechnic effect. Therefore, pyrotechnic substance are also included in this class.

RAC notes that in Directive 2014/28/EU, it is specifically mentioned that "*certain articles were identified following the United Nations recommendations on the transport of dangerous goods as being pyrotechnic articles or ammunition, thus falling outside the scope of this Directive*". RAC recommends that it should be made clear in the conditions of the restriction that articles considered to be explosives are those defined in Directive 2014/28/EU to avoid potential misunderstanding that pyrotechnic articles would not be intended to be within the scope of the restriction. In addition, RAC recommends that the definition of pyrotechnic articles is included in the conditions of the restriction. Pyrotechnic articles are those defined in Directive 2013/29/EU.

Indeed, one of the articles containing 2,4-DNT identified by the Dossier Submitter as within the scope of the restriction were seat-belt pretensioners. According to the UN recommendations on transport of dangerous goods, the hazard divisions/class of the seat-belt pretensioners are 1.4G and class 9 corresponding to UN number 0503 and 3268. Sub-class 1.4 G from class 1 is defined as a pyrotechnic substance, or article containing both an explosive substance and an illuminating, incendiary, tear or smoke-producing substance (other than a water-activated article or one containing white phosphorus, phosphides, a pyrophoric substance, a flammable liquid or gel, or hypergolic liquids). Similarly, ammunition is identified in class 1 of the UN recommendation. Therefore, the definition of explosive as proposed by the Dossier Submitter may be too broad and may include articles intended to be covered by this restriction proposal.

The proposal is to exempt explosive articles from the scope of the restriction. 2,4-DNT is not classified as an explosive but may be used in explosive articles. The substance may also be an impurity in 2,4,6-trinitrotoluene (TNT).

Non-military exposure to explosive articles containing 2,4-DNT has been previously reported in miners that manipulated explosives with bare hands leading to dermal exposure. In addition, miners were exposed to inhalation of fumes after explosion. Brüning *et al.* (1999) reported cancer in a group of miners. In the document prepared for the recommendation for the inclusion of 2,4-DNT in Annex XIV, ECHA (2010) highlighted that the use of the substance in explosives is of concern and fulfilled the criteria for wide dispersive use. It was further pointed out that the end use of explosives in mines, quarries and construction sites is expected to occur at a high number of sites with possibly uncontrolled exposure of workers when

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handling the explosives and (after detonation, particularly in mines and subterranean construction sites) to fumes containing residues of the substance. Potential exposure to end users in quarries and construction sites may still occur in a number of sites.

According to the Dossier Submitter, there are existing measures applying to the manufacture, storage or use of explosives:

- Directive 2014/28/EU⁴ on making available on the market and supervision of explosives for civil uses. This Directive requires that each explosive must be designed, manufactured and supplied in such a way as to present 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. In addition, propellants must be stabilised against decomposition when necessary. However, RAC notes that there is no specific requirements for hazardous properties, risk assessment or measures foreseen to protect human health in this directive.
- Under the Waste Framework Directive (2008/98/EC), wastes containing 2,4-DNT would be regarded as hazardous waste.
- Under the Industrial Emission Directive (2010/75/EU), a substance is regarded as 'hazardous' as long as it is classified. Production of explosives is covered in Annex I and so all the appropriate preventive measures are taken against pollution and the best available techniques are applied, for example. Such sites must also be permitted.
- The SEVESO Directive (2012/18/EU) lays down rules for the prevention of major-accident hazards involving dangerous substances. The Directive applies to establishments (whole location under the control of an operator where dangerous substances are present in one or more installations, including common or related infrastructures or activities). The classification of TNT as explosive category 1.1 (P1a explosives) triggers lower tier requirements at 10 tonnes and upper tier requirements at 50 tonnes related to major accident hazards.
- The worker protection measures (CAD and CMRD) apply to protect workers using 2,4-DNT and TNT. Several national OELs also are in force.

Overall, there are specific provisions for the placing on the market of explosives. In addition, at national level, specific technical agreements and risk assessment may be requested for handling and use of explosive articles. However, no assessment of the effectiveness of existing measures at national level was provided by the Dossier Submitter and it is unknown whether such measures are in place in all EU Member States. As there are no specific EU measures related to chemical safety hazard for the use of explosives, the general worker protection provisions will apply for the use of 2,4-DNT in explosives. In addition, RAC notes that any OEL in force at national level may not necessarily be health-based and may not be sufficiently protective against the non-threshold carcinogenic properties of the substance.

Risk management measures may be difficult to implement in *e.g.* mines, quarries and construction sites. Although RMM may be implemented before the detonation, RAC notes that there is no information in the Background Document justifying that exposure is well controlled after the explosion. Therefore, the inclusion of explosive articles for civilian uses where RMM are not sufficient to address the human health risks to workers handling explosives is discussed further in Section 3.3 below and in the uncertainty analysis section.

Other derogations are discussed in Section 3.3.

⁴ DIRECTIVE 2014/28/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 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).

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

3.1.2. Information on hazard(s)

Summary of proposal:

2,4-DNT is classified as Carc. 1B (H350), which was the basis for its identification as a SVHC. The Dossier Submitter referred to the available European Union Risk Assessment Report (EU RAR, 2008) for the toxicological profile of 2,4-DNT. In addition, some recent epidemiological studies were summarised in the Background Document. The Dossier Submitter assumed that the carcinogenic potential of the substance is non-threshold based as the substance is also mutagenic. In view of that, the Dossier Submitter proposed a qualitative risk assessment.

Nevertheless, quantitative risk assessment was performed by the Dossier Submitter in three illustrative examples. The Dossier Submitter used the current lowest national OEL (8-hour) in Europe (as available on Gestis database) of 0.15 mg/m³ and the long-term derived no effect level (DNEL) of 0.009 mg/m³ for the general population as proposed in the REACH registration dossier of DNT. The Dossier Submitter had no information on how the OEL and the DNEL were derived and the basis of the derived values was not provided.

RAC conclusion(s):

- RAC notes that 2,4-DNT has been identified as a SVHC based on its carcinogenic properties.
- A qualitative approach to risk assessment and minimisation of exposure is an appropriate risk management objective, as 2,4 DNT is a non-threshold carcinogen. Genotoxicity is a likely underlying mode of action and no threshold could be identified.
- The illustrative examples provided by the Dossier Submitter to show, in a quantitative way a potential risk, were based on an OEL for occupational exposure and a DNEL for the general population. RAC notes that the OEL is based on non-neoplastic findings, which most likely do not cover the carcinogenic hazard of 2,4-DNT. Furthermore, it is not clear how the DNEL for the general population was derived. Therefore, RAC considers that the Dossier Submitter's quantitative approach is only useful as an illustration to support the need for a restriction but not as an acceptable approach for risk assessment.

Key elements underpinning the RAC conclusion(s):

- a. Non-threshold based approach

2,4-DNT is classified in Annex I of the CLP regulation for human health hazards as Carc. 1B (H350), Muta. 2 (H341) and Repr. 2 (H361f), STOT RE 2 (H373) and Acute Tox. 3 (H301, H311 and H331). The Member State Committee concluded that 2,4-DNT was an SVHC based on its carcinogenic properties. On this basis, the substance was included in the candidate list for Authorisation and in Annex XIV of REACH based on its carcinogenic properties (Art 57(a)).

Toxicokinetics – absorption

According to the EU RAR for 2,4-DNT, the oral and inhalation absorption of 2,4-DNT was considered to be 100% (EU RAR, 2008).

According to the Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profile for dinitrotoluenes, although the low vapour pressure of DNT isomers makes inhalation of vapours unlikely, it can occur when contaminated particulate material is in the air (ATSDR, 2016).

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Dermal absorption is also a potentially significant route of 2,4-DNT exposure as shown in worker occupational exposure studies. Woolen *et al.* (1985) suggested that skin contact may be the most important exposure pathway during DNT manufacturing in industrial settings, resulting in absorption of significant quantities of the substance. In addition, in an *in vitro* study on excised pig skin, 2,4-DNT was absorbed at 36% in an acetone solution (Reifenrah *et al.*, 2002).

Carcinogenicity

The carcinogenicity of DNTs including 2,4-DNT has been reviewed in several reports (EU RAR, 2008; ACGIH, 2001; IARC monograph, 1996 and ATSDR, 2016).

- Animal data

As described in the EU RAR, there are few studies available in rats and mice adequate for hazard identification and risk assessment. Two studies were carried out under similar methodology as OECD TG 451 (NCI, 1978) and two other published chronic studies were considered adequate (Ellis *et al.*, 1985; Hong *et al.*, 1985). There are some limits in the Fischer F344 rat and mice studies (NCI, 1978) as the study duration was only 18-months over a 24-month observation period and only two dose levels were used. In males, a dose-related statistically significant increase in the incidence of fibromas of skin/subcutaneous tissue was observed (0 in controls, 7/49 at 4.7 mg/kg and 13/40 at 11.8 mg/kg). In addition, a non-statistically significant increase in squamous-cell papillomas, hepatocellular carcinoma, basal-cell carcinoma, hepatocellular carcinoma (3/49 at 4.7 mg/kg and 3/48 at 11.8 mg/kg vs 0 in controls), fibrosarcomas and lipomas (subcutaneous tissue or skin) were noted (1 to 3 out of 49 animals in exposed groups). In females, a dose-related statistically significant increase in mammary gland tumours were noted (13/71 pooled controls, 12/49 at 6.3 mg/kg and 23/50 at 15.7 mg/kg). In mice, treatment groups and controls did not differ significantly in the incidence of the primary tumours. In addition, in a chronic published study (Ellis *et al.*, 1985; Hong *et al.*, 1985), the same tumour profile was found after 1-year exposure (skin/subcutaneous tissue fibromas in males, mammary gland fibroadenomas in females and hepatocarcinomas in both sexes). Effects were seen from 5.1 mg/kg onward in female rats and 34 mg/kg onward in male rats. In mice, an increase in renal benign and malignant tumours were observed in male mice in groups exposed 1 year at 13.3 and 96.9 mg/kg

In the EU RAR, a T25 of 14.39 mg/kg was calculated for male hepatocarcinoma from the carcinogenicity study in rats and considered as the critical value for carcinogenicity risk characterisation. On this basis the EU RAR concluded that the activity of 2,4-DNT was in the medium potency range ($1 < T25 < 100$ mg/kg). Nevertheless, RAC notes the additional factors increasing the concern: multi-site carcinogen in both sexes and both species, non-threshold genotoxic carcinogen, short latency times (e.g. tumours observed following 1-year exposure).

