Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restriction on

2,4-dinitrotoluene

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

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

Adopted

2 June 2022

2 June 2022

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

3 June 2022

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

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

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

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

Chemical name(s): **2,4-dinitrotoluene**

EC No.: **204-450-0**

CAS No.: **121-14-2**

This document presents the opinion adopted by RAC 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**.

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. [4].

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

The opinion of SEAC

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

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

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

[1] Delete the unnecessary part(s)

Contents

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1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Table 1: Proposed restriction by Dossier Submitter

Substance Identity (or group identity)	Conditions of the restriction
2,4-dinitrotoluene, CAS number: 121-14-2 EC number: 204-450-0	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: 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: 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. Uses of articles already in use in the Union before {EIF} containing 2,4-DNT shall be allowed. 5. For the purposes of this entry: a. Professional uses mean uses by workers outside an industrial installation; b. Explosives mean the 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. The restriction should enter into force 12 months after entry into force.

1.1. THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and 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

See opinion of SEAC.

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of proposal

The aim of the restriction is to restrict the placing on the market of articles containing 2,4-DNT that present risk to human health. The proposed restriction also aims at preventing future import of articles containing 2,4-DNT. It targets both consumer and professional users.

2,4-dinitrotoluene (2,4-DNT) is classified under the CLP regulation as carcinogen category 1B, (H350) "may cause cancer" and mutagen category 2 (H341) "suspected of causing genetic defects". The substance is included on Annex XIV of REACH (Commission Regulation (EU) No 143/2011). No applications for authorisation were submitted to ECHA. The restriction proposal has been prepared based on Article 69(2) of the REACH Regulation (EC) No. 1907/2006. ECHA considers that after the sunset date, there are uses of the substance which may lead to a risk from the presence of 2,4-DNT in articles that is not adequately controlled.

2,4-DNT is an isomer of the multi-constituent substance DNT (EC no. 246-83-1).

There is no information available on the current manufacture, import or export of 2,4-DNT in the European Union (EU)/EEA and ECHA has received no registrations for the substance 2,4-DNT (this isomer).

Currently, there is one registration for DNT (>10 tonnes/year) with a life cycle description covering when the substances are used as mixtures in explosives.

The Dossier Submitter considered that there are articles that contain the substance, probably imported on the following basis:

- Two Article 7(2) notifications (substance in articles, SiA): for use as a plasticiser in plastic sample bottles and use in propellants for military ammunition articles.
- The US EPA lists possible uses of 2,4-DNT in sports equipment and in outdoor toys such as sandboxes. No details were available to the Dossier Submitter.
- The SCIP (Substance of Concern In articles) database indicates that there are articles in the EU containing the substance used in vehicles, ceramic articles and electronic devices.

The following articles have been identified from previous or current uses of the substance inside the EU: refractories, automotive airbags and seat belt pretensioners, plastic bottles used in industrial settings for taking samples, propellants for military and civil small-arms ammunition, gelatinising-plasticising agent in explosive compositions, and as a plasticising and waterproofing agent for propellants in gun powders.

DNT is considered as a non-threshold carcinogen and mutagen. DNT exposure in copper mining industry, at ammunition production facilities or in miners has been associated with cancer.

The Dossier Submitter provided examples of professional and consumer exposure to specific articles to illustrate where potential exposure could occur.

For professional uses, the Dossier Submitter indicated potential exposure to 2,4-DNT as a softener in plastic sampling bottles as the substance may diffuse easily in the plastic matrix and migrate from the surface to a contact medium (water, saliva or skin). The Dossier Submitter concluded that the possibility of migration and worker exposure cannot be excluded. The Dossier Submitter further notes that traces of 2,4-DNT may also be found in refractory products, such as fired carbon cathodes.

For consumer uses, civilian small-arms ammunition may contain 2,4-DNT. Exposure *via*

inhalation or dermally may occur after shooting. In addition, risk of dermal and inhalation exposure to 2,4-DNT from deployed seat belt pretensioners and air bags may occur for driver/passengers, emergency responders and repair technicians after automotive accidents.

