Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

TDFAs: (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives

ECHA/RAC/RES-O-0000001412-86-142/F

ECHA/SEAC/ RES-O-0000001412-86-150/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 10 March 2017) and SEAC's opinion (adopted 15 June 2017)

10 March 2017

ECHA/RAC/RES-O-0000001412-86-142/F

15 June 2017

ECHA/SEAC/RES-O-0000001412-86-150/F

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

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

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

Chemical name(s): ***TDFAs:(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives***

EC No.: N.A. (group entry)

CAS No.: N.A. (group entry)

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. 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 public consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

Denmark 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: http://echa.europa.eu/web/guest/restrictions-under-consideration on **15 June 2016**. Interested parties were invited to submit comments and contributions by **15 December 2016**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION **OF RAC:**

Rapporteur, appointed by RAC: ***Yvonne MULLOOLY***

Co-rapporteur, appointed by RAC: ***Agnes SCHULTE***

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 ***10 March 2017***.

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

ADOPTION OF THE OPINION **OF SEAC**

Rapporteur, appointed by SEAC: ***Åsa THORS***

Co-rapporteur, appointed by SEAC: ***João ALEXANDRE***

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 **16 March 2017*.***

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

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

The draft opinion was published at ***https://echa.europa.eu/restrictions-under-consideration*** on ***22 March 2017***. Interested parties were invited to submit comments on the draft opinion by ***22 May 2017***.

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 ***15 June 2017***.

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

The opinion of SEAC was adopted ***by a simple majority*** of all members having the right to vote. The minority position, including its grounds, is made available in a separate document that has been published at the same time as the opinion.

Contents

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is as follows:

(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives, including among others: (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)trimethoxysilane CAS No. 85857-16-5 EC No. 288-657-1 (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)triethoxysilane CAS No. 51851-37-7 EC No. 257-473-3 (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)triisopropoxysilane – CAS No. 1240203-07-9	Conditions of the restriction 1. Shall not be used in the formulation of mixtures with organic solvents in spray products intended for supply to the general public. 2. Shall not be placed on the market, in a concentration equal to or greater than 2 ppb by weight, in spray products containing organic solvents for supply to the general public. 3. Spray products should in this context be understood as aerosol dispensers, pump and trigger sprays and mixtures marketed for spray application by any means. 4. Organic solvents mentioned in paragraph 1 and 2 include organic solvent used as aerosol propellants.

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 proposed restriction on **mono-, di- or tri-O-(alkyl) derivatives of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol *(TDFAs)*** and **3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol** 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, provided that the scope and conditions are modified, as proposed by RAC.

The conditions of the restriction proposed by RAC are:

Substance Identity (or group identity)	Conditions of the restriction
	1. Shall not be (formulated/used) with organic solvents in the manufacture of spray products which are for supply to the general public. 2. Shall not be placed on the market, in a concentration equal to or greater than 2 ppb by weight of the mixture, in spray products containing organic solvents, for supply to the general public.

(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives, including among others: (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)trimethoxysilane CAS No. 85857-16-5 EC No. 288-657-1 (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)triethoxysilane CAS No. 51851-37-7 EC No. 257-473-3 (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)triisopropoxysilane – CAS No. 1240203-07-9	3. Organic solvents referred to in paragraph 1 and 2 also include organic solvents used as aerosol propellants. 4. For the purpose of this restriction spray products should be interpreted as any aerosol cans, pump or trigger (impregnation/proofing) spray. 5. Paragraph 1 & 2 shall not apply to spray products for use by professionals. Spray products for use by professionals shall be labelled "for professional use only". 6. REACH Annex II Section 2.3 (Other Hazards) shall contain the following information. Mixtures of TDFA's in a concentration equal to or greater than 2ppb and organic solvents intended for professional use shall be labelled "fatal if inhaled". 7. This restriction shall entry into force on the "date".

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on ***3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives,*** is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope or conditions are modified, as proposed by RAC or SEAC, as demonstrated in the justification supporting this opinion.

The conditions of the restriction proposed by SEAC are:

Substance Identity	Conditions of restriction
(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives, including among others: (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)trimethoxysilane CAS No. 85857-16-5 EC No. 288-657-1 (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)triethoxysilane CAS No. 51851-37-7 EC No. 257-473-3 (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)triisopropoxysilane CAS No. 1240203-07-9	1. Shall not be placed on the market in mixtures with organic solvents in proofing/impregnation spray products for supply to the general public in a concentration equal to or greater than 2 ppb by weight. Spray products should in this context be understood as aerosol dispensers, pump and trigger sprays and mixtures marketed for proofing/impregnation spray applications. 2. The products should be labelled with information that the product can only be placed on the market for professional use.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

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

Summary of proposal:

The main objective of the proposal is to reduce or prevent consumers' exposure to mixtures containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol/TDFAs and organic solvents in spray products intended for use by consumers across all EU Member States. The main risk is not related to (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives but is associated with the hydrolysis and condensation products of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives in combination with organic solvents.

The scope of the restriction proposal is targeted at all spray products containing organic solvents and (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives on the market for supply to consumers and the general public which are manufactured in the EU or imported into the EU. The mixtures are sold in different forms of packaging, one packaging type allows application in spray form (aerosol cans, pump or trigger spray) and the other packaging type allows for alternative methods of application such as a brush or a cloth. **The proposal only targets the forms sold in packaging that permits spray application i.e. aerosol cans, trigger and pump sprays and not the form that is sold for brush or cloth application.** Inhalation of aerosol particles in the respirable range is the exposure route of concern. Using alternative application methods e.g. application by brush, roller or using a cloth will not result in the formation of respirable or inhalable particles.

The concern presented in the proposal relates to mixtures of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents that are used to provide water, stain and oil repellent properties to different surfaces when applied as a spray by aerosol dispensers, pump or trigger spray. These products are often referred to as 'stain proofing', 'water proofing', 'impregnating" or "sealing" sprays. Note: For the purposes of the opinion RAC has used the term "impregnating" to describe these group of uses/products.

The active substances in the mixtures are hydrolysed (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives monomers dissolved in a solvent. After spraying, the solvent vaporises and the (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives remain on the treated surface by forming a polysiloxane-based (polymer) coating with polyfluorooctyl as a side-chain which provides the water and oil-proofing coating.

Mixtures of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents appear to account for a minor part of the total consumption of impregnating sprays. It is estimated that 20-40% of the 725 incidents reported in the EU were most likely related to spray products that contained (3,3,4,4,5,5,6,6,7,7,8,8,8-

tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents intended for use by the general public. While professionals are expected to be the main group of users of these impregnating mixtures, consumers are expected to account for a higher share of the users of these impregnating mixtures sold in spray product form. Spray impregnating products containing mixtures of TDFAs and organic solvents are marketed for application to non-absorbing surfaces.

The Dossier Submitter considers the risks of lung injury from spray "impregnating" products, containing mixtures of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents, as potentially high and likely to occur in every EU country because "impregnating" spray products are distributed in several Member States.

The type of spray containers can be divided into two classes:

(i) aerosol spray cans, which use the expansion of a prepressurized propellant gas to drive out the aerosol, and

(ii) pump and trigger sprays, which operate by means of mechanical force.

Over the last three to four decades many cases involving spray "impregnation" products resulting in respiratory effects were observed in several Member States. The incidents have ranged from single occurrences to larger out break occurrences. The "impregnation" products associated with the incidents were marketed for either non-absorbing and/or absorbing surfaces. Very little information is available on the chemical identity of the polymeric active ingredients, as their active ingredients are usually present in low concentrations and the products have in general only been classified and labelled by the formulator according to the organic solvent properties and its content in the product.

While a number of incidents involving proofing sprays among the general public have occurred, where respiratory effects and hospitalisation were observed, unfortunately data from the national poison centres on the composition of the products involved (including identification of the active ingredient) was not confirmed. Nor has, data on the exact composition of the substance been obtained from the manufacturers of these products or during the public consultation.

While a number of the products contained fluorinated or fluorocarbon compounds (silanes, polymers, others) no robust information about the occurrence of fluorinated compounds in combination with a solvent could be derived to explain the observed intoxications. Thus, other fluorinated compounds were not included in the scope of this restriction proposal. The reported human incidents demonstrates a relationship between short term exposure to certain proofing/impregnation sprays and the development of respiratory illness.

It has been shown that aerosolised mixtures of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents can cause serious acute lung injury in mice. The mechanism behind the observed effects has been studied in mice and is believed to involve inhibition of the pulmonary surfactant in the deeper parts of the lungs (bronchioles) by depletion of the pulmonary surfactant protein, SP-B. The SP-B protein is embedded in the phospholipids of the pulmonary surfactant, and it is believed that the solvents (depending on their octanol-water partitioning coefficient) facilitates contact

between hydrolysates and condensates of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and the SP-B proteins. This may also explain why no effect on the lungs are seen for spray products based on hydrolysed (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives where water is the solvent when these mixtures reach the bronchioles (particle size <10 µm). Thus, the toxicity of the products in rats and mice depends on hydrolysates and condensates of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives, the solvents, particle size distribution and particle concentration. This rationale can explain numerous cases where consumers have experienced acute pulmonary distress following proofing/impregnation spray products containing fluorinated substances. The Dossier Submitter has justified the proposed restriction on the basis of risks to human health from such impregnating products containing mixtures of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents.

The restriction proposal notes, that at present, no consumer spray product appears to be on the EU market that contain mixtures of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents. Information from the Swedish Product Registry obtained during the public consultation identified that (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives were used in 4 spray products for non-absorbing surfaces, three of these were reported between 2010-13 and three contained organic solvents. Since 2014 (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives in consumer impregnation products are no longer registered in Sweden.