Although most of the available data are available by oral route of exposure, similar hazard is expected by inhalation or dermal route of exposure.

- Human data

The human data can be used as supportive information for observations in animals regarding identification of target organs and to support the carcinogenic potential of the substance. One study in mine workers reported an association between DNT exposure and kidney cancer. Other studies reported associations between DNT exposure and bladder cancers in workers. However, the available studies did not report dose-response data for 2,4-DNT. Genotoxicity is likely the underlying MoA.

Overall, RAC notes that the substance has been identified as an SVHC based on its carcinogenic properties and that no threshold could be identified. On this basis, RAC agrees with the qualitative approach used by the Dossier Submitter and the aim to minimise any

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exposure to human.

b. Threshold-based approach

Existing occupational exposure limits for 2,4-DNT

The Dossier Submitter's proposal was to use the lowest OEL value in Europe as available in the Gestis database of 0.15 mg/m³. The basis of this exposure limit is not provided in the restriction dossier.

The table below gives an overview of the OELs available in the Gestis database (provided in Annex XV report) or in other international reports (identified by RAC).

Table 2: Overview of OEL derivation

	8h-TWA	References
USA (ACGIH)	0.2 mg/m ³	ACGIH, 2001
Finland	0.2 mg/m ³	Gestis database
Spain, Sweden, Denmark, Singapore, Norway	0.15 mg/m ³	Gestis database
Latvia	1 mg/m ³	Gestis database
Australia (SWA)	0.5 µg/m ³	Safe work Australia, 2019

According to ACGIH (2001), the value of 0.15 mg/m³ was intended to minimise the potential for low-grade anemia and neuromuscular, hepatic, renal and reproductive effects. They retained 0.2 mg/m³ as a rounded value as this would not change the degree of protection of workers compare to 0.15 mg/m³.

In the registration dossier of DNT, the DNEL for long-term effect by inhalation was set at 0.3 mg/m³.

In 2019, Safe work Australia recommended a TWA of 0.5 µg/m³ (rounded value) for DNT to minimise the potential for cancer in exposed workers. The value was derived at a minimal cancer risk level by applying an oral slope factor (6.8 x 10⁻¹ per (mg/kg)/day). The oral slope factor is based on the significant increases in the incidence of malignant tumour types at multiple sites in rats (two strains) and malignant renal tumours in male mice. The report notes that the recommended value is likely to be below the current limit of detection for standard sampling and analysis techniques, highlighted the need to minimise exposure.

In the EU RAR, a T25 approach was used to calculate life-time cancer risk for workers. The human equivalent of T25 was calculated to be 1.34 mg/kg based on male hepatocarcinoma from the carcinogenicity study in rats (critical value for carcinogenicity risk characterisation). A supralinear dose-relationship was considered and a lifetime cancer risk for humans exposed via the environment was calculated.

As the OEL may not sufficiently cover the carcinogenic potential of the substance, a Derived minimal effect level (DMEL) was calculated based on the T25 of 14.34 mg/kg derived in the EU RAR, 2008. The methodology used in the ECHA REACH guidance document R8 was used. A corrected T25 of 70.1 mg/m³ is obtained (14.34*1/0.384*6.7/10*2.8). Using the large assessment factor approach a DMEL of 22 µg/m³ would be calculated (=70.1/3,125), which is 147 times lower than the DNEL used by the Dossier Submitter. RAC notes that this DMEL should not be considered as a safe level but indicates that the OEL will underestimate the risk.

Overall, the use of 0.15 mg/m³ by the Dossier Submitter is useful tool to support the current restriction proposal. However, RAC notes that the use of an OEL rather than a DMEL, not

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based on cancer, may underestimate the risk.

Existing general population exposure limit for 2,4-DNT

For consumer risk assessment, the long-term DNEL from the DNT registration was used by the Dossier Submitter, who noted that the basis of the DNEL derivation is unknown. RAC notes that according to the chemical safety report, the starting point for the long-term DNEL derivation for general population was an oral repeated dose toxicity study. The point of departure may have been the LOAEC of 3.5 mg/kg in the combined repeated dose and carcinogenicity toxicity study in rat based on liver weight and histopathological findings. Nevertheless, it is not specified how a DNEL of 0.009 mg/m³ was obtained, as use of default assessment factors (ECHA guidance R8) would not result in this value. In addition, in the registrant's CSR for DNT, a DNEL for the dermal route was derived at 0.01 mg/kg bw and an oral DNEL for long-term exposure at 0.005 mg/kg.

Nevertheless, considering default assessment factor (REACH guidance document R8) and the derived OEL for workers of 0.15 mg/m³, the proposed value of 0.009 mg/m³ seems rather conservative. Indeed, in a practical approach deriving the consumer DNEL from the worker DNEL, a default DNEL of 0.04 mg/m³ would be obtained (Consumer DNEL inhalation= worker DNEL inhalation/2 (factor 5 to 10) and *10/20 for respiratory volume correction from worker to general population respiratory volume).

The US EPA recommendations to define a safe lifetime daily maximum oral dose of 0.002 mg/kg per day for 2,4-DNT (drinking water standard and Health advisories table, 2012), which is only slightly below the oral DNEL proposed by the Dossier Submitter.

Nevertheless, as for the OEL, the use of a threshold-based DNEL for the general population may not cover the carcinogenic risk potential of 2,4-DNT.

As the long-term DNEL was not based on carcinogenicity and may not sufficiently cover the carcinogenic potential of the substance, a DMEL was calculated based on the T25 of 14.34 mg/kg derived in the EU RAR, 2008. The methodology used in the ECHA REACH guidance document R8 was used. Using the large assessment factor approach a DMEL of 0.57 µg/m³ for the general population (=T25/25 000) would be obtained, which is approximately 14 times slower than the long-term DNEL used by the Dossier Submitter. RAC notes that this DMEL should not be considered as a safe level but indicates that the DNEL will underestimate the risk.

Overall, RAC considers that the exposure limit values proposed by the Dossier Submitter are a useful tool to illustrate a risk and support the need of a restriction but are not sufficiently protective of the carcinogenic potential of 2,4-DNT.

3.1.3. Information on emissions and exposures

Summary of proposal:

Current or previous uses of 2,4-DNT have been identified in various assessments, i.e. a temperature specific, cross-linking agent for refractories, automotive airbags, seat belt pretensioners, plastic bottles used in industrial settings for taking samples, propellants for military ammunition, gelatinising-plasticising agent in explosives and as a plasticising and waterproofing agent for propellants in gun powders. However, only two substance in article notifications (SiA) have been made under Article 7(2) of REACH for 2,4-DNT; one as a plasticiser in plastic sample bottles used at industrial settings, for which the notifying entity has now ceased, and one for the use in propellants for military ammunition.

The Dossier Submitter also refers to the US EPA 'Chemical and Products Database (CPDat)' that indicates other potential uses of 2,4-DNT that have not been previously identified in the EU i.e., products used outside the home (including outdoor toys, canopies and shelters,

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outdoor lighting or power equipment) and sporting equipment (soccer balls, fishing rods, etc.).

There is no current manufacture or import of 2,4-DNT in the EU; ECHA has not received any applications for authorisation for 2,4-DNT and has no information whether there is manufacture for the uses exempted from authorisation or for export.

Overall, the Dossier Submitter considers that, whilst there is some uncertainty about the extent of actual uses in and exposures from articles, it is likely that exposure to 2,4-DNT via consumer and professional articles occurs in the EU.

In the exposure section, the Dossier Submitter provided illustrative examples on specific articles where exposure to 2,4-DNT may occur.

For worker exposure assessment, the Dossier Submitter provided a qualitative assessment for the use of 2,4-DNT in TNT and other explosives and for the use of 2,4-DNT in seat-belt pretensioners and a semi-qualitative assessment for the use of 2,4-DNT in plastic containers;

a. Worker exposure assessment for plastic containers

A substance in article notification for the use of 2,4-DNT in plastic sampling bottles as a softener was made in 2010. The bottles were used in industrial workplaces only. The use is no longer active for the notifying entity but the Dossier Submitter considered that it is not clear if such containers or other plastic articles, possibly containing 2,4-DNT, are used elsewhere in the EU.

The Dossier Submitter had no information that would indicate whether, and to which extent, 2,4-DNT is released from plastic containers. Neither is there information on exposure to 2,4-DNT from plastics available. Thus, a qualitative assessment was proposed by the Dossier Submitter for these articles.

The Dossier Submitter assumed that the exposure potential of 2,4-DNT as softener / plasticiser in plastic articles and more in general as an additive in any plastic material can be predicted to be high, since, based on its physical properties (e.g. solubility, molecular weight, log K_{ow}), it is assumed to diffuse easily within the plastic matrix and partition from its surface to contact medium (water, saliva or skin).

b. 2,4-DNT in TNT and other explosives

2,4-DNT can be found as an impurity in TNT (from the use of DNT as an intermediate in the manufacture of TNT) or intentionally added as a plasticiser. 2,4-DNT may also be present in TNT from explosive and ammunition recycling.

The Dossier Submitter assumed that, currently, all the articles may be related to import as no applications for authorisation for these uses were received.

c. Seat-belt pretensioners and airbags

During the consultation on the Annex XV report (#3526), it was confirmed that 2,4-DNT is used in automotive seatbelt pretensioners and bonnet actuators, although in smaller quantities than assumed in the Background Document. Therefore, the Dossier Submitter considers that it is plausible that car repair workers could be exposed to 2,4-DNT following any accident when repairing a vehicle and replacing the seatbelt installation. This could happen on many separate occasions and thus the exposure of an individual worker could be long term.

For consumer exposure assessment, the Dossier Submitter initially proposed a scenario (ES3) on seatbelt pretensioners and airbags. However, the scenario was removed from the Background Document as this would only be relevant during or immediately after an accident and was only included to illustrate a risk using the available threshold based national OELs

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and was not related to the non-threshold properties of 2,4-DNT.

- a. Civilian exposure assessment for hunting outdoor or shooting indoor with small arms containing 2,4-DNT as a propellant in ammunition

A substance in article notification for the use of 2,4-DNT in ammunition is available. Small arms cartridges may contain 2,4-DNT. The same scenario was used for outdoor hunting or indoor shooting but different parameters were used. Some of the parameters of the proposed exposure scenario 2 (ES 2) were based on military use of the substance in ammunition (ES 1). Eight activity scenarios were calculated based on indoor or outdoor shooting and based on a least and a worst-case exposure scenario. Exposure was considered either for 8h/d and compare to the retained OEL or 6h/d and compare to the retained long-term DNEL for 2,4-DNT.