Based on the examples, risk of exposure for 2,4-DNT cannot be ruled out if it is incorporated in articles. The Dossier Submitter considered that as the substance is a non-threshold carcinogen, 2,4-DNT poses a risk to human health that is not adequately controlled.

To address the risks, the Dossier Submitter conducted an analysis of risk management options (RMOs) identifying for each use the most effective, practical and monitorable measure. The RMOs assessed included regulatory measures under REACH and other existing EU legislation.

The restriction options further assessed by the Dossier Submitter were:

- Restriction option 1 (RO1): restriction on placing on the market of all articles containing 2,4-DNT,
- Restriction option 2 (RO2): 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 art. 68(1) of REACH,
- Restriction option 3 (RO3): Restriction of placing on the market of articles containing 2,4-DNT of use by general public under article 68(2) of REACH.

As a result of the analysis, RO2 has been proposed by the Dossier Submitter. RO1 was considered to entail higher cost but for potential similar risk reduction as industrial uses and uses as explosives are assumed by the Dossier Submitter to be well controlled.

2.2. Summary of opinion

2.2.1. Summary of RAC opinion

The scope of the proposed restriction is clear and sufficiently justified and should cover 2,4-DNT.

RAC notes that the substance is included on Annex XIV of REACH (Commission Regulation (EU) No 143/2011), that no applications for authorisation were submitted to ECHA and that the restriction proposal had been prepared based on Article 69(2) of the REACH Regulation (EC) No. 1907/2006. RAC supports the Dossier Submitter contention that after the sunset date, there are remaining uses within the EU which may lead to a risk from the presence of 2,4-DNT in articles that are not adequately controlled.

Based on the hazard assessment of ECHA's Member State Committee, 2,4-DNT is a non-threshold carcinogen and was identified as a SVHC. As a non-threshold carcinogen a quantitative risk characterisation was not considered appropriate. A qualitative approach to risk assessment and a 'minimisation of exposure' approach to risk management was carried out. During the development of the 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 ammunitions. Other uses have been identified in the past.

The extent of the current use and the presence of imported articles on the EU market is uncertain but potential future import of articles on the EU market may lead to 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 risk for consumers and professionals on a Union-wide level from exposure to 2,4-dinitrotoluene. However, from a risk minimisation perspective, RAC assumed that RO1, which was a restriction on all uses irrespective of setting, such as at industrial installations and for

civilian uses of explosives, would increase risk reduction compared to RO2. RAC noted that the Dossier Submitter had not undertaken a risk assessment for these uses assuming that existing risk management measures were sufficient. RAC did not assessed these uses either and could not therefore rule out the potential for risks for these uses.

RAC concludes in line with the Dossier Submitter that exemption for uses in toys, medical devices and articles intended to come into contact of food or as second-hand articles is justified.

RAC highlighted several potential misunderstandings on the scope, related to explosives and professional uses, and suggested alternative definitions to address these. Uses by workers in industrial installations and non-military uses of explosives is not included 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, but the Dossier Submitter did not assess whether such OCs and RMMs are indeed in place. Acknowledging that it is not within the scope as proposed by the Dossier Submitter, RAC recommends that these aspects may need further consideration outside the context of this restriction.

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

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 implementable, manageable both by industry and National Authorities, 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 sector and aerospace/defence sector) in the consultation on the Annex XV report and one from a Member State. These included a request for derogations for automotive pyrotechnic articles (e.g. bonnet actuators, seat-belt pretensioners) and to support the existing derogation 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 the automotive sector 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 to assess in the future the inclusion of DNT and its isomers (e.g. 2,6-DNT) in the scope of the restriction to increase the risk reduction capacity of the restriction.

2.2.2. Summary of SEAC opinion

See SEAC opinion

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

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

Summary of proposal:

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 amounts 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 that 0.1% of 2,4-DNT then the isomers will also be included in the 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 who are using substances outside of a controlled workplace 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 in most towns of a certain size, 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, all of which are not highly efficient in reducing risk and exposure to the environment will also be difficult to prevent. In addition, the self-employed 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 there 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".