The Dossier Submitter has confirmed that the intention of the use of the term "spray" is to cover all types of spray products containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvent (not just impregnating products) for supply to the general public. The justification provided by the Dossier Submitter is that if at some time in the future other product uses were identified and placed on the market in spray products they would pose the same risk as impregnation/proofing sprays. This would be a precautionary restriction approach for other potential but currently unknown uses.

RAC conclusion(s):

RAC agrees that the scope of the proposal in the dossier is clear, however, RAC has suggested some amendment to the proposed legal text to provide additional clarity that the focus of the restriction proposal is to address both the EU manufacture/formulation of sprays products along with the import of spray products from outside the EU.

RAC notes the only reported uses of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents mixtures in the restriction proposal is for 'stain proofing', 'water proofing', 'impregnating" or "sealing" sprays.

RAC agrees that the risks associated with pump sprays are likely to be lower based on the lack of supporting human cases involving pump sprays including the NFP1 product that was studied in animals whose results are the basis for the proposed restriction.

RAC recommends that Safety Data Sheets (SDS) for 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives should in Section 2.3 (Other Hazards) contain the following information: Mixtures of TDFAs and organic solvents, intended for

professional use, shall be labelled *"fatal if inhaled"* to ensure workers and professionals are aware of the hazards associated with using these mixtures.

Following advice from the Forum, RAC supports that professional products of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents should be labelled "for professional use only".

Following advice from the Forum, RAC supports a clear indication of an entry into force date in the legal text entry of Annex XVII.

Key elements underpinning the RAC conclusion:

While the cases reported involving impregnation products are likely to be linked to their use, the cause of sudden outbreaks of respiratory disorders associated with impregnation products remains unknown. The dossier has indicated that such outbreaks have been linked to changes in the aerosol nozzle spray design in products that were previously on the market with no effects reported, and/or associated with a change in the type of organic solvent used.

Toxicity is dependent on the concentration of aerosol in the respirable range (conc. of mist with an MMAD (Mass Median Aerodynamic Diameter) <10 µm) (Yamashita et al 1997b[1]). Parameters such as application pressure, type of nozzle and volatility of the mixture influence mist aerodynamic particle size. The importance of the concentration of MMAD particles <10 µm to toxicity for impregnation/proofing sprays was also recognised in some countries around the world. A Japanese Aeorosol Industry Association voluntary guidance recommended that the ratio of aerodyamic particles <10 µm should not exceed 0.6% (Kawakami et al. 2015, based on measurements at 15 cm distance from the nozzle). Studies on different aerosol sprays have also documented variations in the percentage of particles <10 µm in different types of aerosol sprays, ranging between 0.1% to 18% (Delmaar & Bremmer, 2009) [2].

RAC agrees that the dossier has provided evidence of acute inhalation toxicity from impregnation/proofing aerosol products but the incidence data alone is not robust. RAC agrees to the use of the evidence from animal data, as the test mixtures of TDFA and isopropanol used in the animal study by Norgaard was nebulised and therefore available for inhalation in the respirable range. The data indicates that based on the most conservative DNEL of 0.068 mg/m³, the fraction of particles with an MMAD <10 µm should not exceed 0.6%. However no data is available to inform about the concentration limits of the ingredients in the formulation that produces less than 0.6% of <10 µm particles.

While evidence has been provided that aerosol sprays achieve sufficient concentrations in the MMAD range (<10 µm) (Magic Nano cases), limited evidence has been provided to support that mists generated from pump sprays reach low level concentrations in the MMAD range <10 µm. Losert et al. 2015 indicated that impregnation spray applications using pump spray generate particles in nanometer sizes.

Koch et al. (2009) estimated that about 0.9% of particles in the pump spray were <10 µm however the analytical methods used by Koch et al. (2009) were not appropriate to characterise particles in the Nano size scale. No human incidents were reported in the pump

[1] Yamashita M., Yamashita M., Tanaka J., et al(1997b) Toxicity of waterproofing spray is influenced by the mist particle size.VetHum Toxicol39, 332-33

[2] Delmaar J.E., & Bremmer H.J. (2009) The ConsExpo spray model; Modelling and experimental validation of the inhalation exposure of consumers to aerosols from spray cans and trigger sprays.

spray product (NFP1) that was studied intensely in the animal studies by Norgaard et al. before it was removed from the Danish market in 2010. In addition, no human incidents were reported for the pump spray form of the "Magic Nano Bath & WC" product and only limited effects were seen in an inhalation study in rats.

While the reported consumer incidents, both in the EU and outside, are linked to aerosol dispensers one product reported in Canada (1992-1993) which resulted in two incidents of respiratory problems and 14 calls to the poison centre is described as a "pump spray". However, this pump sprays contained Stoddard solvent which RAC notes is classified to cause respiratory effects which places doubts as to whether the incidents involving these pump sprays are relevant to the presented risk associated with TDFA's and organic solvents.

Two occupational cases with three incidents were reported from trigger sprays containing fluoroacrylates in Switzerland (2002-2003) suggesting the potential for respirable particle generation from trigger sprays but also noting the causative agent belonged to the chemical group of fluoroacrylats, Vernex et al. (2004)

As no robust information is available to establish a concentration limit based on a particle concentration with an MMAD <10 µm, therefore, any consumer spray products containing 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents are expected to result in inadequately controlled risks.

As the risk is associated with the hydrolysis and condensation products formed it is also important that those involved in the manufacture, import and use of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives are aware of the inhalation hazards generated when 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives are mixed with organic solvents and sprayed. Therefore, RAC recommends that the associated Safety Data Sheets (SDS) for 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives should in Section 2.3 (Other Hazards) contain the following information: Mixtures of TDFAs and organic solvents, intended for professional use, shall be labelled "Fatal if inhaled" (where the concentration of TDFAs is equal to or greater than 2ppb).

RAC notes that the Dossier Submitter has indicated that the scope of the restriction is not intended to cover the formulation of TDFAs and organic solvents for export. However, RAC notes that such formulations would present a risk to non EU consumers if applied by consumers as a spray. The Annex XVII text therefore addresses the EU manufacture of sprays product mixtures containing TDFAs and organic solvents offered for sale to consumers or the general public, as well as, imported spray products. Both EU manufacturers of impregnating/proofing sprays and importers will need to demonstrate compliance with the proposed restriction.

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

Information on hazard(s)

Summary of proposal

This restriction proposal targets the placing on the market of spray products[3] containing mixtures of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivative and organic solvents intended for use by the general public. Inhalation is the exposure route of concern.

Animal studies have shown that 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives alone were not able to induce lung injury and mortalities, the fatal effect became obvious only in combination with organic solvents. Thus the Dossier Submitter concluded that 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents in the aerosol products were involved in the cases of lung injury and fatalities observed in consumers.

Evidence that supports the information from the animal studies comes from data on a previous outbreak involving impregnation products in 2006. The outbreak consisting of 154 cases of intoxication caused by two aerosol spray products (Magic Nano Glass & Ceramic and Magic Nano Bath & WC); these products are no longer on the market. There is no ingredient data available for these two products and therefore no data on the concentrations of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives in the mixtures used but analytical investigations at the time of the incidents did identify fluorosilanes and organic solvents in these products.

Nørgaard et al. (2010b) tested 10 impregnation spray products ("nanofilm spray products") from three Danish suppliers and found TDFAs with organic solvent in two spray products for non-absorbing materials.

In an animal study (Nørgaard et al., 2010a) which tested the effects of TDFAs and 2-propanol on mice, it was found that exposure to the aerosolised mixture had decreased the tidal volume (VT) of the mice following short term exposure. Higher toxicities (measured as the time until a 25% reduction in the VT was reached) were seen for 2-propanol in comparison to other solvents with shorter chain length and lower octanol-water partitioning coefficient (2-propanol>ethanol>methanol) (Nørgaard et al. (2014)). In vitro tests demonstrated that the lipophilicity of the solvent determined the toxicity of TDFA's on the surfactant function.

The hypothesis regarding the toxicity of mixtures of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents is that in the deeper parts of the lung, the organic solvent (depending on its octanol-water partitioning coefficient) facilitates contact between the hydrolysates and condensates of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and the SP-B proteins in the lung thus inhibiting the pulmonary surfactant through depletion of the pulmonary surfactant protein, SP-B. This hypothesis of the solvent facilitating contact between the hydrolysates, condensates and the SP-B protein is also the hypothesis used to explain why no effects on the lungs are seen for spray products that contain no solvent but

[3] Aerosol dispensers, pump and trigger sprays

only hydrolysed TDFAs and water. Therefore, toxicity of the product is dependent on the presence of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives with organic solvents that reaches the deeper parts of the lungs.

RAC conclusion(s):

- RAC agrees that the dossier has provided evidence of acute inhalation toxicity in animal studies following exposure to TDFA's an organic solvents and from impregnation/proofing aerosol products but that the cause of sudden outbreaks of respiratory disorders associated with impregnation products remains unknown.
- RAC agrees on the link between the 154 cases reported to occur after the use of two aerosol spray products ('Magic Nano Bath & WC', 'Magic Nano Glass & Ceramic) and mixtures of fluorosilanes formulated with organic solvents. It appears to be plausible that fluorosilanes were the active substances that have contributed to the lung injury.
- RAC agrees that the proposed mechanism behind the effects observed as presented in the dossier is plausible and the risk depends on the mixture having a concentration in the respirable range to reach the alveolar/bronchiolar regions of the lungs.
- RAC concluded that mixtures of TDFAs in combination with organic solvents with a particle MMAD <10 µm are necessary to cause acute lung injury.
- RAC agrees that pulmonary toxicity depends on the ability of the reaction products and solvent reaching the respirable area of the lungs. The lipophilicity of the solvent facilitates contact between the hydrolysates and condensates of TDFAs and the SP-B proteins in the lung. Solvents that are have a lower octanol-water partitioning coefficient than 2-propanol, are shown to have a slightly lower toxicity whereas mixtures of TDFAs and more lipophilic solvents are expected to have a higher toxicity (in terms of earlier onset of the effect).
- RAC found it difficult to assess how much the cases with less defined components contribute to the evidence for the mixtures of TDFAs and organic solvents that is proposed for restriction.