The parameters used by the Dossier Submitter are summarised in the table below:

Table 3: Parameters used in the exposure assessment for ES 2

Parameter	Least exposure	Worst case	Reference
Number of shots (N)			None
- Outside hunting	10		
- Indoor shooting	50		
Bullet weight (g)	3.6	28	Companies webpages
Concentration of DNT in the bullet	2%		Publicly available safety datasheet
Residual DNT (%)	0.05	0.5	Walsh <i>et al.</i> , 2011
Release to air (%)	80-100%		None
Exposure duration (h)			None
- outside hunting	2.5		
- indoor shooting	1		
Volume/room (m ³)			None
- outdoor	100 m ³		
- shooting galleries	20 m ³		
Dilution factor			ECETOC TRA consumer V.3.1.
- outdoor	0.6		
- indoor	2.5		
Frequency	> 15 times per year, no correction factor		None
Relevant duration	6h for general population (compare to long-term DNEL)		
	8h for professional (compare to OEL)		

For indoor shooting, exposure between 0.015 mg/m³ and 1.63 mg/m³ was obtained for professional and 0.02 to 2.18 mg/m³ for the general population. For outdoor shooting, exposure was calculated between 0.0004 and 0.039 mg/m³ in workers and 0.0005 and 0.052 mg/m³ for the general population. The Dossier Submitter considered the worst-case scenario as the most relevant due to the non-threshold MoA. The Dossier Submitter added that skin exposure is possible for hands, arms and face but no estimation were made. Exposure to humans *via* environment was also considered possible but unlikely by the Dossier Submitter.

- b. Seat belt pretensioners and airbags

2,4-DNT is used as an inflator in pyrotechnic pretensioners. An explosive charge causes the gas generator to produce a volume of gas and thus pressure which acts on a mechanical linkage to tighten the seat belt. The pretensioner needs replacing after deployment. The deployment consumes the explosive in the seat belt assembly. The Dossier Submitter

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assumed that if the substance is used in these applications there will be releases to the interior of the vehicle in case of a crash. This use has been confirmed in the consultation on the Annex XV report (#3526).

The Dossier Submitter noted that the possibly exposed groups may contain, apart from the driver, also people and occupational groups that often attend accident sites e.g. the police or emergency services. Also, car repair technicians handling and replacing pretensioners and air bags may be at risk of exposure. Ford advises that potential exposure to customers is minimised if the car and its parts are used, repaired, maintained and disposed as intended⁵. Disposing an end-of-life vehicle legally in the European Union takes place in Authorised Treatment Facilities (ATF).

For environmental exposure assessment, in relation to the uses discussed, the Dossier Submitter noted that 2,4-DNT is mainly found on the topsoil layer where it accumulates when using propellants in small arms ammunition and heavy weapons such as artillery (Walsh *et al.*, 2011).

RAC conclusion(s):

- The Dossier Submitter heavily relied on the data reported in a 2010 technical report prepared for ECHA for the use of 2,4-DNT in articles.
- RAC concludes that there is evidence that articles have been present in the EU market in the past.
- RAC concludes that there is evidence that articles may be currently present in the EU, most likely from import. The notification of articles in the SCIP database provide evidence that there could be articles in the EU containing the substance. In addition, the presence of the substance in seat-belt pretensioners in cars was confirmed during the consultation on the Annex XV report. However, RAC notes that information on the current amount of imported articles and on their uses are uncertain as no updated information are available since 2010.
- Although a decreasing trend was expected in 2010 for the use of 2,4-DNT, RAC has no information on the potential future trend for the potential placing on the market or use of 2,4-DNT in articles. However, RAC notes that future import is plausible.
- RAC concludes that the quantitative exposure scenarios used as illustrative examples by the Dossier Submitter provide evidence that there is potential for inhalation exposure to 2,4-DNT from professional and consumer articles. Nevertheless, due to the high uncertainties identified for the parameters used in the scenarios, the extent of possible exposure is very uncertain and would depend on the type of article and the concentration of 2,4-DNT used.
- RAC notes that inhalation and dermal exposure may significantly contribute to human health risk. In addition, oral route (hand-to-mouth contamination) and exposure of human *via* environment may also lead to potential source of exposure.

Key elements underpinning the RAC conclusion(s):

a. Qualitative approach

Information on use of 2,4-DNT in articles

Use of DNT

⁵ <https://www.ford.co.uk/content/dam/guxeu/uk/useful-information/reach/Art-33-1-Information-Example-U502-Explorerer.pdf>

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In 2010, according to a technical report prepared for ECHA (2010), DNT was manufactured and used in the production of toluene diisocyanate (TDI) and toluene diamine, which are intermediates in the production of polyurethane foams and polymers. In addition, one company was manufacturing DNT 95, DNT 65 and DNT 50 at 10 to 1000 t/y. The substance was also used as a binding agent in the non-ferrous metal industry (100-1000t/y of 50-55% 2,4-DNT). DNT (unknown 2,4-DNT content) was also reported to be used as a propellant in ammunition. Propellants which contain DNT can be used for both military ammunition and recreational (hunting/sporting) ammunition. Nevertheless, in 2010 it was stated that DNT has been largely abandoned in civilian ammunition. The report also stated that DNT had been used in the past in explosives (e.g. dynamites and octol). According to the technical report (2010), DNT was not used in automotive airbags, engine fuels or in azo dyes. Potential export of DNT was also reported.

Currently, there are five active registrations for DNT and two joint submissions but none for 2,4-DNT itself. The first joint submission includes four active registrants for the manufacture and its use as an intermediate under strictly controlled condition (Art. 18(4)). The second joint submission include one active registrant for the use of DNT (containing approximately 80% 2,4-DNT and 20% 2,6-DNT) in formulation into mixture as a plasticiser in explosives. The tonnage is ≥ 10 tons per year. RAC notes that as authorisation applies to the use(s) of the substance included in Annex XIV of REACH on its own (2,4-DNT), authorisation does not apply to DNT, being a substance with multiple constituents, including 2,4-DNT and 2,6-DNT.

The registered use of the substance as a binder and curating agent in refractory products to produce pitch coke (SU13: manufacture of other non-metallic mineral products, e.g. plaster, cements) also under strictly controlled condition is no longer active (revoked status). The vast majority of volume of DNT is still expected to be the use of the substance as an intermediate for TDI manufacture.

One potential exposure is from residual 2,4 DNT in polyurethane (used as an intermediate in the process). The Dossier Submitter has not included information relating to this use in the Background Document and no responses on this use were submitted in the consultation on the Annex XV report.

Overall, 2,4-DNT, present as a mixture in technical DNT, may still be supplied to the explosive sector. There is no clear indication of the amount of substance supplied to this sector and the potential amount present in the EU market and the definition of explosive articles in the registration dossier (e.g., it is not clear whether pyrotechnic articles are included). Nevertheless, it is likely that it still represents a small fraction of the total amount of DNT used in EU. In 2010 there was a trend in decline for the use of DNT in explosives and ammunitions. No specific foreseeable trend in the future can be described.

Recycling of 2,4,6-trinitrotoluene (TNT) and other explosive articles

DNT may be a by-product in the production of the explosive TNT or be present as an impurity in the final TNT product. DNT may also have been present during the recycling of old explosives and ammunition. DNT may also be present during the recycling of old gun powders containing DNT-based propellants (military ammunition and sporting ammunition sector).

2,4-DNT in articles

There is no information on the past, present or future quantities of 2,4-DNT in articles placed on the EU market.

As no applications for authorisation were received, the Dossier Submitter assumed that the uses of 2,4-DNT in articles are related to imported articles. There is no current registration of the substance. Therefore, the Dossier Submitter has no information as to whether there is manufacture for exempted use or for export. However, a response in the consultation on the

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Annex XV report (#3541) indicated there are several existing Member State exemptions from REACH in the interests of defence that allow the continued use of 2,4-DNT in the production of propellants for use in (military) ammunition. These Member State exemptions mean that no applications for authorisation would have been received.

Nevertheless, two REACH substance in articles notifications (required under Art. 7(2)) were submitted. The first is for the use of 2,4-DNT in plastic bottles with a widespread use with low release (indoor use). In this use the substance is used as softener. The article is a plastic sample bottle used to take samples of process fluids for further analysis at industrial settings. The manufacture of the bottles takes place outside EU and only the finished article containing plastic components were imported.

The second notified use is as an energy releaser (explosive, motive propellants) use in an explosive casing of outdoor military ammunition. There is no information on the tonnage for this use.

In addition, 2,4-DNT may be used in pyrotechnic devices including airbags, seat-belt pretensioners and pyrotechnics. The Dossier Submitter has noted that current use of the substance in seat-belt pretensioner have been indicated by vehicle manufacturers according to Article 33 of REACH, e.g. Toyota and Ford⁶. This was confirmed during the consultation on the Annex XV report.

Companies supplying articles containing SVHC substances in a concentration above 0.1% w/w on the EU market have to submit information to the SCIP (Substances of Concern In articles and Products) database. Information in SCIP on articles containing 2,4-DNT is available throughout the whole lifecycle of products and materials, including at the waste stage. The articles notified to SCIP were mainly electronic equipment and their parts but also corrugated sheets, vehicles (e.g. seat-belt pretensioner), military arms and ammunition, plastics and articles thereof (e.g. 3-way fluid connector in commercial printing inks, toners and related finishing products), iron, steel or aluminium based articles.

The SCIP database contains substances present or previously present in articles (the database covers the whole life cycle). Nevertheless, some of the notifications in the SCIP database are recent (August 2021). RAC agrees with the Dossier Submitter that it could be assumed that the SCIP entries relate to actual uses unless information is received otherwise. Overall, this database provides supporting evidence that, currently, there are articles in the EU market containing 2,4-DNT, including plastics, ammunition and seat-belt pretensioners. Nevertheless, there are no information on the potential total tonnages, comparative volumes and no precision on the exact part of the articles containing 2,4-DNT that may lead to potential exposure or on the legacy uses of the substance.

Although the current number of imported articles containing 2,4-DNT is unknown, the current tonnage of articles containing the substance and placed on the EU market is expected to be low. The substance is not registered, no application for authorisation were submitted and there is no current notification of 2,4-DNT in articles (Article 7(2) of REACH regulation). Moreover, a decreasing trend was expected in 2010 .

Although there are uncertainties with regards to foreseeable trend, RAC agrees that future import of the substance in articles in the EU market is plausible.