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 points out that the risk reduction capacity of the restriction may in the future be improved by the expansion of the scope to cover all DNT isomers.
- RAC agrees with the proposed concentration limit of 0.1%, as a pragmatic choice for all the articles in the scope of the restriction.
- RAC agrees that the targeting of professional users and 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 installation, where RMM can be implemented, can be minimised. However, RAC notes that the Dossier submitter did not assess whether such OCs and RMMs are in place.
- RAC considered that the definition of explosive 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 the 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 proposal is limited to 2,4-DNT, which is on Annex XIV and whose sunset date has passed. The Dossier Submitter concludes that the use of 2,4-DNT in articles is not adequately controlled in light of article 69(2) of the REACH regulation. The restriction proposal aims to restrict the placing on the market and the use of articles containing 2,4-DNT that present risks to human health and aims to prevent future import of this substance in articles.

RAC considered the concentration limit of 0.1 % w/w of 2,4-DNT, proposed by the Dossier Submitter for all articles, based on the concentration limit applied for substance in Article (SiA) notification and information requirements under REACH, as a pragmatic choice.

The restriction proposal covers the placing on the market but also cover the '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 human health as a primary concern is justified due to the concern identified for the mutagenicity and carcinogenicity as a consequence of potential 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 may be present in mixture with 2,4-DNT. 2,6-DNT has been considered as 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 2,6-DNT a complete hepatocarcinogen (ACGIH, 2001). RAC agrees that as 2,6-DNT is often found in smaller amounts than 2,4-DNT and in case articles contain 2,6-DNT ≥ 0.1%, they will usually be covered by the restriction proposal on 2,4-DNT. Nevertheless, potential cumulative risk could be relevant as at least the two isomers 2,4-DNT and 2,6-DNT share common carcinogenic and mutagenic properties. The non-inclusion of DNT in the scope of the restriction may lead to underestimation of the risk in 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 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, no detail is given in the difference between the two. The current R.12 IR/CSR guidance defines professional use as" *The terminology "industrial" and "professional" is used in two different contexts:*
- To differentiate between life cycle stages,
- 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."
The document also highlighted that some cases could be considered borderline. As an example car 'repair and finishing', that may be relevant in the case of 2,4-DNT, was described as a borderline case.

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 (Chemical Agent Directive and Carcinogens and Mutagens Directive). In addition, RAC agrees with the Dossier Submitter that the risk can be minimised where OCs and RMMs can be implemented at industrial sites. 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. In the CSR, a threshold-based DNEL was derived, which may not appropriately address the risk of workers in the handling of explosive articles containing 2,4-DNT if such articles exist. There is also no information in the CSR on potential exposure assessment and risk characterisation. In addition, a response in the consultation (#3541) indicated there are several defence exemptions that allow for the continued use of 2,4-DNT in the production of propellants that are later used in the production of (military) ammunition. However, RAC notes that no risk assessment for these uses was made by the Dossier Submitter. The effectiveness and practicality, including enforceability, 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 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 to include in the conditions of the restriction, the definition of pyrotechnic articles as those articles may be also considered as mixtures in containment. 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 pyrotechnic substance, or article containing 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 are 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 use 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 the explosive with bare hands leading to dermal exposure. In addition, miners were exposed to inhalation of fumes after explosion. Brüning *et al.* reported cancer in a group of miners (Brüning *et al.*, 1999). In the document developed in the context of 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 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/EU[2] 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. RAC notes that in this Directive there is no requirements on hazardous properties, risk assessment or measures foreseen to protect human health.
- 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 CM Directive) apply to protect workers using 2,4 DNT and TNT. Several national OELs also are in force.

Overall, there are specific provision 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 existing measures at national levels were provided by the Dossier Submitter and it is unknown whether it would be in place in all EU countries. As there are no specific EU measures related to chemical safety hazard for the use of explosive, 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 sufficiently cover the non-threshold carcinogenic risk of the substance.

RMM may be difficult to be 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.

[2] 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).