In addition, following assessment of the available evidence, RAC concludes the following:

- Inhalation toxicity testing of each individual substance is not sufficient to assess the hazards from formulated products of TDFAs and organic solvents.
- To derive a DNEL, RAC agreed to use animal data as a starting point. In a weight of evidence assessment two different approaches to derive a DNEL were considered which resulted in a range of DNELs. In contrast to the initial proposal of the Dossier Submitter (using the large assessment factor approach) RAC found the 1 hour LC_{50}-value more appropriate (in comparison to the expected application by consumers) than the extrapolation to a 4-hour value. In line with the Background Document (revised accordingly by the Dossier Submitter) two approaches – the LC_{50}-value in combination with a large assessment factor and the NOAEL as a starting point - are taken forward for DNEL derivation. The two DNELs (0.068 mg/m³ and 0.21 mg/m³) are then used for risk calculation.
- At present no specific (TDFAs-related) information on pump and trigger sprays is available.

- Taking the recent information from commercially available impregnation pump and trigger sprays into account that identified particle sizes <11 µm (Kawakami et al. 2015) or in the nanometer range in pump and trigger sprays (Losert et al., 2015), the generation of respirable particles <10 µm cannot be excluded. The percentage of particles <10 µm is likely to be lower for trigger and pump sprays than from aerosol. The potential risk for trigger and pump spray applications have been quantified based on the limited information on the generation of particles <10 µm from trigger and pump spray products.

Key elements underpinning the RAC conclusion(s):

Hazardous effect linked to exposure to spray products

The restriction proposal identified two aerosol spray products ('Magic Nano Bath & WC', 'Magic Nano Glass & Ceramic[4]) containing fluorosilanes and organic solvents as the responsible agents that induced acute lung injury in 154 cases in 2006. The Dossier Submitter considered the ingredients in both products as probable of being TDFAs and organic solvents.

At the time of the outbreak in 2006 no information on the composition was available. In 2009, Koch et al. published information on the ingredients of the Magic Nano aerosol spray products which indicated the presence of (w/w) 0.46-2.3 % of silanes and 26.2 % ethanol.

The aerosol fraction in the spray was low (1-3%) indicating that a large fraction of the spray is volatile. X-ray emission spectroscopy revealed high peak concentrations of silicon and fluorine in the Magic Nano Glass & Ceramic aerosol spray that justified the assumption that fluorosilanes were the toxic agents. As a corrosion inhibitor (0.83% w/w) was not found in the aerosol spray Magic Nano Bath & WC, it was not likely to be the cause of the intoxications.

Measurements with ICP-MS on the suspension revealed low concentrations of tin in the Magic Nano products (37-50 µg/g in Glass & Ceramic, 18-29 µg/g in Bath & WC, 0.01-0.03 µg/g in the pump spray); no evidence on tin was found in the aerosol analysis using X-ray emission spectroscopy (Koch et al., 2009). A commenter (PC Comment No. 1488) suggested that organotins produced in the formulation were responsible for the inhalation toxicity. Tin (like other metals) was found in (other) spray product formulations and their aerosols and thought to originate from the spray can (Losert et al., 2015). However, production of organotin compounds has not been demonstrated for impregnation sprays and is considered unlikely to result from metallic tin (this would require a strong acid or base). Several conditions such as surfactant/alveolar surface active chemicals (as a result from combined exposure to TDFAs and organic solvent), respirable particle sizes and the relevant concentrations (at the site of effect) seem to be necessary in causing acute lung injury. However, no information is available on threshold concentrations.

There may be other fluorosilanes than TDFAs (other fluorinated compounds) in mixtures used for spray products that are not covered by the restriction proposal since information on the ingredients in spray products along with evidence on specific links to effects in consumers is insufficient. No confirmative studies using the relevant (fluorsilane-based) products in animals are available either except one study in mice using a commercial spray product (based on fluororesin, silicone resin and organic solvents) that observed alveolar atelectasis and

[4] The name was referring to the thickness of the waterproofing film on the surface rather than on nano-sized particles (Pauluhn, 2008).

inflammation responses after inhalation of repeated 20 sec spray application (Yamashita and Tanaka, 1995[5]). However, neither the formulation nor the aerosol were analysed with regards to their compositions and the particle size distribution.

Clinical signs

The clinical symptoms in 154 persons observed following the use of the two Magic Nano aerosol sprays were strong cough and dyspnoea, in 13 cases also severe lung edema was diagnosed (Table 6 of the BD, Pauluhn, 2008, BfR, 2010). A detailed description of the clinical symptoms was reported for 10 out of the 154 incidents (Groneberg, 2010). For six of them information was available that treatment by a physician or at hospital were needed. Taking the information from Groneberg (2010) on strong cough, strong dyspnoe or persistent dyspnoe for more than 24 h as indicators for severe effects, seven out of the 10 incidents could be considered as severe cases.

Animal studies

TDFAs alone do not cause lung injury. This evidence comes from animal studies showing that mixtures of TDFAs in combination with organic solvents are essential to cause acute lung injury.

Mice exposed to aerosolised mixtures containing (polyfluorinated silanes) TDFAs and 2-propanol (hydrolysates and condensates of polyfluorooctyl triisopropoxysilane) at certain concentration levels have been shown to develop serious lung injury following short term exposure (60 min) (Nørgaard et al., 2010). A significant concentration-dependent decrease of the tidal volume (VT) was seen, which was still significantly suppressed in the 18.4 mg/m³ group one day after exposure. Three out of 20 mice died at 18.4 mg/m³ and 10 out of 10 died at 24.4 mg/m³. Histological examinations revealed atelectasis (collapsed alveoli), haemorrhage, and emphysema or lung over-distension (emphysema) because of maldistribution of ventilation.

Nonfluorinated alkylsilanes in combination with organic solvents were unable to induce the toxic effects in mice. It was also shown that water-based products containing hydrolysates and condensates of TDFAs were unable to cause lung effects. The effect on the tidal volume increased with the length of the carbon chain/octanol-water partitioning coefficient of the alcoholic solvents methanol, ethanol and 2-propanol (Nørgaard et al., 2014) or by adding 0.5, 0.75 or 1.0 mol water leading to more free hydroxyl groups (Nørgaard et al., 2010).

A similar picture was observed for the aerosol spray product "Magic Nano Glass & Ceramics" when tested in Wistar rats where the 4-hour LC_{50} was calculated by the Dossier Submitter as 10 mg/m³ (dry weight) (Pauluhn et al., 2008).

Inhalation of organic solvents alone did not cause pulmonary disorder (Norgaard et al. 2010a, Yamashita & Tanaka, 1995).

The lack of toxicologically significant changes in rats exposed to the 28 100 mg/m³ aerosol spray 'Magic Nano Bath & WC' (Pauluhn et al., 2008) appears to be inconsistent to the observed cases in humans. Although the authors demonstrated that the aerosol particles were in the respirable size (aerosol concentration 30%, calculated concentration at MMAD 5.81 was 148 mg/m³), neither they nor the Dossier Submitter could explain the unexpected

[5] Yamashita M, Tanaka J (1995) Pulmonary collapse and pneumonia due to inhalation of a waterproofing aerosol in female CD-1 mice. Clinical Toxicology 33(6), 631-637.

negative outcome in rats.

Mode of action

The mechanism behind the observed effects have been studied in mice and is believed to involve inhibition of the pulmonary surfactant in the deeper parts of the lungs by depletion of the pulmonary surfactant protein, SP-B. The SP-B protein is embedded in the phospholipids of the pulmonary surfactant, and it is speculated that the solvents (depending on their octanol-water partitioning coefficient) facilitate contact between hydrolysates and condensates of TDFAs and the SP-B proteins. This can also explain why no effect on the lungs are seen for spray products based on hydrolysed TDFAs with water as a solvent, even when the product can reach the deep parts of the lungs. Thus, the toxicity of the products in rats and mice depends on hydrolysates and condensates of TDFAs, the solvents, particle size distribution and particle concentration (application method). It is likely that interaction between the impregnation product and the pulmonary surfactant SP-B protein in a similar way is responsible for the effects seen in humans.

Supporting evidence from other spray products

Symptoms consistently reported after the exposure to other spray products (than the Magic Nano products), which most contained fluorinated polymers are: cough, dyspnea, pulmonary oedema, nausea, fever, shivers and headache. The Dossier Submitter noted that respiratory symptoms have been reported to appear shortly after exposure or with some delay. Symptoms usually resolved within a few days, but sometimes supportive treatment with oxygen, bronchodilators or corticosteroids was needed.

The restriction proposal suggested that the presence of substances/monomers for polymers, with per- or polyfluoroalkyl side-chains as ingredients in mixture with organic solvents are a common characteristic of many of the spray products that caused acute lung injury (Page. 37). However detailed information on ingredients were lacking for these products. The lack of detailed information justified the narrow scope of this restriction proposal.

No human cases of lung injury were observed for the 'Magic Nano Bath & WC' pump spray which contained even higher fractions of silanes (1-5%) and ethanol (57.5%) than the two Magic Nano aerosol sprays. This may be explained by a low aerosol fraction of <0.9% of respirable particles (<10 µm) from the pump spray (which was 20 fold below those of the two Magic Nano aerosol sprays in a model room of 60 m^3 without ventilation following the release of a 200 g spray within 5 min).