In addition, the Dossier Submitter also refers to the US EPA Chemical and Products database that indicate potential other uses of 2,4-DNT (e.g. outdoor lighting or power equipment).

⁶https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKewi3ytek6tHsAhVJsaQKHZ2BC8wQFjAAegQIAhAC&url=https%3A%2F%2Fwww.toyota.hu%2Fdownload%2Fcms%2Fhuhu%2FToyota%2520Aygo_SVHC%2520Information_032019_tcm-3033-1572338.pdf&usq=AOvVaw15sytWN_78pxTfiJITxILL

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However, RAC has no information whether these articles could potentially be on the EU market.

Table 4: Summary of potential presence of 2,4-DNT in articles based on DNT and TNT past uses (adjusted from technical report, 2010 and Background Document)

Use	Presence of DNT or 2,4 DNT in final product	Scope	Expected trend in 2010, current evidence in articles
Use of DNT in the manufacture of TDI	Not expected. Potential presence in polyurethane not confirmed during the consultation on the Annex XV report	Not expected to be present	No information from the consultation on the Annex XV report
Explosives (mining and demolition)	Yes (<1% in melting/solidification moderator; a few percentage in dynamite (old use) <1% in TNT as an impurity	derogation proposed for explosive articles	Use in decline in 2010. One registered use for DNT in explosives. Unknown for the use of TNT based articles
Ammunition (weapon and propellants for civilian and military use)	2.5-17% or coating <1% in TNT ammunition	Derogation for military use articles, civilian ammunition articles in scope	Use in decline. SiA notification, SCIP database notification for military ammunition
Refractory products	Possible as trace	Production of refractories products in the scope of authorisation	Varying demand, no foreseeable trend for refractories, unknown current status, SCIP database notification
Engine fuel	Probably yes but unknown	Yes	No information
Propellants for automotive airbags, bonnet actuators and seat-belt pretensioners	Assumed to be 10%	Yes	Not identified in 2010, SCIP database notification, confirmation for bonnet actuators and seat-belt in consultation on Annex XV report (10-14% of the propellant)
Dyes	Very low	Yes	May be an historical use
Softener in plastic articles	Hypothesis: up to 30%	Yes	SiA for plastic bottles withdrawn. SCIP database notification, US EPA database notification
Electronic devices	No information	Yes	SCIP database notification

SCIP database: Substance of Concern In articles, as such or in complex objects (Products) established under the Waste Framework directive; SiA: Substance in Article

Exposure assessment

Inhalation, dermal and oral route (hand-to-mouth) could all be relevant routes of exposure to 2,4-DNT in humans.

The Dossier Submitter provided qualitative illustrative example for professional workers on

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some specific articles that may result in 2,4-DNT exposure:

- Plastic containers (professional workers),
- 2,4-DNT in TNT and other explosives (professional workers)
- Seat-belt pretensioners and air-bags

- *Plastic articles*

The Annex XV report presents a qualitative estimate of exposure to 2,4-DNT in plastic articles. 2,4-DNT is used as a softener/plasticiser. To exert its function, 2,4-DNT need to be use at high concentration. According to the Dossier Submitter, the concentration of plasticiser need to be 35%.

There are no migration data for 2,4-DNT. Nevertheless, evidence was provided on the possible diffusivity of 2,4-DNT in plastic material based on its physicochemical properties. According to the JRC equation used to estimate the diffusion coefficient of plasticisers in soft PVC used as a food contact material, 2,4-DNT would have a high diffusion potential . Diffusion is inversely proportional to molecular weight and 2,4-DNT has a relatively low molecular weight (183 g/mol). Solubility and Log K_{ow} are also important parameter in the partitioning between the plastic matrix and the contact media (e.g. skin). The Dossier Submitter considered that based on these physical parameters, the substance would be expected to diffuse more easily than phthalates (e.g. DEHP). RAC considers that the use of the physicochemical properties only to estimate the diffusion potential of the substance in plastics is uncertain. Indeed, there are uncertainties in the migration rate as there are no specific data on the type of plastics containing the substance. As discussed with phthalates, migration may vary greatly depending on multiple factors, such as static or dynamic conditions. In addition, the presence of the substance in the article does not automatically mean that under normal conditions of use, migration will be high with a high risk of exposure. In addition, the substance being an energetic plastifier, its use may differ greatly from phthalates and comparison with these compounds may not be fully appropriate. Nevertheless, RAC agrees that under certain conditions, exposure to 2,4-DNT may occur via migration.

There are uncertainties as to whether the plastic articles containing 2,4-DNT within the scope of this restriction proposal could come into contact with professional or consumers. Indeed, for example, the use of sampling bottles was only reporting at industrial settings for which an exemption is proposed by the Dossier Submitter. Nevertheless, it is plausible that other plastic articles may be on the market, such as those reported in the SCIP database. These types of articles may be in contact with professionals during repair activity using spare parts containing the substance. In case the substance is used as a softener in plastic articles, the concentration of the substance will need to be high to exert its function. In case of manual handling, dermal exposure is likely. Nevertheless, no conclusion can be drawn on the extent of the exposure.

RAC notes that potential wide consumer exposure could be from residual 2,4 DNT in polyurethane (used as an intermediate in the process). Nevertheless, there were no information submitted in the consultation on the Annex XV report to support this.

- *Explosives*

No specific information on potential exposure were provided by the Dossier Submitter in this section except details of the previous potential use of DNT, 2,4-DNT in explosives or as an impurity in TNT.

RAC notes that there is currently an active registered use for the use of DNT (containing approximately 80% of 2,4-DNT) in explosives. However, it is unknown if there are current import of DNT for this use as this was not confirmed during the Annex XV report consultation. It is unlikely that authorisation would apply to this use as 2,4-DNT is present as a constituent together with 2,6-DNT and not registered on its own. There was no information provided by the Dossier Submitter to confirm that the use currently exists.

Exposure to explosive articles containing 2,4-DNT has been previously reported in miners,

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that manipulated the explosive with bare hand. Miners were exposed dermally. In addition, miners were also exposed via inhalation of fumes after explosion. Cancer has also been reported in miners exposed to 2,4-DNT (Brüning *et al.*, 1999).

Exposure of workers may also occur from demilitarisation of explosives and ammunition and releases from the waste lifecycle stage. Professional worker exposure may occur during the disposal of military waste. There are uncertainties on the amount of releases as it will depend, for example, on environmental conditions and the type of containers used. Overall, although military use is out of scope, exposure during civilian use of explosives may occur under certain conditions.

b. Quantitative approach

The Dossier Submitter provided quantitative illustrative examples on some specific articles that may result in 2,4-DNT exposure:

- Propellant in civilian small arm in hunting/shooting (non-military use),
- Seat belt pretensioners and airbags (non-military use).

The supply of 2,4-DNT to the general public is currently restricted as a substance and in a mixture containing ≥ 0.1 % 2,4-DNT and also 2,6-DNT (Annex XVII of REACH, entry 28 and appendix 2).

- *Exposure scenario for civilian small arms use in hunting/shooting*

Sport shooting or hunting using small arms may result in exposure to 2,4-DNT. Exposure can occur indoor or outdoors. There are many ways to define small arms. Small arms cover at least pistols and rifles in the Background Document. In small arms ammunition, 2,4-DNT is used only in small quantities as a plasticiser. There is no detonation generally in small arms.

There is information that military training with howitzers (artillery guns) and mortars produce excess propellant that can result in accumulation of residues in the surface of soils at military training firing points.

When a gun is fired, the combustion of the propellant is never complete. Energetic residues will be deposited on the ground from the end of the gun barrel. The residues will contain the constituents of the original propellant formulation. Combustion is influenced by the barrel length, combustion temperature and pressure, the propellant formulation and propellant age. The nitrocellulose matrix within which most of the propellant components such as 2,4-DNT are embedded traps the components within the matrix.

Walsh *et al.* (2007) sampled soil 1.05 meters from several howitzer firing points in Alaska (. The concentration of 2,4-DNT was 10% of the used propellant. 2,4-DNT was detected in most of the soil samples. 2,4-DNT in soil was in particulate form. 2,4-DNT seems to remain in the nitrocellulose matrix of propellants as discrete fibres were found to be distributed on the soil surface. Most of the 2,4-DNT was found in the 0.595 to 2 mm particle size range. Walsh *et al.* (2007) concluded that the unburned propellant grains can constitute an accumulative environmental hazard. The authors also assessed propellant residue deposition in different weapon systems (Walsh *et al.*, 2011). The rate of deposition in hunting (rifles) is considered much worse than for artillery firing as the long barrels of artillery provide better conditions for combustion (higher temperature and pressure) than rifles. For small arms, residues were estimated to range between 0.05% to 0.56%. Concentrations ranged from less than 0.05 mg/kg to 17 mg/kg for DNT at small arms firing points. In this study, DNT was not detected in groundwater. The nitrocellulose matrix may inhibit the leaching of the residues. The use is considered frequent (> 15 times per year).

The following parameters were used by the Dossier Submitter to estimate the 2,4-DNT concentration that may be inhaled during hunting and sport shooting with small arms containing 2,4-DNT (proposed equation are assumption from RAC). RAC agrees to use the worst-case and least-case parameters proposed by the Dossier Submitter in the absence of

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existing default parameters or measured data as no other assumptions were provided during the consultation on the Annex XV report.

A	Bullet weight: 3.6 to 28g		g
B	Concentration of 2,4-DNT in bullet	$B=A*1000*2\%w/w$	mg
C	Release to air: 80 to 100%		%
D	Residual DNT: 0.05% to 0.5%		%
E	Quantity of 2,4-DNT released to air per bullet	$E=B*C*D$	mg
F	Volume: 20 m ³ (indoor) or 100 m ³ (outdoor)		m ³
G	Dilution factor (ventilation rate): 0.6 (indoor) and 2.5 (outdoor)		
H	Number of shots during exposure: 10 (outdoor) and 50 (indoor)		
I	Concentration in air:	$I=E*H/FG$	mg/m ³
J	Exposure duration: 1h or 2.5 h exposure		h
K	Relevant exposure duration: 6h or 8h		h
L	Concentration in air during exposure:	$L=I*J/K$	mg/m ³

There are uncertainties on the exposure scenario. The Dossier Submitter used a dilution factor of 0.6 for indoor and 2.5 for outdoor for air volume changes, but these values were not justified. In addition, the use of 100 m³ for outdoor as a room volume is not justified. This might be the worst-case choice in the calculation of the air concentration of 2,4-DNT. RAC considered that the calculation of air concentration in the breathing zone may have been more appropriate (1 m³). The duration of exposure for outdoor hunting was not justified. Although a long duration of exposure may be considered, ventilation by wind should also have been considered. Exposure during such a long period outdoors is uncertain and may overestimate the risk. Conversely, the exposure duration conversion done for air concentration may underestimate the risk. RAC also notes that the use of 6h exposure for the general population is questionable as the basis of the DNEL setting is unknown and usually 24h exposure is considered for the general population.