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

3.1.3. 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 Annex XV report. 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 for 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/m^3 and the long-term derived no effect level (DNEL) of 0.009 mg/m^3 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.
- RAC agrees to use a qualitative approach to risk assessment and minimisation of exposure as 2,4 DNT is a non-threshold carcinogen. Genotoxicity is a likely underlying MoA 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 risk potentials of 2,4-DNT, being a non-threshold carcinogenic substance. Furthermore, it is not clear how the DNEL for the general population was derived. Therefore, RAC views the Dossier Submitter's quantitative approach only as illustration to support the need for a restriction but not as an acceptable approach.

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 a 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 risk assessment report (RAR) on 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).

Dermal absorption is also possibly a significant route of entry for 2,4-DNT as shown in worker occupational exposure studies. Woolen *et al.* suggested that in DNT manufacturing plant operators, within industrial settings, skin contact may be the most important exposure pathway, resulting in absorption of significant quantities of the substance (Woolen *et al.,* 1985). 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-month 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 RAC, 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 a 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 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/m^3. 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/m^3 was intended to minimise the potential for low-grade anemia and neuromuscular, hepatic, renal and reproductive effects. They retained 0.2 mg/m^3 as a rounded value as this would not change the degree of protection of workers compare to 0.15 mg/m^3.

In the registration dossier of DNT, the DNEL for long-term effect by inhalation was set at 0.3 mg/m^3.

In 2019, Safe work Australia recommended a TWA of 0.5 µg/m^3 (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 minimised exposure.

In the EU RAR, for carcinogenicity, 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 risks 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/m^3 is obtained (14.34*1/0.384*6.7/10*2.8). Using the large assessment factor approach a DMEL of 22 µg/m^3 would be calculated (=70.1/3,125), which is 147 fold 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/m^3 by the Dossier Submitter is a pragmatic way forward to support the current restriction proposal. RAC notes that the use of a pragmatic OEL instead of a DMEL, not based on cancer, may underestimate the risk.

Existing general population exposure limit for 2,4-DNT

For consumer risk assessment, the long-term DNEL derived by the registrant of DNT was used

by the Dossier Submitter. The Dossier Submitter 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/m^3 is obtained as using default assessment factors (ECHA guidance R8) would not lead to this value. In addition, in the registrant's chemical safety report (CSR) of DNT, a DNEL for 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/m^3, the proposed value of 0.009 mg/m^3 seems rather conservative. Indeed, in a practical approach deriving the consumer DNEL from the worker DNEL, a default DNEL of 0.04 mg/m^3 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 pragmatic 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/m^3 for the general population (=T25/25 000) would be obtained, which is approximately 14- fold lower than the long-term DNEL used by the Dossier Submitter. RAC notes that this DMEL should not be consider as a safe level but indicates that the DNEL will underestimate the risk.

Overall, RAC agreed to use the exposure limit values proposed by the Dossier Submitter only to illustrate a risk and support the need of a restriction but consider that these values are not sufficiently protective of the carcinogenic potential of the substance (non-threshold effects).

3.1.4. Information on emissions and exposures

Summary of proposal:

Current or previous uses of 2,4-DNT have been identified in various articles, i.e. temperature specific cross-linking agent for refractories, automotive airbags, seat belt pretensioners, plastic bottles used in industrial settings for sample taking purposes, propellants for military ammunitions, gelatinising-plasticising agent in explosive compositions, and as a plasticising and waterproofing agent for propellants in gun powders. However, only two notifications of a SiA have been made under Article 7(2) for 2,4-DNT; one for the use of 2,4-DNT 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 articles.

The Dossier Submitter also refers to the US EPA chemical products and database that indicate potential other uses of 2,4-DNT that has not been previously identified in the EU market with potential consumer exposure: products used outside the home, including outdoor toys, canopies and shelters, 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 as ECHA has not received any authorisation for applications for this substance and has no information if 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 pervasiveness of actual uses in and exposures from articles, it is likely that exposure to 2,4-DNT via consumer and professional articles does occur 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

SiA notification reported a use of 2,4-DNT in plastic sampling bottles as a softener 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 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 in the plastic matrix and partition from surface to contact medium (water, saliva or skin).