Most outbreaks on other spray products resulted from using aerosol dispensers. Some incidents in 1992 resulting from the use of a pump spray were reported from cases in Canada. The active substances in these formulation did however include stoddard solvent, heptane, fluorinated polymer resin, silicon and polymerised C10 alkanes which could be the causative agents responsible for the effects. Based on the cases linked to pump sprays (with limited knowledge on the ingredients) the evidence is weaker for including pump sprays in the restriction proposal.

In rats exposed for 4 h to the pump (Magic Nano Bath) spray following nebulization the tested concentration (81 222 mg/m^3, aerosol conc. 5-7%, calculated concentration at MMAD 4.59 µm 21 mg/m^3) was in the beginning lethal range (Pauluhn, et al., 2008). The authors stated that this concentration is markedly above the recommended maximum concentration recommended for animal welfare reasons. The rats exposed to the nebulised pump spray displayed clinical signs including breathing abnormalities, neurobehavioral changes and lower

rectal abnormalities that were interpreted by the authors as indicative for upper respiratory tract sensory irritants. Broncheoalveolar lavage (BAL) revealed significant higher fraction of polymorphnuclear neutrophils (PMN), a non-significant decrease of the fraction of alveolar macrophages and a tendency for higher protein content and increased lactate dehydrogenase (LDH, indicating cell damage). All these effects were also observed in the rats exposed to Magic Nano Glass & Ceramic aerosol spray using an intermittent generation during 120-240 min exposure duration, at more pronounced significant effect levels.

In conclusion, observations in rats exposed to a high concentration of the Magic Nano Bath nebulised pump spray (mainly the occurrence of breathing abnormalities and similarities of the BAL parameters) can be interpreted as supporting that mixtures of TDFAs and organic solvents contained in pump sprays cause lung injury[6] if the spray mist is in respirable range. However, this information on its own does not give sufficient evidence to support the inclusion of pump sprays in the conditions of the restriction as the test pump spray was nebulised in the rat study and particle size distribution results of the nebulised spray (NFP 1, ethanol, 2-propanol) had a large fraction that can end up in the bronchioles and alveoli. As no human cases of lung injury were seen with the pump spray 'Magic Nano Bath & WC' that was characterised by a low aerosol fraction of <0.5% (<4.5 µm) and of < 0.9% of respirable particles <10 µm (Fig. 8 in Koch et al., 2009), the question raises whether pump sprays in general are able to produce relevant amounts of mixtures as respirable particles.

A study by Yamashita et al. (1997b)7 tested 4 identical waterproofing sprays but with different mist particle sizes supported suggestions that the toxicity of waterproofing sprays is influenced by mist particle size generated. The study also highlighted that while there are many brands on the market only few are associated with respiratory effects.

The U.S. Silicones Environmental, Health and Safety Council (SEHSC) recommends that when considering a consumer aerosol application for any silicone-based material, regardless of the method of aerosol generation, the particle size MMAD should be at least 30 µm with no more than 1% of the particles having an aerodynamic diameter of 10 µm or less. Following this guidance should ensure that virtually all aerosol particles will be trapped in the nasopharyngeal region and very few if any particles will be deposited in the tracheobronchial region. However, this recommendation should be taken with care since it does not take into account that spray droplets released into the air may shrink due to solvent evaporation. This leads to a considerable shift of the size distribution towards smaller particles and an increase of the respirable fraction.

In December 2008 authorities from Germany, The Netherlands, Japan and Switzerland published a safety guideline limit on waterproof aerosol sprays to improve product safety by avoiding acute lung injury from fluorine-based or silicone based compounds. The guidance given by Aerosol Industry Association of Japan recommends to limit aerosol particles of diameter less than 10 µm to less than 0.6% of the sprayed aerosol particles[8]. Another

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6 This conclusion takes the uncertainties into account (high dose tested only, no data on single animal findings, mode of action may differ (at least partly) as the tidal volume was not reduced and inspiration time was prolonged and followed by a post inspiratory apnoea, but two modes may also run in parallel). The mortality (1/16 rats died) is not considered to be kick-off criteria, as mortality may result from the primary lung injury and was also observed in rats exposed to Magic Nano Glass & Ceramic spray.

7 Yamashita M., Yamashita M., Tanaka J., et al (1997b) Toxicity of waterproofing spray is influenced by the mist particle size. VetHum Toxicol39, 332-33

8 Kawakami et al. 2015 https://www.ncbi.nlm.nih.gov/pubmed/26821469

voluntary guidance document from the IKW (Industrieverband Körperpflege und -Waschmittel e.V)[9] remains open with regards to the critical concentration of particles <10 µm. Losert et al. (2015)[10] showed that in two pump sprays analysed the water-based impregnation pump sprays for glass (like propellant aerosol spraying) resulted in mean particle sizes in the nanometer range. Also the particle numbers were comparable to the aerosol for a propellant spray with alcohols or even higher than for the tested water-based propellant spray. The authors concluded that pump sprays also can release nanoparticles. The analytical methods in the Koch study, performed a decade earlier with less developed techniques than those used by Losert et al., were not expected to characterise the distribution and numbers of aerosol particles in the lower nano ranges. This could be interpreted as supporting evidence to include pump sprays in the restriction.

While there were no reported cases of acute lung injury due to inhalation of aerosols from hand pump sprays containing fluorine or silicone based compounds in Japan, a second study[11] investigated the aerosol particle size distribution of 16 household hand-pump sprays. The samples surveyed included sprays for waterproofing textiles, and kitchen and bathroom (8 samples), ironing sprays (2 samples), clothing care sprays (2 samples), and sprays to prevent adhesion of pollen to masks and clothing (4 samples). Although the constituents were not described for three product types these products were selected because a waterproofing effect was expressed on the product label. Three of the products tested came from the EU (UK). In 7 samples, the ratio of fine particies (<11 µm) in aerosols exceeded 0.6% of the voluntary guidance recommendation. This study confirmed that hand-pump sprays available in the Japanese market can spray fine particles (<11 µm). However, personal communication of the Dossier Submitter with the authors revealed that 6 out of the 7 sprays assumed to be pump sprays were in fact trigger spray products (see Table 2-5 in Appendix 2 of the Background Document). Regarding the limited database on pump and trigger sprays in general, more data is needed to characterise the particle size in pump and trigger sprays and the effects of technical design of sprays such as nozzle type.

DNEL calculations

Point of departure

The available human data show that the lung injury manifested shortly after application of the spray product, however, the data does not allow identification of a no-effect concentration and no information on the application duration can be derived from the case reports.

The observed effects are acute toxicity effects, only in exceptional cases exposure durations longer than 15 min/day (for which ECHA Guidance, Chapter R. 8 recommends to derive a long-term DNEL) are to be expected.

As a starting point to derive the DNEL, the Dossier Submitter in his initial proposal suggested to take the LC_{50}-value in mice from the study of Nørgaard et al. (2010a). Based on this the Dossier Submitters estimated 1-hour LC_{50} of 20.4 mg/m^3 (after correction to a 4-hour exposure), 5 mg/m^3 was estimated as the starting point to derive the DNEL. Comparing the LOAEC and the 4-hour LC_{50} values the mouse was more sensitive than the rat in the study on

9 http://www.ikw.org/fileadmin/content/downloads/Haushaltspflege/HP_Example-impregnation-spray.pdf

10 Online Characterisation of nano- aerosols released by commercial spray products using SMPS-ICPMS

11 Particle size distribution of aerosols sprayed from household hand-pump sprays containing fluorine-based and silicone-based compounds. Tsuyoshi Kawakami, Kazuo Isama. Yosluaki Ikaraslu. Bull. Nati Inst. Health Sct, 133, 3741 (2015) Technical Data

Magic Nano products by Pauluhn et al. (2010).

Assessment factors

The Dossier Submitter in their initial dossier proposal suggested using an assessment factor (AF) of 100 for the severity of effect to the LC_{50}-value. According to the ECHA Guidance (Chapter R.8) using mortality as a starting point to derive a DNEL ignores the possibility of serious sub lethal effects and substantial uncertainty regarding the toxicity at lower doses remains. The guidance recommends to determine the size of an additional severity factor to be applied to the LC_{50}-value (without giving any further suggestions or examples) to cover the significant inherent uncertainties. The Dossier Submitter's proposal to take an AF of 100 coherent with the guidance was accepted by RAC.

In addition, an AF of 3 is used because of the very steep concentration-response curve. The derived 4 hour no-effect concentration (DNEL) for TDFAs and 2-propanol is calculated using the total assessment factor of 300:

DNEL (as initially proposed by the Dossier Submitter)

$$DNEL(acute) = \frac{5\ mg/m^3}{300} = 0.017\ mg/m^3$$

DNEL estimate 1 based on 1hr LC_{50} and AF 300

RAC considered that the use of the 1 h LC_{50}-value of 20.4 mg/m³ is more appropriate than the 4 h LC_{50}-value suggested by the Dossier Submitter.

$$DNEL(acute) = \frac{20.4\ mg/m^3}{300} = 0.068\ mg/m^3$$

DNEL estimate 2 based on NOAEC and AF 75

Other starting points to derive a DNEL such as the NOAEC or LOAEC for the effects of concern should also be considered.

The guidance (R.8.2) recommends that in the case of a steep dose-response curve the derived NOAEL can be considered as more reliable (the greater the slope, the greater the reduction in response to reduced doses); in the case of a shallow curve, the uncertainty in the derived NOAEL may be higher and this has to be taken into account in the DNEL derivation.

Neither an effect on the tidal volume nor on the BAL was observed in mice exposed to 16.1 mg/m³ (Nørgaard et al. (2010a); this concentration based on specific effects on the respiratory system is considered as a NOAEC to be used for DNEL calculation.

Weight loss within 22-24 h was the most sensitive effect that increased concentration-dependently from 15.7 mg/m³. The corresponding NOAEC of 3.3 mg/m³ is considered less robust and will not be selected as the effect on body weight may be an unspecific effect.