RAC concludes that the assumptions used for the exposure scenario are doubtful and would be expected to lead to an underestimation of the risk. RAC also notes that in the case of indoor exposure, more than one person could be using small arms ammunition at the same time, leading to a potential increase in exposure.

Using the equation above, the Dossier Submitter estimate inhalation exposure to 2,4-DNT shooting indoors and outdoors of between 0.0004 and 0.52 mg/m³ for outdoor and 0.015 to 2.18 mg/m³ for indoor.

Although not taken into account by the Dossier Submitter, RAC notes that dermal route could also be a significant relevant route of exposure as dermal absorption is expected to occur. Hofsteffer *et al.* (2017), indicated that gunshot residues can be found on the hands and other parts of the upper body of the shooter including clothing. However, no exposure assessment was reported by the Dossier Submitter for this route and this may underestimate risks. Hand-to-mouth exposure may also occur. The contribution of each route of exposure is unknown but human exposure from the civilian use of ammunition is likely.

- Seat-belt pretensioner

Based on the information received during the consultation on the Annex XV report, 2,4-DNT can be used as a micro gas generator in safety critical pyrotechnic applications. Two types of articles were described. First, as a propellant in bonnet actuators used to raise the bonnet upon impact with a pedestrian to reduce the force that the head is exposed to during an accident. Secondly, as described by the Dossier Submitter, in seat-belt pretensioners that are used to restrain the occupants of vehicles from being thrown forward during an accident. From the comment submitted in the consultation on the Annex XV report, it was not confirmed that the substance could be used in airbags.

RAC considers that exposure of people inside the car due to airbag/seat-belt pretensioner

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exposure is expected to be acute rather than chronic and may occur only a few times in a life.

However, professional workers may be exposed during car maintenance/car repair, mainly *via* dermal exposure. There are no quantitative data available on this exposure scenario although chronic exposure of this targeted population by dermal or oral (Hand-to-mouth) route may occur. People that are present within vehicles, or in the vicinity of a car accident, may be exposed for a short period of time. In addition, during the disposal of car, 2,4-DNT may be released to the environment and accumulate in soil and potentially in groundwater.

Although exposure assessment is uncertain, the overall impression is that exposure is plausible and that the generation of inflation gases may produce particulates of 2,4-DNT. Professionals may be exposed chronically, mainly by dermal route, during maintenance/repair.

- Other articles

There are a number of other potential uses in articles, but the information available to RAC is very limited. The presence of these type of articles in the EU market is uncertain but may be of concern.

c. Humans *via* the environment

RAC agrees that potential human exposure via the environment may occur through the accumulation of 2,4-DNT in surface soil and leaching to groundwater. Indeed, contamination of groundwater has been reported in some publications at sites where 2,4-DNT is used (e.g. waste disposal, military training area). Nevertheless, Walsh *et al.* (2011) indicates that groundwater contamination in highly contaminated soil will not generally occur as the nitrocellulose matrix containing the 2,4-DNT may inhibit the leaching of the residues to groundwater. 2,4-DNT contamination of soil is significant but may not generally lead to groundwater contamination. Therefore, RAC considers indirect exposure to humans *via* the environment to be plausible although the extent of potential contamination is uncertain.

3.1.4. Characterisation of risk(s)

Summary of proposal:

Potential exposure may arise from dermal, inhalation or oral route of exposure. In addition, 2,4-DNT may accumulate in soil and could result in exposure to humans via the environment. The Dossier Submitter concluded that the exposure potential of 2,4-DNT in any plastic articles where it is used as a softener/plastifier cannot be excluded. A risk of carcinogenicity for military personnel and other users of artillery ammunition cannot be excluded. Furthermore, exposure to 2,4-DNT from firing artillery ammunition and other exposure articles such as small arms ammunition cannot be excluded through environmental accumulation and subsequent human exposure via the environment. Finally, a risk to humans from imported articles cannot be excluded.

The Dossier Submitter also notes that the risk of the use of 2,4-DNT in explosives is known but that there is no current indication of use of such articles in the EU.

In terms of human health risk characterisation, the Dossier Submitter quantitatively assessed the risk associated with the civilian use of small arms and seat-belt pretensioners for illustrative purposes. Except for these illustrative uses, the information on uses and exposure are not sufficient to quantify the risks and, therefore, the Dossier Submitter described risks in a qualitative manner.

For the civilian use of ammunition, for indoor shooting, RCRs between 0.1-11 were obtained for professional workers and 2.22 to 242 for the general population. For outdoor shooting, an RCR <1 was calculated for professional workers and between 0.95 and 5.8 for the general population. The Dossier Submitter concluded that these calculations supported a risk to 2,4-

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DNT and considered the worst-case scenario as the most relevant due to the non-threshold MoA. The Dossier Submitter added that skin exposure is possible for hands, arms and face but no exposure estimates were made.

The Dossier Submitter also compared the estimated inhalation exposure to 2,4-DNT to the available OELs and long-term DNEL for general population for seat-belt pretensioner. Risks to humans (comparison with DNEL), if 2,4-DNT is released to the interior of the car were calculated to have an RCR of 33 considering 30% release or an RCR of 11 considering 10% release for a scenario involving five airbags/seatbelt pretensioners. RCR values were 0.7 and 2 for 10% or 30% release, respectively, compared to the OEL value. The Dossier Submitter took note of the comments received during the consultation on the Annex XV report and the uncertainties on the concentration of 2,4-DNT in seat-belt pretensioners. Thus, the Dossier Submitter discarded this scenario highlighting that this illustrative scenario was only to illustrate potential risks as the substance is acknowledged to be a non-threshold carcinogen.

RAC conclusion(s):

- As 2,4-DNT, is a non-threshold carcinogen, it is not appropriate to perform a quantitative risk characterisation against a threshold value. RAC concludes that exposure to 2,4-DNT is likely by inhalation, dermal or oral route depending on the type of articles. In addition, human exposure via the environment cannot be excluded as 2,4-DNT may accumulate to the environment.
- Based on the non-threshold carcinogenic properties of 2,4-DNT, and its identification as an SVHC on this basis, minimisation of risk can be achieved by preventing the placing on the market and use of articles containing 2,4-DNT.
- The current extent of use of import articles is uncertain but potential future import of articles on the EU market may lead to risk to human health.
- The quantitative risk characterisation provided, as illustrative examples, to support the restriction proposal is uncertain. However, the assessment supports a conclusion that exposure to and risk of 2,4-DNT is plausible under certain conditions.

Key elements underpinning the RAC conclusion(s):

a. Human health: qualitative risk assessment

The substance has been identified as a substance of very high concern, based on its carcinogenic properties. RAC agrees with the qualitative risk assessment performed by the Dossier Submitter.

There are uncertainties relating to the current uses of the substance in articles. However, at least for some articles (i.e., seat-belt pretensioners and ammunition), the presence of 2,4-DNT was confirmed in the consultation on the Annex XV report.

With regards to seat-belt pretensioners, exposure to people inside a vehicle may lead to exposure in certain conditions. Although risk is associated with very infrequent exposure, professionals may be exposed chronically during car maintenance/car repair.

Based on the semi-qualitative assessment of the Dossier Submitter, professional exposure to plastics bottles (or other plastics articles e.g., spare parts) may also lead to exposure. Although the migration rate from the plastic articles is uncertain, exposure is likely.

Risks from other types of articles (reported outside of the EU), that may be imported in the future, may also lead to a concern. Nevertheless, the absence of any relevant information makes the assessment difficult.

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Based on the available data (Walsh *et al.*, 2007; ATSDR, 2016), DNTs have been detected in groundwater near a source where 2,4-DNT is manufactured or used, such as munitions sites. Thus, exposure to the general population may occur near areas where 2,4-DNT is used. Nevertheless, DNT was not found in groundwater in training contaminated site (Walsh *et al.*, 2007; Walsh *et al.*, 2011). Thus, 2,4-DNT embedded in nitrocellulose may not generally leach to groundwater. Overall, although exposure is plausible, the extent is unknown.

In conclusion, exposure from the uses reported in the Background Document may occur and therefore a restriction is warranted.

b. Human health: quantitative risk assessment

Based on the quantitative example of the use of 2,4-DNT in small arms ammunition, there is evidence that regular practicing (e.g. at shooting ranges) may lead to exposure and risks by inhalation. In addition, exposure via dermal and oral routes is also likely but was not taken into account in the Background Document, leading to an underestimation of the risk. RAC also notes that the use of OEL and DNEL values that were not based on the carcinogenic potential of 2,4-DNT underestimate the risk, at least 150 times for the OEL and 15 times for the DNEL used by the Dossier Submitter, considering a DMEL approach.

3.1.5. Uncertainties in the risk characterisation

a. Qualitative risk characterisation

- There are significant uncertainties on the extent of current uses. There is a high reliance on data from 2010, which may not have been representative of whole EU situation. There are few information on current uses of 2,4-DNT in articles and no information on future potential use/import of articles containing 2,4-DNT. There are also some uncertainties on current manufacture as based on a comment from the consultation on the Annex XV report there are existing exemptions from REACH in the interests of defense that allow the use of 2,4-DNT in the production of propellant used in ammunition.
- There are significant uncertainties in the exposure assessment of all human health effects which are due to very limited information on use and exposure.

Table 5: Uncertainties in the risk characterisation according to RAC: qualitative exposure assessment

The representativeness of the use as surveyed in 2010 leads to uncertainties on current and potential future use	↑↓
There is no information on potential concentration of 2,4-DNT in articles leading to potential uncertainties on exposure. There is no information on current tonnage estimation of articles containing 2,4-DNT placed on the market	↑↓
Lack of data on if and how the substance is use in articles	↑↓
No information on exposure parameters such as amount used in articles, exposure duration, ventilation	↑↓

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Dermal and oral exposure is likely	↓
2,4-DNT may accumulate to the environment and potentially leads to human risk via the environment	↓
Potential risk from explosive and military ammunition are exempted	↓

↓ Underestimation of the risk; ↑ Overestimation of the risk

b. Quantitative risk assessment: uncertainties

- The representativeness of the illustrative quantitative exposure assessments is unknown as the current use of the substance is uncertain. No real data were available to estimate whether the proposed scenarios are representative of realistic worst case conditions. Both overestimation and underestimation of exposure parameters were noted.
- In addition, quantitative assessment is likely to result in an underestimation of risk because of the uncertainties around the DNEL and OEL values used, which do not fully take into account the potent non-threshold carcinogenic potential of 2,4-DNT.