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

The Dossier Submitter provided a brief overview of the use of the substance as available in the technical report in 2010. 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 authorisation for application 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 cars in seatbelt pretensioners and bonnet actuators, although in smaller quantities than assumed in the Dossier Submitter's original estimation. 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 provided quantitative estimates for the use of 2,4-DNT in ammunition. The Dossier Submitter also initially proposed a scenario (ES3) on seatbelt pretensioners and airbags. However, the scenario was removed as this would only be relevant during an accident when the system reacts and was only included to illustrate a risk using the available threshold based national OELs and not related to the non-threshold effects of the substance. In addition, the Dossier Submitter noted that there are likely to be further potential uses in articles for other consumer uses but that there are limited information on any potential exposures.

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

SiA notification reported a use of 2,4-DNT in ammunition. 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) - Outside hunting - Indoor shooting		10 50	None
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 *et al.*, 2011
Release to air (%)	80-100%		None
Exposure duration (h) - outside hunting - indoor shooting		2.5 1	None
Volume/room (m^3) - outdoor - shooting galleries		100 m^3 20 m^3	None
Dilution factor - outdoor - indoor		0.6 2.5	ECETOC TRA consumer V.3.1.
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/m^3 and 1.63 mg/m^3 was obtained for professional and 0.02 to 2.18 mg/m^3 for the general population. For outdoor shooting, exposure was calculated between 0.0004 and 0.039 mg/m^3 in workers and 0.0005 and 0.052 mg/m^3 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. Human *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 the pyrotechnic version of pretensioner. An explosive charge causes the gas generator to produce a volume of gas and thus pressure which acts on a mechanical linkage to pull the seat belt. The pretensioner needs replacing after deployment. The deployment consumes the explosive in the seat belt assembly. The Dossier Submitter assumed that if the substance is used in these applications there will be releases to the interior air 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 attending accident sites often e.g. the police or fire personnel. 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 intended[3]. 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 data available in 2010 technical report 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 has been confirmed during the consultation on the Annex XV report. However, RAC notes that information on the current amount of imported article and on the use 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 scenario used as illustrative examples by the Dossier Submitter provides some evidence that there is potential for inhalation exposure to 2,4-DNT from professional and consumer articles. Nevertheless, due to the high uncertainties identified in the parameters used in the scenarios, the extent of the 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

In 2010, according to the technical report (2010), DNT was manufacture and used in the production of toluene diisocyanate (TDI) and toluene diamine, which are intermediates in the making 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 for the manufacture of ammunition. Propellants which contain DNT can be used for both military ammunition and

[3] https://www.ford.co.uk/content/dam/guxeu/uk/useful-information/reach/Art-33-1-Information-Example-U502-Explorer.pdf

recreational (hunting/sporting) ammunition. Nevertheless, in 2010 it was stated by one of the leader in civilian ammunition that DNT has been largely abandoned in civilian ammunition. The report also stated that DNT had been used in the past intentionally 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 in 2010.

Currently, there are 5 active registrations for DNT and 2 joint submissions but none for 2,4-DNT itself. The first joint submission includes 4 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, actual or future potential tonnage of 2,4-DNT in the articles in the scope placed on the EU market and leading to exposure to the general population or professional workers.

As no applications for authorisation were received, the Dossier Submitter assumed that the uses of 2,4-DNT in articles are related to import. There is no current registration of the substance. The Dossier Submitter has no information if there is manufacture for exempted use or for export. However, a response in the consultation on the Annex XV report (#3541) indicated there are several defence exemptions that allow for the continued use of 2,4-DNT in the production of propellants which are later used in the production of (military) ammunition. This would mean no authorisation applications for these exempted uses were required.

Nevertheless, there two REACH substances in articles notifications (Art. 7(2)) have been submitted in the past. The first is for the use 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 use 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 manufacturer according to Article 33 of REACH, e.g. Toyota and Ford[4]. This was confirmed during the consultation on the Annex XV report.

According to the SCIP database, companies supplying articles containing SVHC substances in a concentration above 0.1% w/w on the EU market have to submit information on the articles to ECHA, as from 5 January 2021. Information in the database on articles containing 2,4-DNT is available throughout the whole lifecycle of products and materials, including at the waste stage. The articles included in the database were mainly include in article category electronic equipment and their parts but the substance was also notified in 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 cover the whole life cycle). Nevertheless, it may be noted that 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 supportive 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 the substance that may lead to potential exposure or on potential legacy use 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 for the use of 2,4-DNT.