Allometric scaling to correct for the impact of interspecies differences of inhalation volume on (systemic) kinetic processes is not appropriate for local effects on the respiratory tract. The default AF of 2.5 for remaining interspecies differences and the default AF of 10 for intraspecies differences are proposed. An AF of 3, as suggested by the Dossier Submitter, is applied for the steepness of the dose-response.

$$DNEL(acute) = \frac{16.1\ mg/m^3}{75} = 0.21\ mg/m^3$$

Information on emissions and exposures

Summary of proposal:

There are two types of surfaces that water, stain proofing, impregnating or sealing spray products are designed to treat (1) absorbing surfaces such as textiles and leather e.g. shoes or clothing and (2) non-absorbing surfaces such as ceramic tiles or shower doors.

Spray products for consumers containing TDFAs in mixtures with organic solvents are used for non-absorbing surfaces. Exposure depends on the product's ability to reach the deep lung tissue; so is dependent on the particle size distribution which depends on the application method of the product.

The exposure scenarios presented in the dossier are based on

a) exposure modelling under realistic worst case conditions where mixtures of TDFAs and 2-propanol are sprayed onto different surface types to be treated.

b) data from studies involving Magic Nano glass and ceramic/formulations of NFP 1 and

c) evidence of reported incidents involving proofing sprays in EU Member States and non EU Member States.

The Dossier Submitter has indicated that consumption of the mixtures for spray coating is indicated to be about 10 – 70 ml/m^2 depending on the application.

More detailed information on manufacture and uses of TDFAs and related sprays, as well as on the exposure assessment (particle sizes and distributions from animal and spray chamber experiments, summary of human exposure incidents and exposure modelling calculations) are presented in the Background document.

RAC conclusion(s):

- RAC agrees that the risk depends on the respirable fraction (<10 µm) generated with an ability to reach the deep lung tissue which is dependent by the application method (pressurised aerosol can, pump or trigger spray) of the spray (impregnating/proofing) product. Therefore, RAC agrees that the % of spray that is respirable is important when considering potential exposure concentration.

- RAC agrees that numerous factors determine the initial size distribution of droplets or particles released from a spray product, including the product formulation (e.g., volatile or non-volatile solvent), can size, propellant and differential pressure through the nozzle for propellant sprays, and formulation and nozzle characteristics.

- As data from the Koch study supports that 20% of particles are <10 µm for aerosol products and fraction of particles <10 µm is lower for pump sprays (less than 0.9%) RAC agrees that the Dossier Submitters initial exposure assessment overestimated the risk as they assumed that all aerosols generated have relevant fractions of MMAD <10 µm.

- Based on limited information for pump and trigger spray products (not specific to TDFAs) and using modelled exposure information RAC assessed quantitatively whether the use of pump or trigger sprays under realistic worst case or normal realistic use conditions present a risk that is not controlled. RAC concluded that mixtures containing

TDFAs and organic solvents in pump and trigger sprays may also pose a risk, although at a lower level than the aerosol spray products.

- Spray products containing TDFAs in mixtures with organic solvents are normally used for non-absorbing surfaces. RAC agrees that the exposure scenario based on the application of the spray product to tiles in a bathroom is an appropriate model scenario presented for risk assessment. It cannot however be ruled out that some users could use organic solvent-based agents containing TDFAs for absorbing surfaces. However, based on the information available these products are not marketed for such applications and such use could constitute misuse.
- RAC agrees that there are uncertainties with the applicability of the ConsExpo and SprayExpo models. Both use mass generation rates instead of applied amount. RAC agrees that SprayExpo is a more appropriate model to assess exposure for this use as ConsExpo assumes instantaneous evaporation of the solvent, instantaneous uniform dispersion of the spray throughout the whole room upon its release independent of the actual dispersion conditions. SprayExpo contains a droplet impaction module for calculating the overspray during spraying onto a surface.
- RAC agrees that input parameters relating to the mass generation, airborne fraction and initial droplet/particle size distribution have a huge impact on the estimated mean event concentrations. While input data on mass generation, airborne fraction and initial droplet/particle size distribution is limited, the other model input parameters used (room size, ventilation rate, spray/exposure duration) by the Dossier Submitter are considered appropriate and acceptable for the purpose of risk assessment.
- SprayExpo calculations for pump sprays using the realistic case initial droplet/particle size distribution from Kawakami et al. (2015) identified RCR < 1 which supports that some pump sprays likely to be on the market do not pose a risk that is not adequately controlled. However, under worst case conditions calculations with SprayExpo indicates a potential risk from pump spray exists under certain applications.
- RAC agrees that it is plausible, depending on the spray nozzle design of a pump or trigger spray that, immediately upon application, an inhalable fraction of aerosol may be generated that may reach the deep lung tissue.
- RAC agreed to derive exposure estimates based on the potential for particles to be <10 µm.

Key elements underpinning the RAC conclusion(s):

Due to the intended use of these products (e.g. in bathrooms) it is likely and reasonably foreseeable that consumers will use the proofing and impregnating products in small enclosed spaces with poor ventilation and without respiratory protective equipment. This is supported by reported incidents showing consumers occasionally use impregnation sprays indoors in small rooms without opening windows or doors and without any personal protection.

The original dossier indicated that consumption of the mixtures for spray coating is indicated to be about 10 – 70 ml/m^2 depending on the application. RAC notes that the Norgaard (2009) publication reports an application of 10-40 g/m2 these values are the ones used in the exposure estimates.

Spray products for consumers containing TDFAs in mixtures with organic solvents are

marketed for use on non-absorbing surfaces. Volatile organic solvents like ethanol or 2-propanol are used for non-absorbing substrate as they enhance cross linking and make a good wetting of the substrate. Ethanol is able to penetrate into the material (stone, wood) and infiltrate the material. The hydrophobic and oleophobic TDFAs will go deeper into the material (a few millimeters up to a few centimeters) and will therefore protect the substrate for a longer time even if the material is subject to abrasion on the surface.

Koch et al

RAC notes that Koch et al. (2009) released one aerosol spray can (approximately 200 g and not 120 g as indicated in the dossier) of "Magic Nano Glass & Ceramic" over a 5 minute period in a 60m^3 room. A peak concentration of approximately 11.5 mg/m^3 was able to reach the bronchioles and/or alveoli (< 10 µm) after 9 minutes and remained at a concentration above 4 mg/m^3 during the first 30 minutes of measurements. Koch also showed that when using pump sprays, less particles (peak concentration < 1.2 mg/m^3) are released. The use of pump sprays was associated with an approximately 20 fold lower risk of inhalation exposure to respirable aerosols than aerosol sprays.

Exposure Modelling

There is a substantial difference in how the two models handle droplet/particle distribution. SprayExpo takes shrinking of particles due to evaporation of the solvents into account whereas ConsExpo 4.1 does not. While ConsExpo model can be used for non-volatile compound released as an aerosol from a spray can or a trigger spray sensitivity analysis undertaken during the development of another exposure model SprayExpo[12] revealed that along with the substance release rate, the droplet spectrum is the process parameter that has a decisive impact on the exposure level. In contrast, the vapor pressure of the solvent only plays a secondary role for the exposure concentration of the active ingredient. SprayExpo was developed to estimate aerosol exposure during spray application of non-evaporating biocidal substances. This model takes into account turbulent diffusion, droplet evaporation and gravitational settling. In addition, it includes an droplet impaction module for calculating the overspray during spraying onto a surface. For room spraying and spraying onto walls, comparisons between this model and experiments revealed that spray applications estimates from SprayExpo can generally be reproduced with an uncertainty of a factor of 4/5 or lower. Unlike SprayExpo, ConsExpo assumes instantaneous evaporation of the solvent, instantaneous uniform dispersion of the spray throughout the whole room immediately upon its release independent of the actual dispersion conditions which mean that it is more suitable to calculate exposure in small rooms rather than larger spaces. SprayExpo was considered by RAC as a more suitable for modelling exposure for this use application (spray).

It is possible in SprayExpo to choose floor, ceiling or wall lining. When choosing floor treatment it is not possible to set exposure duration different from spray duration. The treated area is set through mass generation rate (same as ConsExpo) and spray duration.

It is noted that the Dossier Submitter initially used a mass generation rate for impregnation sprays of 4 g/s, while no default values are available for impregnation sprays this mass generation rate differs significantly from the default values in ConsExpo for spray cans (0.8 and 2.2 g/sec). The Dossier Submitter subsequently revised the mass generation rate in the new exposure assessments. Mass generation rate for aerosols & trigger sprays of 0.3 g/s and

[12] http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/SprayExpo.html

0.55 g/s. Mass generation rate for pumps of 0.1 g/s and 0.2 g/s.

The use of data on the number of particles generated from the Norgaard study is not appropriate for pump sprays and may not reflect exposure from pump or trigger sprays even under worst case conditions. The spray exposure estimates from the ConsExpo model for pump and trigger spray have greater uncertainty than for aerosols and are likely to underestimate exposure as they do not take evaporation into account. However, when calculations using CONSEXPO take evaporation into account similar exposures to those generated by SPRAYEXPO are achieved. It is plausible that spray products that use pump and trigger sprays, depending on their spray nozzle design, will immediately upon application result in the generation of an inhalable fraction of aerosol and some of which may reach the deep lung tissue.

Particle size is an important factor as the size of the aerosol particle strongly influences the rate at which particles are removed from the air (no longer available for inhalation) as well as the degree of inhalability. Aerosol particles with aerodynamic diameters smaller than about 10 µm are of relevance to this exposure estimation. Data from the Koch et al. suggest that the respirable fraction (<10 µm) is less in pump sprays. Based on studies from Yamashita et al. 1997, Saldo, 2011, Kawakami et al. 2015 and Losert et al. 2015 RAC agrees that 20% of the aerosol is <10 µm for aerosol cans, 3% for trigger sprays and 0.9% for pump sprays.