Table 6: Uncertainties in the risk characterisation according to RAC: quantitative exposure assessment

The representativeness of the illustrative example for the different use of the substance in article remains uncertain	↑↓
The lack of measured data used in the models leads to uncertainties with regards to inhalation exposure. No sensitivity analysis has been provided on the different parameters used in the exposure scenarios.	↑↓
Exposure from dermal route or hand to mouth (oral) exposure were not considered in the exposure scenario leading to uncertainties with regards to overall exposure assessment.	↓
Exposure of human via the environment was not considered and lead to uncertainties on potential exposure from this route.	↓
The use of OEL/DNEL leads to uncertainties on non-threshold carcinogenic risk assessment.	↓

↓ Underestimation of the risk; ↑ Overestimation of the risk

3.1.6. 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:

This restriction proposal targets consumer and professional uses in articles where release and exposure of 2,4-DNT cannot be excluded. Operational conditions (OC) and risk managements measures (RMMs), such as level of containment and use of personal protective equipment, are not implementable by consumers and are also often difficult to

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implement by professional users. The only way to manage the risk in the case of articles where there is exposure to consumers and professional users is to limit the presence of unwanted substances.

RAC conclusion(s):

RAC concludes, in line with the Dossier Submitter that, based on the available information, OCs and RMMs are not sufficient to control the risk.

Key elements underpinning the RAC conclusion(s):

No detailed assessment of implemented operational conditions and risk management measures was presented in the Background Document. In terms of article use and the release to the environment during their service life and their waste stage, RAC agrees that OCs and RMMs for the use of articles by the general population is not implementable and may be difficult to be implemented in the case of professional users. Therefore, there are currently no OCs or RMMs for the general population or professional users that are effective in reducing the risks.

RAC agrees with the Dossier Submitter that potential exposure from the use of the substance in articles at industrial sites, where RMM can be implemented, can be minimised. However, it was not analysed whether such OC and RMM are in place.

RAC notes that for the use of explosives, risk management measures may be difficult to implement (e.g., mines, construction sites).

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

Summary of proposal:

The Dossier Submitter assessed that under REACH, 2,4-DNT was included in the candidate list for authorisation (13/01/2010; ED/68/2009) and included into Annex XIV of REACH (Commission Regulation (EU) No 143/2011) on the basis of art 57(a) Carc 1B. with a sunset date of 21/08/2015. By this sunset date ECHA did not receive any applications for authorisation. The authorisation process, however, does not cover placing on the market of articles containing 2,4-DNT and therefore does not cover imported articles. Therefore, articles may still contain 2,4-DNT.

REACH has several requirements for substances on the candidate list including notification of 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)).

2,4-DNT as a substance or a constituent of other substances, or mixtures containing it is restricted for supply to the general public in concentrations > 0.1 % (Annex XVII entry 28, appendix 2)⁷. This does not apply to:

- Medicinal products for human or veterinary use, as defined by Directive 2001/83/EC and Directive 2001/82/EC, respectively;
- Cosmetic products as defined by Directive 76/768/EEC;
- The following fuels and oil products: motor fuels which are covered by Directive

⁷ Commission Regulation (EU) No 109/2012 of 9 February 2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (CMR substances)

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98/70/EC, mineral oil products intended for use as fuel in mobile or fixed combustion plants, fuels sold in closed systems (e.g. liquid gas bottles);

- Artists' paints covered by Regulation (EC) No 1272/2008.

RAC conclusion(s):

RAC concludes that the existing regulatory risk management instruments are not sufficient.

Key elements underpinning the RAC conclusion(s):

RAC concludes in line with the Dossier Submitter that the scope of these directives are limited and product-specific and, considering the uncertainties concerning the presence of 2,4-DNT in those articles, none of the above-mentioned EU legislation would be suitable for managing the identified risks and reducing exposure to the substance.

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
- 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 appropriate 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:

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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 exemptions from REACH in the interests of defence), 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 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 or professional uses of explosives as it is assumed that industrial uses and uses of explosives by professionals take place under well controlled conditions. Ammunition for military use and the police are out of scope of the proposal.

SEAC notes that, according to the SCIP database, some (imported) articles containing 2,4-DNT are currently placed on the EU market. The proposed restriction would prevent these 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 options:

- 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 sufficient to reduce the potential exposure to 2,4-DNT from all articles,

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- 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 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.

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 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.

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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).
- 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	low, expected to affect	low, expected to affect

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	only limited number of imported articles	only limited number of imported articles	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

Summary of proposal:

The Dossier Submitter conducted an analysis of risk management options (RMOs) to identify the most appropriate measure to address the identified risks, identifying for each option, risks, impact and efficiency consideration. The RMOs assessed include different type of population covered by the restriction, regulatory measures under REACH other than restriction, other existing EU legislation, and other possible Union-wide RMOs.

As a result, a number of potential restriction options was considered by the Dossier Submitter for a potential restriction. Limit value of higher than 0.1 % of 2,4-DNT weight by weight is proposed for all options being a practical value used for the notification of substances in articles according to article 7(2) of the REACH Regulation.

The restriction options further assessed by the Dossier Submitter were:

- Restriction option 1 (RO1): restriction on placing on the market and use of all articles containing 2,4-DNT. RO1 is disregarded by the Dossier Submitter as industrial uses and uses as explosives are assumed to be well controlled and this option may entail a higher cost. In addition, some decrease of the efficiency is possible in case Member States use article 2(3) of REACH to allow exemption to this restriction in the interest of defence.
- Restriction option 2 (RO2): Restriction of placing on the market and use of articles containing 2,4-DNT of use by general public or specified uses by professional under art. 68(1) of REACH. This option is considered as the best option by the Dossier Submitter. The only way to manage the risk in the case of articles where there is exposure to consumers and professional users is to limit the presence of unwanted substances.
- Restriction option 3 (RO3): Restriction of placing on the market and use of articles containing 2,4-DNT of use by general public under article 68(2) of REACH. This option is disregarded by the Dossier Submitter as it would not cover the risks to professional

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users. Related to exemptions, the Dossier Submitter proposed to exempt articles covered by Regulation (EU) 2017/745 on medical devices, toys regulation and food contact materials.

Related to the use in explosives, the Dossier Submitter proposed to exempt this use from the restriction as it is assumed that these are well-regulated and since general safety measures are in place for handling of explosive these should limit any exposure to 2,4-DNT.

Following the reasoning in the lead in ammunition restriction proposal, the Dossier Submitter proposed to exempt military ammunition from this restriction and pointed out that information received during the consultation on the Annex XV report indicated the continued use of 2,4-DNT in the production of propellants for the production of military ammunition, confirming the necessity of this exemption.

The Dossier Submitter proposed to add an exemption for second-hand articles as, in general, this has been previously discussed to cause difficulties in enforcement and high costs if these are not exempted.

Related to the transitional period, as there is no EU production of articles, the Dossier Submitter noted that there is no need to transition to alternatives or stocks. If there are any imported articles, time is needed for importers to transition to different articles not containing 2,4-DNT. Therefore, the Dossier Submitter assumed 12 months as a sufficient transitional period except for the production of military ammunition.

In as far as such exposures occur, the Dossier Submitter considered that the proposed restriction would also decrease the exposure of humans *via* the environment.

Justification for the opinion of RAC

RAC conclusion(s):

- RAC concludes that a REACH restriction is at present the most appropriate regulatory measure to control the risks identified of articles containing 2,4-DNT.
- RAC concludes that a restriction using a concentration limit of 0.1% w/w 2,4-DNT for articles placed in the market and used by consumer or professional is consistent with the risk assessment. RAC agrees that the proposed concentration limit value of 0.1% would prevent future uses and thus potential risk to human.
- Regarding the proposed exemption included in RO2 (proposed restriction) for explosive and military ammunition RAC concludes that:
 - RAC agrees that an exemption for the use of ammunition by the armed forces or the police is warranted.
 - For the end use of civilian (non-military) explosives, no risk assessment was made by the Dossier Submitter. The presence of 2,4-DNT may lead to uncontrolled exposure of workers when handling the explosive and to fumes containing the substance. Therefore, from a risk perspective, RAC does not consider the exemption has been sufficiently justified. However, RAC agrees that an exemption for the use of explosives by the armed force or the police is warranted.
- RAC agrees with the Dossier Submitter that potential exposure from the use of the substance in articles at industrial sites, where appropriate OCs and RMMs can be implemented, can be minimised. However, it was not assessed if such Operational Conditions (OCs) and RMMs are implemented. No risk assessment for industrial installations was undertaken. Therefore, from a risk perspective, RAC does not consider that excluding industrial installations from the scope of the restriction has been sufficiently justified.

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- RAC agrees that a derogation of articles already regulated by other legislation (Toy directives, food contact material and medical devices) is warranted and that no uses were identified in this area in the EU.
- A derogation on articles already in use is proposed and supported by RAC. This follows the difficulty of enforcement a restriction on such articles.
- RAC agrees that 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 period is short enough to ensure that risks are addressed within a reasonable period.

Key elements underpinning the RAC conclusion(s):

RAC notes that the same concentration limit is proposed in the three restriction options. RAC concludes that a restriction using a concentration limit of 0.1% w/w 2,4-DNT for articles placed in the market and used by consumer or professional is consistent with the risk assessment as outlined in this document. The concentration limit of 0.1% w/w may be effective to prevent future intended use of the substance in articles and thus potential risk to human health. However, RAC has no information on the potential amount of 2,4-DNT that may be present in articles below this limit, e.g. when present as an impurity in ammunition, refractories, explosives or other complex articles.

RAC agrees that other measures are not considered applicable to reduce the risks from articles place on the market for consumer or professional uses.

During the consultation on the Annex XV report one comment #3540 questioned why the scope of the restriction proposal is limited to consumers and professional users. They agreed with the Dossier Submitter that professional workers are typically more comparable to consumers in terms of their capacity to use of appropriate OCs and RMMs when using articles. When handling articles, no special measures are usually taken to protect against SVHCs that may be present. However, also for industrial workplaces the member state was not aware of specific measures taken when handling (explicitly not manufacturing/producing) articles. Containment does not seem plausible in this context. RAC agrees with this comment and notes that, as discussed in Section 3.1.1, RAC considers that the exclusion of workers at industrial setting has not been sufficiently justified in the Background Document. However, RAC acknowledges that the Dossier Submitter may choose the scope of the risk assessment underpinning an Annex XV restriction proposal and this informs the scope of any potential restriction.