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 products and database that indicate potential other uses of 2,4-DNT (e.g. outdoor lighting or power equipment). However, RAC has no information whether these articles could potentially be on the EU market in the future.

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)

[4]https://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&usg=AOvVaw15sytWN_78pxTfiJITxILL

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 human.

The Dossier Submitter provided qualitative illustrative example for professional workers on some specific articles that may results 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/plasticizers. To exert its function, 2,4-DNT need to be use at high concentration. According to the Dossier Submitter, the concentration of plasticizers need to be 35%.

There are no migration data on 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 under food contact material to estimate the diffusion coefficient of plasticizers in soft PVC, high value of the diffusion for a given temperature would be given for 2,4-DNT. Diffusion is inversely proportional to molecular weight and 2,4-DNT as a relatively low molecular weight (183 g/mol). Solubility and Log K_{ow} are also important parameter in the partition between the plastic material and 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 leads to uncertainties. Indeed, there are uncertainties in the migration rate as there are no specific data on the type of plastics and the plastic matrices containing the substance. As discussed with phthalates, the migration may greatly vary depending on multiple factors, such as the 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 greatly differ from phthalates and comparison with these compounds may not be fully appropriate. Nevertheless, RAC agrees that undercertain conditions, exposure to 2,4-DNT may occur.

There are uncertainties whether the plastic articles containing the substance could be in contact with professional or consumers that are under the scope of this restriction proposal. Indeed, for example, the use of sampling bottles were 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 effect. 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 hypothesis.

- *Explosives*

No specific information on potential exposure were provided by the Dossier Submitter in this section except 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 also unclear whether authorisation would apply to this use as 2,4-DNT is present in mixture 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, that manipulated the explosive with bare hand. Miners were exposed dermally. In addition, miners were also exposure to inhalation of fumes after explosion. Cancer has also been reported in a group of miners exposed to 2,4-DNT (Brüning *et al.*, 1999).

Exposure of worker may also occur from demilitarisation of explosives and ammunition and releases from waste stage. Professional worker exposure may occur during the disposal of military waste. There are uncertainties on the amount of releases as it will depend on environmental condition, the type of barrels. 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 results 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 results in exposure to 2,4-DNT. Exposure can occur indoor or outdoor. There are many ways to define small arms. Small arms cover at least pistols and rifles in the Background Document. In small arms cartridges, 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 accumulation of residues in the surface soils of 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 a gun barrel. The residues will contain the constituent 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 trapped the components within the matrix.

Walsh *et al.* analysed the soil at 1.05 meters from several howitzer firing points in Alaska (Walsh *et al.*, 2007). 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 a particulate form. 2,4-DNT seems to remain in the nitrocellulose matrix of single-base propellants as discrete fibers were distributed on the soil surface. Most of the analyte of interest containing 2,4-DNT was found in the 0.595 to 2 mm range. Walsh *et al.* 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%. Concentration 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 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 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 m^3 for outdoor as a room volume requires explanation. 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 m^3). 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 outdoor is uncertain and may overestimate the risk. Moreover, 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 is in the opinion that the assumptions used for the exposure scenario are doubtful and would be expected to lead to 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 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/m^3 for outdoor and 0.015 to 2.18 mg/m^3 for indoor.

Although not taken into account by the Dossier Submitter, RAC notes that dermal route could be a significant relevant route of exposure as dermal absorption is expected to occur. Hofsteffer *et al.,* indicated that gunshot residues can be found form hands and other part of the upper body of the shooter including clothing (Hofsteffer *et al.*, 2017). No exposure assessment was proposed by the Dossier Submitter by this route and this may underestimate the risk of cancer. 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 for automotive application as a micro gas generator in safety critical pyrotechnic application. 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 when coming into contact with the bonnet and engine components. Secondly, as described by the Dosser 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 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. Persons present in on the vicinity of a car accident may be exposed for a short period of time but more frequently than the person inside the car. In addition, during the disposal of car, 2,4-DNT may be release 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. Professional may be exposed chronically, mainly by dermal route, during maintenance/repair.