The exposure assessment in the dossier was refined and updated by the Dossier Submitter during the opinion development process for realistic and realistic worst case exposure using both the ConsExpo 4.1 with and without a correction for evaporation and SprayExpo models. Even though NFP1 is for floor treatment, wall treatment was chosen for the models for scenario 1) and 2) so as to compare output from SprayExpo and ConsExpo.

The following four exposure scenarios were undertaken for NFP 1 (TDFAs & 2-propanol) for non-absorbing surfaces.

1) Bathroom of 10 m³, 3.4 m² floor/wall tiles applying a high application of product per m² area (40 g/m^2).

2) Bathroom of 10 m³, 3.4 m² floor/wall tiles applying a lower application of product per m² area (10 g/m^2).

3) Bathroom of 10 m³, 0.3 m² mirror (0.6 m x 0.48 m) applying a higher application of product per m² area (40 g/m^2).

4) Bathroom of 10 m³, 0.3 m² mirror (0.6 m x 0.48 m) applying a lower application of product per m² area (10 g/m^2).

At 40 g product per m^2 (RWC) a mass generation rate of 0.55 g product/sec is used for the aerosol dispenser and trigger sprays and 0.2 g product/sec for pump sprays.

At 10 g product per m^2 (RC) a mass generation rate of 0.3 g product/sec is used for the aerosol dispenser and trigger spray with 0.1 g product/sec for pump sprays.

The duration of application is compared to the actual physical process of spraying 1 m^2 that takes approximately 25 sec. While the mass generation rates impact on exposure the rates used are not considered conservative.

The most critical factor is the sprays ability to reach the deep lung tissue (<10 µm MMD).

The number of particles was estimated from chamber tests. The number of particles generated in the trigger spray chamber experiment was significantly less than the number of particles generated from high pressure nebulization in the animal experiment test chamber. No particle concentration measurements were available for NFP1 aerosol or pump sprays. The high pressure nebulizer generated significantly higher particle concentrations than trigger/pump sprays (1.4 x 105 – 4.6 x 106 particles/cm³) equating to a concentration of 0.5 mg/m³ – 42.4 mg/m³ (dry weight) i.e. the concentration mice were exposed to in the study. The droplet/particle size distribution of NFP1 from Norgaard (2009) was not used in updated exposure estimates as it was confirmed that the study did not measure the initial distribution of the spray.

The ratio of fine particles was examined in Kawakami et al 2015 and found that out of the three pump sprays used, two have less than 0.6% (0-0.4%) particles in the <9 µm range and one has 0.8% of the particles in the <11 µm range. For five trigger sprays the ratio was >0.6% for the <9 µm range. However it is difficult to distinguish the initial droplet /particle size distributions from pump to trigger sprays.

The spray nozzle size of 0.5mm was chosen at an angle of 30 degrees for all scenarios in SprayExpo.

NFP 1 is a floor treatment product. When treating a floor one would most likely not spend time in the room immediately after application until the floor is "dry". This means that the exposure time will be identical to the spray duration.

TABLE 1. RWC EXPOSURE ESTIMATES USING CONSEXPO, CONSEXPO CORRECTING FOR EVAPORATION EFFECTS AND SPRAYEXPO.

Scenarios	Model	Spray type	Mean event concentration [mg/m³]
1) Impregnation of 3.4 m² tiles in a 10 m³ bathroom (approx. use 40 g/m²)	ConsExpo 4.1	Aerosol	1.9
		Trigger	0.0043
		Pump	0.0016
	ConsExpo 4.1 With evaporation	Aerosol	89.6
		Trigger	20.7
		Pump	7.5
	SprayExpo	Aerosol	97.1
		Trigger	39.2
		Pump	14
2) Impregnation of 3.4 m² tiles in a 10 m³ bathroom (use approx. 10 g/m²)	ConsExpo 4.1	Aerosol	0.56
		Trigger	0.0013
		Pump	0.00043
	ConsExpo 4.1 With evaporation	Aerosol	25.7
		Trigger	6.1
		Pump	2.0
	SprayExpo	Aerosol	27.3
		Trigger	11.1
		Pump	3.6
3) Spraying of a 0.3 m² mirror in a 10 m³ bathroom (use approx.40 g/m²)	ConsExpo 4.1	Aerosol	0.20
		Trigger	0.00046
		Pump	0.00017
	ConsExpo 4.1 With evaporation	Aerosol	9.3
		Trigger	2.2
		Pump	0.79
	SprayExpo	Aerosol	7.5
		Trigger	2.9
		Pump	1
4) Spraying of a 0.3 m² mirror in a 10 m³ bathroom (use 10 g/m²)	ConsExpo 4.1	Aerosol	0.0056
		Trigger	0.0013
		Pump	0.000043
	ConsExpo 4.1 With evaporation	Aerosol	2.5
		Trigger	0.6
		Pump	0.2
	SprayExpo	Aerosol	2.5
		Trigger	1
		Pump	0.34

when evaporation is taken into account in ConsExpo calculations it supports the SprayExpo modelled results.

Human Cases

There are many uncertainties in the incident cases reported, making it difficult to identify scientific evidence to support the proposal. . With the exception to the incident cases reported for Magic Nano™ Glass & Ceramic and Magic Nano™ Bath & WC the EU incidents provide limited supporting evidence of the components in the sprays and whether an organic solvent was also present in the spray product. However most of the non EU incidents with impregnating proofing sprays did provide supporting evidence of the presence and use of organic solvents in the products. From an exposure perspective, the human incidents reported for Magic Nano appears to be the only incidents that a relationship has been established for exposure to TDFAs and organic solvents in the EU.

Worker exposure

The scope of the Dossier Submitter's proposal is focused on consumer exposure however the reported workplace incidents suggests that risks to workers can also arise from proofing sprays where occupational operational controls and risk management measures are not followed (the incidents reported was following a failure to use RPE and control emissions from spray booth in Scotland).

Environmental exposure

Environmental exposure from consumer spray products is considered to be very limited as use is indoors with limited release to the external environment. For professional uses the main application is via brushes, roller or high-volume-low-pressure (HVLP) guns. The latter or which could be the major source of direct release of the substances to the environment.

Characterisation of risk(s)

Summary of proposal:

Consumers

A quantitative risk assessment was carried out for the reaction product of TDFAs and 2-propanol applied by pump spray and in aerosolised form. The risk assessment is based on the product named NFP 1 in the articles by Nørgaard et al. The active substances in this product are hydrolysates and condensates of TDFAs in 2-propanol. Chemical analysis of NFP 1 using electrospray ionization mass spectrometry (ESI-MS) showed that it contained 1.1 ± 0.1 % active substances. The acute 4 hour DNEL was calculated to 0.017 mg/m^3

The risk characterisation ratio (RCR) is calculated by dividing the derived exposure concentration with the derived DNEL.

Error! Reference source not found.2 shows the measured and calculated exposure concentrations along with the characterisation ratios. A risk characterisation ratio above 1 shows that the risk is not adequately controlled.

TABLE 2. EXPOSURE ESTIMATES AND RISK CHARACTERISATION RATIOS FOR NFP 1 IN DIFFERENT SCENARIOS

Scenarios			Mean event concentration (mg/m³)	RCR	
a1	Spraying of 4 m² in a 10 m³ bathroom	Pump spray	13	765	ConsExpo
		Aerosol dispenser	41	2412	
a2	Spraying of 7 m² in a 17.4 m³ bathroom	Pump spray	11	647	ConsExpo
		Aerosol dispenser	42	2471	
a2	Spraying of 7 m² in a 17.4 m³ room	Pump spray	1.4	82	Measured values
		Aerosol dispenser	46	2718	
b	Impregnation of a 6.2 m² sofa in a 58 m³ living room	Pump spray	3.5	206	ConsExpo
		Aerosol dispenser	11	647	
c1	Impregnation of a pair of shoes/boots in a 15 m³ kitchen	Pump spray	1.6	94	ConsExpo
		Aerosol dispenser	5.4	318	
c2	Impregnation of a pair of shoes/boots in a 10 m³ bathroom	Pump spray	2.5	147	ConsExpo
		Aerosol dispenser	8.1	476	

For all of the scenarios there is a risk that is not adequately controlled when applying mixtures containing TDFAs and 2-propanol by both aerosol dispenser and pump spray.

No particle concentration measurements or calculations exist for NFP 1 in trigger sprays, however, it is expected to comparable to the particle concentration measured for pump spray. Therefore the risk is expected to be similar to the risk seen for pump sprays.

Table 2 should be interpreted very carefully, the expected exposure values calculated by ConsExpo are based on a number of assumptions (see Background document B.8.3.2). Exposure concentrations are estimated for exposure durations from 5 minutes to 1 hour. The acute DNEL is based on a standard 4 hour LC_{50}. Thus, the RCR may be overestimated. The 4 hour LC_{50} used for calculating the DNEL is based on TDFAs with 2-propanol as a solvent. As described in section 5.2.1 pulmonary toxicity also depends on the chain length and the octanol-water partitioning coefficient of the solvent. Mixtures of TDFAs and solvents that have a lower octanol-water partitioning coefficient than 2-propanol (e.g. methanol) are expected to have a higher LC_{50} value and therefore a higher DNEL. Mixtures containing TDFAs and methanol are expected to have a LC_{50} value that is only slightly higher than mixtures containing TDFAs and 2-propanol (see Background document 5.11). Mixtures of TDFAs and solvents that are more lipophilic than 2-propanol are expected to have a lower LC_{50}. This seems to be the case for the product Rim sealer, tested by Sørli et al. (2015). The solvent used in this product is a mixture of 2-propanol, 1-methoxy-2-propanol and ethylacrylate (see 5.2.1).