RAC notes that the implementation of a binding OEL for 2,4-DNT would not help the situation for consumer or professional workers where the control of risk is very difficult to achieve.

Since there seems to be no need for substitution, RAC considers that a period of 12 months, as proposed by the Dossier Submitter, should be sufficiently long for the currently impacted supply chains to adapt their operations (if at all needed). At the same time RAC considers the transition period short enough to address risks within a reasonable period of time, namely from imported articles. For imports into the EU, RAC considers that a transition period is mainly needed to allow current importers to ensure that they purchase articles that do not contain 2,4-DNT above the proposed concentration limit.

Derogations / exemptions

- Explosives

The exemption is discussed under Section 3.1.1. There is a registration for DNT in the formulation of explosive articles. It is thus likely that 2,4-DNT may have been present in such articles. It is unknown if explosive articles containing 2,4-DNT for military or non-military uses are currently on the market. ECHA received no applications for authorisation and there was

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no confirmation of this use during the consultation on the Annex XV report. However, RAC notes that risk has been identified in the past on the use of explosives (non-military use) containing 2,4-DNT. Although RAC agreed to the exemption of explosive for use by the armed forces and the police, RAC considers that there is potential risk for the use of explosives for civilian use. Therefore, from a risk perspective, RAC does not consider that this exemption from the proposed restriction has been sufficiently justified.

- Ammunition intended for use by the armed forces or the police

The Dossier Submitter proposed to exempt military ammunition from the restriction in analogy to the proposed restriction on lead in outdoor shooting and fishing. RAC agrees that the exemption for military ammunition is justified. If this exemption is not granted there is indication from comments that there are existing defence exemption according to Art.2 (3) of the REACH regulation that will be used by Member States. RAC also agrees with the Dossier Submitter to add the police force in the exemption as they may not be covered by the armed force as highlighted by the Forum.

Military training with howitzers (artillery guns) and mortars were reported to produce point source of 2,4-DNT at the firing position and propellant disposal areas and potential exposure. There are uncertainties on the amount of releases as it will depend on environmental conditions and the type of barrels but this could lead to human exposure *via* the environment. RAC notes that accumulation of the articles containing 2,4-DNT in the environment and potential groundwater contamination should be minimised.

Information received during the consultation on the Annex XV report indicated that there is continued use of 2,4-DNT in the production of propellants used in (military) ammunition, confirming that this exemption would be necessary for this sector. However, RAC notes that there is no quantitative information on this exempted use.

- Exemption to avoid double regulation

RAC agrees with the exemptions proposed by the Dossier Submitter for toys, food contact material and medical devices to avoid double regulation.

RAC notes that no uses in the EU were identified in these areas in the EU. However, the potential presence of 2,4-DNT in toys was identified in the US.

- Harmonised classification Carc. 1B is restricting the use of 2,4-DNT in articles such as toys, medical devices or food contact materials.

According to the Dossier Submitter, even if 2,4-DNT has been identified in electrical and electronic equipment (SCIP database), regulating the substance under the WEEE Directive 2011/65/EU would not be useful in terms of risk reduction capacity.

- Second-hand articles

The revised wording of the entry proposed to exempt the use of articles containing 2,4-DNT already in use in the EU before the entry into force of the restriction. The restriction proposal only targets articles that are placed on the EU market for the first time after entry into force. This follows as it may be difficult to enforce existing uses as the user may not be informed of the presence of the 2,4-DNT in affected articles.

- Derogation for the automotive sector

Based on the amount of DNT in bonnet actuators or seat-belt pretensioners, ACEA #comment 3526# calculated a maximum Risk Characterisation Ratio (RCR) of 0.0533 based on the exposure scenario proposed by the Dossier Submitter for five seatbelt pretensioners being deployed simultaneously in a vehicle accident (Annex 2 of the Annex XV). As the association concluded that a risk to the occupants does not exist they requested a derogation. The

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Background Document pointed out that quantitative assessment was included to illustrate a risk using the available threshold based national OELs and is not related to the non-threshold effects. The Dossier Submitter did not support the derogation. RAC agrees that, from a risk perspective, a derogation is not justified due to plausible worker exposure during car maintenance or disposal.

Although RAC acknowledges that some of the assumptions made by the Dossier Submitter in the discarded exposure scenario on risk to consumers from airbags and seat belt pretensioners were overestimated (e.g. amount of 2,4-DNT in seat-belt pretensioners), other parameters in the exposure scenarios were uncertain and could have led to both underestimation or overestimation of the risk.

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;

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- 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;
- 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.

Additional derogations were requested for uses of 2,4-DNT in Micro Gas Generators (MGGs) and legacy uses of 2,4-DNT in the car industry (i.e., for spare parts). On the basis of the information supporting these derogation requests, SEAC concludes that a time-limited derogation of 36 months after EIF for MGGs appears to be justified to avoid major economic impacts. However, an unlimited derogation for the use of 2,4-DNT in spare parts seems to not be justified on the basis of the information provided. Instead, SEAC considers that a 36-month derogation period after entry into force for this use will minimise any major economic impact.

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

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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.

Exemptions due to double regulation

SEAC agrees with the exemptions proposed by the Dossier Submitter for toys, medical devices and food contact materials. The reason for this is that these articles are already covered by specific regulations relevant to 2,4-DNT, 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;

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- 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 European 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 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 requested by the Commission and included in the scope of the recent restriction proposal on lead in outdoor 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 between these two restrictions. This ensures that the defence capability in Member States is not negatively affected.

SEAC notes that during the consultation on the Annex XV report as well as on the SEAC draft opinion (ref. #1030), the European AeroSpace and Defence Industries Association (ASD) indicated that there is continued use of 2,4-DNT in the production of propellants for manufacturing (military) ammunition. SEAC notes that ASD provided some suggestions on the wording of the exemptions proposed by the Dossier Submitter for military and police use of ammunition as well as for explosives. SEAC notes that the final decision on the exact wording of the scope is made by the Commission and is outside the remit of SEAC. However, SEAC agrees with ASD that the conditions of the restriction should be as clear as possible.

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

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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 (of the restriction or of the underlying risk assessment) assuming that industrial workers are already sufficiently protected by risk management measures in place at 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.

Time limited derogations for automotive applications

SEAC notes that during the consultation on the SEAC draft opinion, relevant industry associations requested a time limited derogation of 36 months (until end of 2026) for Micro Gas Generators (MGGs) to be used in seat belt pretensioners and bonnet actuators (ref. 1045). In addition, SEAC notes that the same associations requested a full exemption for legacy vehicle applications, i.e. spare parts.

Based on the information provided, SEAC supports a time-limited derogation of 36 months for MGGs and a derogation for spare parts containing 2,4-DNT as this will minimise the economic impact of the restriction whilst ensuring the phase out of the use of 2,4-DNT in vehicles. Based on the information provided, SEAC further considers that the engineering validation of available alternatives will only be finished by the end of 2026. Without a time-limited derogation, there might hence be safety issues, namely if seat belt pretensioners would not work correctly due to the impossibility to use 2,4-DNT and in the absence of a

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validated alternative. SEAC therefore considers that the potential safety issues justify the proposed transition period of 36 months.

Concerning legacy vehicle applications, SEAC considers that a time-unlimited exemption is not justified on the basis of the information provided. Specifically, there is no evidence suggesting that spare parts containing 2,4-DNT need to be available indefinitely. However, SEAC considers that, similarly to MGGs in new cars, a 36-month time limited exemption seems to be justified due to similar traffic safety considerations. In addition, SEAC considers that the possibility to use spare parts extends the longevity of vehicles by postponing their disposal. Therefore, SEAC supports a derogation of 36 months after the EIF for the use of 2,4 DNT in spare parts.

SEAC also notes that one comment (ref. 1045) provides additional information to substantiate the claim on the absence of risk to workers, vehicle occupants and the environment. However, SEAC does not assess information on risks and therefore RAC's conclusion that there is a risk to human health that is not adequately controlled remains unaltered.

3.3.1. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

The risk reduction expected from the proposed restriction is assessed qualitatively in the Background Document.

Table 7: Dossier Submitter's considerations related to potential restriction option

	Potential restriction option	Risk considerations	Risk reduction considerations
1	Restriction on placing on the market of all articles containing 2,4-DNT	Risk to all populations addressed (No risk assessment has been made to industrial uses and explosives).	High, even though Member States may use article 2(3) of REACH to allow exemption to this restriction in the interest of defence.
2	Restriction of placing on the market of articles containing 2,4-DNT of use by general public or specified uses by workers (such as professional uses) under article 68(1) of REACH.	Risk to most vulnerable populations and professional workers addressed. It is assumed that industrial uses and uses of explosives would be well controlled.	Medium as military ammunition and explosives are not covered.
3	Restriction of placing on the market of articles containing 2,4-DNT of use by general public under article 68(2) of REACH.	Risk to most vulnerable populations addressed but it could not cover professional uses. It is assumed that industrial uses and uses of explosives would be well controlled.	Low to medium as military ammunition, explosives and other professional uses not covered.

Blue line: preferred Dossier Submitter option

The Dossier Submitter expects the proposed restriction RO2 to be an effective measure for addressing the identified risks, in particular with regard to new articles imported into the EU. The restriction is targeted to the effects or exposures that are of most concern, e.g. consumer and professional uses, within a reasonable period of time.

The Dossier Submitter assumed that for any imported articles covered in this proposal

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containing the substance that there are alternative articles types.

Considering the baseline analysis, the Dossier Submitter considers RO2 to be the best option. RO1 would entail higher costs but would entail a similar risk reduction as industrial uses and uses as explosives are assumed to be well controlled by the Dossier submitter.