- Other articles

There are a number of other potential use in articles, but 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 the 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.* 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 (Walsh *et al.*, 2011). 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.

3.1.5. 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 exposed human via environment. The Dossier Submitter concluded that exposure potential of 2,4-DNT in any plastic articles as 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. Finally, a risk to humans from imported articles cannot be excluded.

The Dossier Submitter also pointed out 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 risk characterisation, the Dossier Submitter quantitatively assessed the human health 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 the Dossier Submitter described it 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-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 estimations 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 people (comparison with DNEL), if 2,4-DNT is released to the interior of the car was calculated to be RCR= 33 considering 30% release and RCR= 11 considering 10% release for 5 airbags/seatbelt pretensioner. RCR 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 acknowledges to be a non-threshold carcinogen.

RAC conclusion(s):

- As 2,4-DNT, is a non-threshold carcinogen, it is neither possible nor feasible to perform a quantitative risk assessment based on the available data. 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 is addressed by preventing the placing on the market and use of articles containing 2,4-DNT.

- The extent of the current use and the imported articles currently present on the EU market is uncertain but potential future import of articles on the EU market may lead to risk to human health.

- Quantitative risk assessment provided, as illustrative examples, to support the restriction proposal is uncertain. However, the exposure and risk assessment support 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 on the current use of the substance in articles. However, at least for some articles (seat-belt pretensioner, ammunition), the presence of 2,4-DNT was confirmed.

With regards to seat-belt pretensioner, also exposure to people inside the car may lead to potential exposure in certain conditions. Although risks is associated with a very infrequent exposure, professional may be exposed during car maintenance/car repair chronically exposed to the substance.

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

Risks from other articles notified outside 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.

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 manufacture or used, such as munitions sites. Thus, exposure to the general population may occur near areas where 2,4-DNT is used. Nevertheless, according to Walsh *et al.,* DNT was not found in groundwater in training contaminated site (Walsh *et al.,* 2007; Walsh *et al.,* 2011). Thus, the substance, 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 the substance in small arms ammunition, there are evidence that regular practicing (e.g. at shooting ranges) may lead to exposure and risks by inhalation. In addition, exposure to dermal and oral route is also likely and was not taken into account, leading to an underestimation of the risk. RAC also notes that the use of OEL and DNEL, not based on the carcinogenic potential of the substance, underestimate the risk, at least 150 fold for the OEL and 15 fold for the DNEL used by the Dossier Submitter, considering a DMEL approach.

3.1.6. Uncertainties in the risk characterisation

a. Qualitative risk characterisation

- There are significant uncertainties on current use. There is a high reliance on data available in 2010, which may not have been representative of whole EU situation. There are few information on current use 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 comment from the consultation on the Annex XV report that there may be existing defence exemption that allow the continuous use of 2,4-DNT in the production of propellant later used in the production of 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	↑↓
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 quantitative illustrative example is unknown as the current use of the substance is uncertain. No real data were available to estimates if the proposed scenarios are realistic worst case. Both overestimation and underestimation of exposure parameters were noted.

- In addition, quantitative risk point toward an underestimation because of the

uncertainties around the DNEL and OEL which does not fully take into account the potent non-threshold based carcinogenic potential of the substance.

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

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

Summary of proposal:

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 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).

3.1.8. 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)[5]. 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 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 is very limited and product-specific and, considering the uncertainties concerning the presence of 2,4-DNT in those articles, none of the above-mentioned EU legislations would be suitable for managing the identified risks and reducing exposure to the substance.

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 concluded that a risk of carcinogenicity from exposure to 2,4-DNT for military personnel and other users of artillery ammunition cannot be excluded. Furthermore, aggregated exposure to 2,4-DNT from firing artillery ammunitions and other explosive articles

[5] 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)

such as small arms ammunition cannot be excluded through environmental accumulation and subsequent human exposure. Finally, the Dossier Submitter concluded that a risk to humans from imported articles cannot be excluded.