Even when taking these uncertainties into account that there is an expected risk that is not adequately controlled for both aerosol dispenser and pump spray containing mixtures of

TDFAs and organic solvent – at least for the worst case scenario.

This risk characterisation ratio shows that the risk is higher for the mixtures containing TDFAs and 2-propanol when the product is applied by aerosol dispenser than when it is applied by pump spray. This is in line with the larger number of incidents reported with use of aerosolised products.

Aerosolised NFP 1 generates higher particle concentrations than is generated by pump spray with approximately the same particle size distribution. Aerosolised NFP 1 therefore present an even higher risk, which also needs to be controlled.

Koch et al. (2009) showed that release of approximately 120 g of the aerosol spray "Magic Nano Glass & Ceramic" in a model room with a volume of 60 m^3 resulted in an exposure concentration of non-volatile components of 11.5 mg/m^3 <10 µm. From this RCRs of 88 and 48 can be derived, which shows that a risk exists which is in line with number of incidents were reported for Magic Nano Glass & Ceramic.

No human incidents are reported for the pump spray "Magic Nano Bath & WC". Koch et al. (2009) estimated that risk of exposure to respirable aerosol is approximately 20-fold lower for the pump spray "Magic Nano bath & WC" than for the aerosol "Magic Nano Glass & Ceramic".

Taking also into account the fraction that is <10 µm, the Dossier Submitter's proposal, this number should be adjusted to 20-45 times lower giving an RCRs of approximately 2 and 1, indicating a risk, for the pump sprays. Pulmonary effects only occurred in rats exposed to the highest dose tested but the chemical composition of the pump spray was different from the aerosol dispenser "Magic Nano Bath & WC", Koch et al. (2009) and the two can therefore not directly be compared.

Measured data

Vernez et al. (2004) and Nørgaard et al. (2010d) indicates that for a trigger spray the mean event concentration of particles in the < 10 µm fraction should be expected to be above 1 mg/m^3. Vernez et al. (2004) predicted the mean overspray concentration in the <10 µm fraction to be 40 mg/m^3 and 45 mg/m^3 for two different proofing/impregnation formulations using the same type of trigger spray in a 12 m^3 room.

Workers

No data are available from manufacturers regarding the occupational exposure of workers by the manufacture of the substances or for professional use in aerosol dispensers, pump and trigger sprays in order to characterise the risk.

RAC conclusion(s):

- RAC agrees that the risks to consumers and the general public from the use of impregnating aerosol sprays containing TDFAs and 2-propanol are not adequately controlled when used under worst case conditions.
- RAC agrees that according to the derived RCR values the risk is higher for aerosols mixtures of TDFA and organic solvents than for trigger and pump sprays, an observation that corresponds with the human incidents reported for aerosol products.
- RAC concludes that the risks from trigger sprays are not adequately controlled under worst case conditions and under realistic conditions where larger areas such as tiled areas may have to be treated.

- RAC also agrees that according to the derived RCR values the risk is higher for trigger sprays compared to pump sprays. However, to consider that exposure may occur, depending on the nozzle design, from the use of pump sprays immediately after application (when the product is applied under worst case conditions where larger areas such as tiled areas may have to be treated) and therefore the risk cannot be excluded.
- As the toxic effect is dependent on the fraction of spray which becomes respirable during or following application, a restriction on the maximum respirable fraction (e.g. 0.6%) that a pump or trigger spray can generate might be a way to control potential risks from pump and trigger spray products. However, it is not clear which concentrations of the (highly variable) ingredients will result in a limit fraction of primary aerosol particles below 0.6%, how technical or design parameters influence the size distribution and how the ageing process (reducing the aerosol particle sizes) may affect the hazardous effects of the mixtures of TDFAs and organic solvents.

Key elements underpinning the RAC conclusion(s):

Based on the range of acute DNEL's of 0.068 mg/m^3 and 0.21 mg/m^3 derived by RAC, a quantitative risk assessment for the reaction product of TDFAs and 2-propanol (NFP 1) in aerosols was undertaken. The following table quantifies the risk based on an exposure assessments from SprayExpo where the concentration is calculated based on exposure to particles <10 µm for aerosol cans, trigger sprays and pump sprays following updated exposure calculations by the Dossier Submitter estimates (Appendix 2 of the background document).

TABLE 3. SUMMARY OF RISK CHARACTERISATION

Scenarios	Model	Spray type	Mean event concentration [mg/m³]	RCR (with DNEL 0.068 mg/m³)	RCR (with DNEL 0.21 mg/m³)
1) RWC Impregnation of 3.4 m² tiles in a 10 m³ bathroom (approx. use 40 g/m²)	SprayExpo	Aerosol	97.1	1428	462
		Trigger	39.2	576	187
		Pump	14	206	67
2) RC Impregnation of 3.4 m² tiles in a 10 m³ bathroom (use approx. 10 g/m²)	SprayExpo	Aerosol	27.3	401	130
		Trigger	11.1	163	53
		Pump	3.8	55	18
3) RWC Spraying of a 0.3 m² mirror in a 10 m³ bathroom (use approx.40 g/m²)	SprayExpo	Aerosol	7.5	110	36
		Trigger	2.9	43	14
		Pump	1.0	15	5
4) RC Spraying of a 0.3 m² mirror in a 10 m³ bathroom (use 10 g/m²)	SprayExpo	Aerosol	2.5	37	12
		Trigger	1	15	5
		Pump	0.35	5	1.6

Table 3 shows that for exposure estimates using SprayExpo all RCR's are greater than 1 for aerosols for both DNEL's and therefore the risk is not adequately controlled for consumers and the general public under realistic and worst case conditions.

For trigger sprays the RCR's are greater than 1 under RWC conditions for both DNEL's. Trigger spray use in RC conditions for larger areas such as tiled area is also above 1 for both DNEL's.

For pump sprays the RCR is also greater than 1 for RWC scenario where the area to be treated is a large are like tiles. The magnitude of the RCR greater than 1 for pump sprays is lower than trigger and aerosols which supports the very low number of incidents involving pump sprays.

Uncertainties in the risk characterisation

Uncertainties relating to the use of models will have an impact on the RCR's. However, they are likely to be less with SprayExpo than ConsExpo (Spray application). Koch et al (2012) found that on average the exposure concentrations are slightly overestimated by SprayExpo the GSD of 2.3 means that in about 70% of cases the model is in agreement with measured values within a factor of 4-5.

When considering the magnitude of the RCR values it is important to note that pulmonary toxicity depends on the ability of the reaction products and solvent reaching the respirable area of the lungs and the and the octanol-water partitioning coefficient of the solvent used, as the solvent facilitates contact between the hydrolysates and condensates of TDFAs and the SP-B proteins in the lung. Solvents that have a lower octanol-water partitioning coefficient than 2-propanol, are expected to have a slightly lower toxicity whereas mixtures of TDFAs and more lipophilic solvents are expected to have a higher toxicity (in terms of the earlier onset of lung injury in comparison to less lipophilic solvents). However, lack of information on impact of lipophilicity of different solvents on toxicity does not allow RAC to determine whether any organic solvents would have no toxicity concerns.

While the mass generation rate for trigger sprays used in the model was higher based on information from Delmaar (2009) than that measured by Norgaard (personal communication) it is still in the lower end of the table values from the Delmaar (2009) & Feilberg (2008) studies which could mean there is still a possibility for higher exposures from aerosol and trigger sprays.

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:

The toxic substances in the Magic Nano Glass & Ceramic™ and the Magic Nano Bath & WC™ are likely to have been fluorosilanes with unknown length of the per/poly-fluoroalkyl chain. The Dossier Submitter assumed that these could be TDFAs, but could not prove their similarity. It is argued by the Dossier Submitter that the observed cases were linked to these specific products.

The toxicity of hydrolysates is dependent on their ability to reach the deep lung tissue (<10 µm) and the presence of an organic solvent to facilitate contact with SP-B protein.

Classification and labelling by the manufacturer or importer based only on the individual parent ingredients of the product will therefore not reflect the actual hazard from the reaction products to users following exposure. No evidence has been provided to show that information on this specific hazard has been included in the "other hazards" section of safety data sheets for TDFAs.

Worker exposure

Only very few incidents of occupational exposure to impregnation sprays in aerosol dispensers resulting in respiratory illness are reported.

RAC conclusion(s):

- Existing risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to reflect the particular hazards associated with consumer exposure to mixtures containing TDFAs and 2-propanol.
- Occupational risk management measures for workers which prevent inhalation of the mixture are considered sufficient. The few incidents reported of occupational exposure relate to misuse of occupational controls.
- RAC agrees that mixtures of TDFAs and solvent mixtures should be labelled "Fatal if inhaled" to ensure that professionals using the products are aware of the specific hazard associated with the use of TDFAs and organic solvents.

Key elements underpinning the RAC conclusion(s):

Evidence from the key animal study, reported incidents involving magic nano and the exposure modelling, all support the contention that the risk is not properly controlled. Incidents among workers appear to only relate to the misuse of the substance or failure to comply with occupational risk management measures and controls. As the toxicity hazards are not related to the individual substances on their own but to the mixture of TDFAs and organic solvents, it is important that the inhalation hazards associated with formulated TDFAs and organic solvents is communicated in the supply chain. No evidence has been provided to support that this was happening. Therefore it is important that the "Other Hazards" sections of TDFAs safety data sheet include the inhalation hazards "Fatal if inhaled" that result when TDFAs are formulated with organic solvents in an aerosol form where MMAD particles <10 µm have the potential to be generated. This is to ensure downstream formulators and users take

appropriate risk management measures and communicate these hazards further in the supply chain.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

Product Safety Directive (PSD) - This option is rejected as it seems that the knowledge by importers/producers about the risk when combining polyfluoroalkyl silanes with organic solvents in spray products is limited (if existing). Furthermore, regulating through this directive can only be done on a case-by-case basis and therefore it is not suitably appropriate to use PSD as the risk management measure to address the risks from other brands of impregnation proofing sprays or other aerosol products containing organic solvents and TDFAs. REACH is the relevant specific Union legislation dealing with regulation of substances and mixtures. For all these reasons the PSD is not considered to be an appropriate measure.