RAC conclusion(s):

- RAC agrees that a restriction will be an effective measure for addressing the identified risks. As 2,4-DNT is a non-threshold substance, the restriction measure is considered as effective to reduce the risks from exposure from articles in the scope. The only way to manage the non-threshold risk in the case of articles where there is exposure to consumers and professional users is to limit the presence of unwanted substances to minimise the exposure.
- RAC agrees that RO2 as proposed by the Dossier Submitter is an appropriate EU wide measure to reduce risk for consumers and professionals on a Union-wide level from exposure to 2,4-dinitrotoluene. However, RAC notes that the effectiveness of the proposed restriction in reducing the identified risks in RO1 and RO2 is highly uncertain. The lack of data on current and future uses of 2,4-DNT in articles do not permit a complete evaluation of risk. In addition, risk assessment for industrial uses and uses of explosives was not assessed by the Dossier Submitter as the uses were assumed to be well controlled.
- From a risk perspective, RAC considers that RO1 could increase risk reduction compared to RO2. Indeed, as discussed above, risk at industrial settings and for explosives cannot be excluded. However, RAC acknowledges the need for an exemption for ammunition or explosive articles containing 2,4-DNT for the used by the armed force or the police.
- RAC agrees that alternatives are available as no comments were received to challenge this assumption. However, RAC cannot evaluate the relative risk of potential alternatives that may present in all sectors due to lack of information.

Key elements underpinning the RAC conclusion(s):

RAC agrees that in the absence of a restriction, the use of articles containing 2,4-DNT (a non-threshold carcinogen) might pose a risk to consumers and professional workers that should be addressed.

The following table summarises the three restriction options proposed by the Dossier submitter.

Table 8: Restriction options (Dossier submitter's proposal)

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	Consumer uses	Professional uses	Industrial uses	Articles included in the scope	Exemptions	Risk reduction
RO 1	x	x	x	All articles containing 2,4-DNT including ammunitions and explosives	None but defence exemption might be requested	High all articles and uses are included
RO 2	x	x		Articles containing 2,4-DNT	Explosives and ammunition for military uses and police	Medium Less than RO1
RO 3	x			Articles containing 2,4-DNT	Explosives and ammunition for military uses and police	Low only consumers are covered and some articles are exempted

RAC concluded that the exclusion of professionals from the scope of the restriction (RO3) may be difficult to implement.

The broad inclusion of articles containing the substance under RO1 would lead to a higher risk reduction potential than RO2. The inclusion of the use of articles at industrial settings and explosives for non-military uses may increase the risk reduction capacity of the restriction. In addition, as noted by the Dossier Submitter, it is assumed that except ammunition and explosives, only a low number of articles is foreseen to be in scope. Nevertheless, RAC acknowledged the likely need for an exemption for the articles (ammunition or explosives) by the armed force or the police.

RAC notes that there are some uncertainties relating to the risk reduction capacity of the restriction proposal due to the uncertainties on the uses and articles containing 2,4-DNT. RAC considers that there are significant uncertainties on the evaluation of risk reduction capacity between RO1 and RO2 due to the lack of risk assessment for explosives and industrial uses.

With regards to alternatives, there is no information in the Background Document that would allow to evaluate risks related to the alternatives. However, during the consultation on the Annex XV report, a full composition of an alternative propellant was included (comment #3526#) for vehicle pyrotechnics (e.g. seat-belt pretensioners). The alternative was nitroglycerin (CAS no. 55-63-0). RAC agrees that this substance is less hazardous than 2,4-DNT as it is not classified for carcinogenic properties. However, nitroglycerin is classified in annex VI of the CLP regulation: Unst. Expl. (H200), Acute Tox.2 (H300)*, Acute Tox. 1 (H310), Acute Tox. 2 (H330), STOT RE 2 (H373)**, Aquatic chronic 2 (H411). It is also stated in the Background Document that sodium azide is used in seat-belt pretensioners. It may be noted that, as nitroglycerin, sodium azide is highly toxic to humans. Work accidents in manufacturing industry or ocular injury and facial burns following air-bag deployment have been reported in the literature.

Therefore, due to the acute toxic properties of nitro-glycerine, RAC cannot conclude that alternatives are lower risk. In addition, RAC cannot evaluate the risk of other potential alternatives that may be present in the automotive sector or other sectors due to the lack of information. In particular, RAC has no information whether other toluene derivative (e.g. 2,6-DNT) could be used as potential alternatives.

3.3.2. Socio-economic impact

Baseline scenario

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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.
- 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 on the EU market that contain SVHC in a concentration above 0.1% w/w have to submit to ECHA, via this database, information on affected 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) this 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 EU 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;

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- 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. For instance, comment ref. 1045 to the SEAC draft opinion indicated that Micro Gas Generators (MGG) for seat belt pretensioners and bonnet actuators are imported from the US and from Japan. 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.

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

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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.

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 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 report nor in the consultation on the Annex XV report after submission, 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 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

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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 consumer surplus is 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 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;
- prices of 2,4 DNT-free articles: European and non-European companies will need to keep their market share and market position relative to 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 with more expensive alternatives. In this case, the resulting costs could be passed 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, 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 the 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.

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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 substantial, no quantitative assessment of the benefit expected from this restriction could be undertaken.⁸ This is for three reasons. First, considering the assumptions made in the costs assessment, there are unlikely to be many workers or consumers exposed. Second, typical exposures to 2,4-DNT from various articles are not known. Third, there is no dose-response function available to link exposure to 2,4-DNT to the associated types of cancer.

Therefore, the Dossier Submitter considers 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

Based on the hazard properties of 2,4-DNT, 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 depend on whether alternative substances or technologies are safer for human health and the

⁸ See SEAC's [Reference willingness-to-pay values for monetising chemicals health impacts](#).

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environment.

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.

In addition, SEAC notes that during a call for evidence⁹ held between January and March 2021 prior to the submission of the Annex XV report to ECHA, 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:

⁹ <https://echa.europa.eu/previous-calls-for-comments-and-evidence/-/substance-rev/27201/term>

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

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 	<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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Benefits for the environment and related socio-economic benefits:

- Avoided contamination of the environment
- 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 compliance with the proposed restriction. Testing and sampling methods exist for several matrices, including water, air, and solid waste, explosive etc. The Dossier

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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.

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.

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 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 etc¹⁰). 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 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 benefit 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, 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 EU level. National control campaigns may be launched as a mean to monitor the compliance,

¹⁰ [Hazardous Substances Data Bank \(HSDB\): 1144 - PubChem \(nih.gov\)](#)

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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;
- custom 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:

The Dossier Submitter considered that the extent of the use of the substance is a major uncertainty. However, whilst there is some uncertainty about the pervasiveness of actual uses in and exposures from articles, the consultation on the Annex XV report was expected to test if the Dossier Submitters assumptions were correct. The Dossier Submitter considered that the information received during the consultation confirms that there are articles (probably from import) that contain the substance.

RAC conclusion(s):

Although several sources of uncertainty have been identified in the qualitative risk and effectiveness, overall, the proposed restriction is considered a justified measure.

Key elements underpinning the RAC conclusion(s):

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Uncertainties on scope and uses

There are some uncertainties on the scope of the articles included in the proposed restriction. The scope of the restriction should be clear that "explosives" are those defined in Directive 2014/28/EU. This would address potential misunderstandings in relation to the scope of the restriction with respect to some pyrotechnics articles or ammunition included in class I of the United Nations recommendations. In addition, it should be clear in the condition of the restriction that pyrotechnic articles are those defined in article 3(1) and (4) of Directive 2013/29/EU in order to avoid potential misunderstandings.

The definition of "professional workers" as a use outside industrial installation may also lead to uncertainties. The difference between professional use and industrial use may in some case depends on the context and lead to misunderstanding in relation to the scope. RAC also notes that the use of "industrial site" instead of "industrial installation" may be considered as some industrial sites do not have industrial installations.

The presence and use of 2,4-DNT in some type of articles is considered as a significant uncertainty (e.g. refractory articles, explosives). Most of the information provided by the Dossier Submitter are based on an ECHA technical report dated 2010 and the registration dossier from DNT. There are significant uncertainties on present or future uses of the substance in articles. However, comments from the consultation on Annex XV report confirmed the use of the substance in articles such as seat-belt pretensioners or bonnet actuators in the automotive sector and in the production of ammunition for military use. RAC notes that the general lack of information on uses to be able to assess the Dossier Submitter assessment on these elements.

There are uncertainties on the concentration of 2,4-DNT in articles in the past or at present. Although the concentration limit of 0.1% w/w may be effective to prevent future intended use of the substance in articles, it is unknown if the presence of 2,4-DNT as an impurity in TNT will be in the scope of the restriction.

Uncertainties on risk characterisation

The uncertainties related to 2,4-DNT exposure are discussed in the section "uncertainties in the risk characterisation" for the qualitative assessment.

There are significant uncertainties on the quantitative illustrative examples provided by the Dossier Submitter. There are also significant uncertainties on the parameters used and in the estimation of exposure to articles containing 2,4-DNT. The main uncertainties point to the use of a DNEL and OEL that do not cover sufficiently the non-threshold effects of the substance.

2,4-DNT may accumulate to the environment (soil, surface and groundwater) near the site where the substance. This restriction may allow to reduced potential environmental hazards and risks from the use of 2,4-DNT.

Uncertainties regarding effectiveness (risk reduction capacity):

- The available data do not permit a complete evaluation of risks, mainly due to the missing information on uses and lack of risk assessment for industrial uses and explosives
- One source of uncertainty in demonstrating the effectiveness of the proposed restrictions results in the future import of the substance in articles.
- There are uncertainties regarding evidence that the implemented OC and RMM are sufficient to control the risk at industrial setting or for non-military use of explosive articles. No assessment was performed by the Dossier Submitter and thus RAC is not able to evaluate the difference in risk reduction capacity of RO1 compared to RO2.

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- Information on alternatives and their potential human health and environmental hazards are limited. The only alternative, pointed out during the commenting period by the automotive sector, indicated nitroglycerin, as a potential alternative. However, this alternative is highly toxic and may thus present some limitation for its use. It is unknown if other toluene derivatives could be used as potential alternative.

- 2,6-DNT is generally present in concentration below 2,4-DNT in articles. As this is an even more potent carcinogenic substance compared to 2,4-DNT, RAC recommend to assess in the future the inclusion of DNT and its isomers (e.g. 2,6-DNT) into the scope of the restriction to increase the risk reduction capacity of the restriction.

- Uncertainties regarding implementability and enforceability. Although the sampling methods are expected to exist, some methods may need to be developed for complex articles and specialists may be needed for analysis of ammunitions.

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.

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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 cannot be completely excluded that some unauthorised production is taking place in the EU, but SEAC considers this possibility as highly unlikely.

Moreover, it cannot 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 SiA notifications and self-classifications, it cannot be completely excluded that some other uses at volumes below one ton per year have 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 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 2,4-DNT can no longer be used due to the proposed restriction, some companies would have to transition 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.

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.

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