The main justification for action on a Union-wide basis to address the risks associated with EU manufactured or imported articles containing 2,4-DNT are:

- To ensure a harmonised high level of protection of human health across the Union;
- To ensure the free movement of goods within the Union, where relevant.

The Dossier Submitter considers that taking regulatory actions at a national or local level would be neither effective nor efficient since these 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 risks associated with this restriction 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 considers that a Union-wide action is needed to address the risks associated with (mostly imported) articles containing 2,4-DNT 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

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 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 possibly 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.

- 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 areas 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 prevent risk.

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 article 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 more comparable to consumers in the use of articles than it is the case with substances and mixtures. When handling articles, no special measures are usually taken to protect against SVHCs that may be present in the article. However, also for industrial workplaces 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 situations 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 long enough 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 prevent any relevant risk, namely from imported articles. For imports into the EU, RAC considers that a transition period is mainly needed to allow current importers to purchase different articles not containing 2,4-DNT.

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 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 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 use 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 later used in the production of (military) ammunition, confirming that this exemption would 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 IEF of the restriction. The restriction proposal only targets articles that are place on the EU market for the first time. This follows enforcement issue as it may be difficult as the user may not be informed of the presence of the 2,4-DNT in such 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 5 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 Background Document pointed out that quantitative assessment was included to illustrate a risk using the available threshold based national OELs and not related to the non-threshold effects. 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 may have led to both underestimation or overestimation of the risk.

Justification for the opinion of SEAC

See SEAC proposal.

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 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)

	Consumer uses	Professional uses	Industrial uses	Articles included in the scope	Exemptions	Risk reduction
RO1	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
RO2	x	x		Articles containing 2,4-DNT	Explosives and ammunition for military uses and police	Medium Less than RO1
RO3	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 inside 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 on 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 R2 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

Justification for the opinion of SEAC

3.3.2.1. Costs

See SEAC opinion.

3.3.2.2. Benefits

See SEAC opinion.

3.3.2.3. Other impacts

See SEAC opinion.

3.3.2.4. Overall proportionality

See SEAC opinion.

3.3.2.5. Uncertainties in the proportionality section

See SEAC opinion

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 that there are alternative articles. In addition, the proposed restriction gives sufficient time to the impacted supply chains to transition. The measure is enforceable as authorities can set up efficient supervision mechanisms to monitor industry's compliance with the proposed restriction. Testing and sampling methods exist for several matrices, including water, air, and solid waste, explosive, *etc*... The Dossier Submitter assumed that suitable methods can be further developed to enforce the restriction. In addition, the Dossier Submitter believes that the restriction is manageable by industry and authorities.

RAC and SEAC conclusion(s):

Although all aspects on the implementability and the enforceability have not been fully elaborated, RAC and SEAC consider that the proposed restriction seems to be practical, as 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 Authorities. 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 please 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, National Enforcement Authorities (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, the proposed restriction is implementable by 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 up to now, RAC and SEAC consider that the proposed restriction appears to be implementable. More information on this point might come from the industry during future consultations.

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 of the EU Member States can set up efficient supervision mechanisms for the proposed restriction.

In fact, 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). Indeed, since SiA notifications have already been reported, information requirements are already foreseen under REACH and some methods are described in the scientific literature for several matrices (including water, air, solid waste, explosives etc[6]). 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 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 might benefit from a derogation due to the difficulties that their enforcement would cause to National Enforcement Authorities.

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

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 procedures 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.

In addition, RAC notes that most of commercial laboratories may not be able to handle ammunition because it requires a specific level of competence, including ammunition-related specialists.

RAC and SEAC note that none of the points for clarification raised by the Forum is challenging the enforceability of the restriction proposal.

In line with the Forum, RAC and SEAC consider that the exemption for second-hand articles will highly contribute to the enforceability of the proposed restriction.

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

3.3.4. 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, 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 effectiveness of the restriction provided that regular national control campaigns are performed (e.g. on complex articles such as seatbelt pretensioners and airbags, ammunition or other complex articles).

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

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

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

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

3.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

3.4.1. RAC

Summary of proposal:

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):

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 on 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 the 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 pretensioner or bonnet actuator 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.

- Information on alternative 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) in 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

See SEAC opinion.

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