Harmonised C&L – The parent substances do not fulfil the criteria in CLP, Article 36(1) for proposing a harmonised classification therefore it is not relevant to consider this risk management option for the mixture.

Amendment to CLP Annex II part 3 on specials rules on packaging – Introducing an amendment to CLP Annex II part 3 stating that "Substances or mixtures classified as Acute Toxic in Category 1 or 2 by inhalation shall not be supplied to the general public in aerosol dispensers, pump and trigger sprays and mixtures marketed for spray application" will remove the most dangerous impregnation products from the market if they are classified correctly. According to CLP Article 53, it is the Commission that may adjust and adapt the Annexes to CLP. Since it appears that none of the products affiliated with the incidents reported were labelled as acute toxic to humans introduction of an amendment to CLP is not considered a relevant RMO in the context of this proposal.

Inclusion in the Candidate List with the aim of inclusion in Annex XIV - The substances do not fulfil the Article 57 criteria for identification as a Substance of Very High Concern and already for this reason this RMO is not relevant.

Voluntary measures

As many importers and or producers of the targeted spray products are likely to be small and medium-sized companies which are not members of the national trade associations it is considered not possible to achieve a comprehensive and effective results through a voluntary agreement.

Guidance

Guidance on waterproofing aerosols has been developed by some national authorities[13] which recommended the characterisation of the particle size distribution of the spray product, and inhalation testing on the formulation (active ingredient and solvent) to be tested in a modified OECD TG 403 test at a MMAD between 0.7 and 1.5 µm. In this document it is referred to the

[13] Guidance for Industry. Recommendations on waterproofing Aerosols in order to Minimisze Consumer Inhalation Toxicity Risks. Authors: Federal Office of Public Health, Switzerland. Food and consumer Product Safety Authority, The Netherlands. Federal Institute for Risk Assessment, Germany, December 2008

US Silicones Environmental, Health and Safety Council (SEHSC) mentioning that particle size MMAD should be at least 30 µm with no more than 1% of particles < 10 µm. The Japanese guideline[14] recommends the ratio of MMAD particles <10 µm should not exceeds 0.6%.

Guidance on Safety Assessment of impregnation sprays is also published by industry[15] refers to the above mentioned guidance document and recommends that the concentration of respirable particles should be outside the critical range. However no information on the thresholds for critical fraction of respirable particles were given neither in this document nor in the linked document of the European Aerosol Federation[16].

Technical solutions may exist in theory assuming that hazardous effects could be prevented e.g. if no relevant fraction of particle sizes < 10 µm were produced during the spray application. However no information is available to estimate which fraction of <10 µm particles could be considered as safe. Whether 1% as recommended by SEHSC is safe, remains open regarding the observations of Yamashita et al. (1997) who observed lung damage in mice at 1.6 ±0.03 % of <10 µm particles of fluorocarbon resins with n-heptane as solvent.

Information campaigns

The Dossier Submitter considers that information campaigns directed to the consumers would have very limited effect, if any, on this problem as only very few consumers are in a position to choose other products than those offered by the retailers and many of the products for bathrooms are used indoors not outdoors. The Dossier Submitter notes that incidents are reported for impregnation product with contents different than mixtures containing TDFAs and organic solvents and an information campaign directed at formulators, producers and distributors on how to classify and label impregnation spray products correctly according to CLP could be suggested but the effect of such a campaign is considered to be uncertain.

RAC conclusion(s):

- RAC considers that for issues relating to individual specific products the existing legislation under PSD could be effective in urgent cases (for a limited duration) in having these products removed from the market once the concern is identified. However, PSD is not an appropriate measure as a long-term instrument in preventing the specific issue relating to the hazards associated with the reaction products of TDFAs combined with organic solvents.
- RAC agrees that a restriction under REACH would send a clear message that TDFAs should not be used in conjunction with 2-propanol or any other organic solvent and as such would be appropriate was to prevent future incidents. As the hazard is associated with the use of formulations of TDFAs and organic solvents along with the generation of particles in the respirable range <10 µm. RAC considers there is merit considering a requirement for impregnation/waterproofing pump and trigger sprays to be tested prior to being placed on the market.

[14] https://www.ncbi.nlm.nih.gov/labs/articles/26821469/ Particle Size Distribution of Aerosols Sprayed From Household Hand-Pump Sprays Containing Fluorine-Based and Silicone-Based Compounds T Kawakami et al. Kokuritsu Iyakuhin Shokuhin Eisei Kenkyusho Hokoku (133), 37-41. 2015.

[15] http://www.ikw.org/fileadmin/content/downloads/Haushaltspflege/HP_Example-impregnation-spray.pdf

[16] http://www.aerosol.org/publications/7/36/Guide-on-Particle-Size-Measurement-From-Aerosol-Products

Key elements underpinning the RAC conclusion(s):

PSD

PSD is applicable and requires that only safe products are placed on the market. It also contains a requirement that producers must inform consumers of the risks associated with the products they supply. The Directive provides for an alert system (Rapid Alert System for non-food dangerous products - RAPEX) between the EU Member States, Norway, Iceland and Liechtenstein, and the Commission to rapidly inform of dangerous products. The directive applies in the absence of specific European regulations on safety of certain product categories and complements the provisions of sector legislation, which do not cover certain matters. The PSD addressed the safety concern for Magic Nano Glass & Ceramic and the Magic Nano Bath & WC as both were withdrawn from the market in 2006. However, as the general knowledge, of importers and producers, about the risk when combining polyfluoro octyl silanes with organic solvents in spray products is limited each occurrence of an incident could only be addressed on an individual product case-by-case basis and therefore it is not suitably appropriate to use PSD as the risk management measure to address the risks from other brands of impregnating/proofing sprays or other aerosol products containing organic solvents and TDFAs.

CLP

Classification

The objective of the CLP Regulation is to determine which properties of substances and mixtures requires classification and labelling, such that any hazards from the substance or mixture is identified and communicated to the user. Based on the evidence from the studies on NFP1, mixtures of TDFAs and organic solvents may fulfil the classification criteria as acute toxic depending on the organic solvent (a mixture of TDFAs and 2-propanol fulfil the criteria for classification with Acute Toxicity, Category 1, while the product NFP 1 fulfils criteria for classification with Acute Toxicity, Category 2). Therefore, producers of spray products containing TDFAs and organic solvents should classify and label the containers appropriately in accordance with this.

Introducing a harmonised classification is only applicable to substances and it is not applicable as the acute toxicity effect is not known for the individual parent substance but only known to occur from the reaction products when TDFAs are present with organic solvents.

The classification (and labelling) on harmonised dangerous properties alone is not an appropriate risk management instrument that prevents the use of (dangerous) ingredients in a product.

Labelling for other hazards

The dossier does not provide evidence as to whether the "Other Hazards" section of safety data sheets (SDS's) for TDFAs substances contains any information that the product should be labelled fatal if inhaled when combined with organic solvents. It appears that in none of the incidents reported, the products were labelled as acute toxic to humans which could be deduced that the "Other Hazards" section of SDS for TDFAs did not contain information on the specific concern with the use of TDFAs with organic solvents.

Packaging

Annex II Part 3 "Special rules on packaging" has no provisions that restrict the use of aerosol packaging on substances and mixtures intended for supply to the general public that are

classified as "Fatal if inhaled".

REACH

REACH Article 129 Safeguard clause.

RAC considers that the outbreak of incidents involving impregnation sprays, such as the case of Magic Nano, are justifiable grounds for considering national action under the REACH safeguard clause. However, Article 129 still contains a provision for the preparation of an Annex XIV dossier where the measure is to restrict the placing on the market.

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

RAC

The Dossier Submitter's justification for acting on a Union-wide basis originates from the EU-wide distribution of incidents of lung injuries due to use of spray products by consumers in order to avoid different legislative requirements in Member States creating unequal market conditions. The proposed restriction addresses the risk for consumers arising from use of spray products containing mixtures containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents where lung injuries in animal studies have been identified. Similar effects have been seen in humans exposed to spray products containing fluorinated polymers and solvents. In order to adequately protect consumers, the dossier submitted considers that a restriction should target imported as well as EU produced spray products intended for use by consumers and the general public.

SEAC

The main objective of the proposal is to reduce or prevent consumers' exposure to mixtures containing TDFAs used in a combination with organic solvents in spray products intended for consumers across all EU Member States. The risk is not related to TDFAs as substances on their own but to the hydrolysis and condensation products of TDFAs when they are used together with organic solvents. The proposed scope of the restriction proposal is targeted to spray products for supply to the general public, used for absorbing surfaces (textile and leather) and non-absorbing surfaces (tile and ceramics).

The Dossier Submitter reported several cases involving respiratory disorders that were observed in a number of Member States following the application of proofing/impregnation spray products on the surface of absorbing or non-absorbing materials since 1979, as evidence that the targeted spray products pose an unacceptable risk. The Dossier Submitter also reported on scientific studies showing that aerosolised mixtures of TDFAs and organic solvents can cause serious acute lung injury in mice. Spray products based on those mixtures for proofing/impregnation surfaces are commercially available for professional users and could also be available for the general public. Therefore, risks to human health caused by such products, specifically for the general public, are according to the Dossier Submitter the justification for the proposed restriction.

To support that action is required on an EU wide basis, the Dossier Submitter argues that

proofing/impregnation spray products may be produced, imported and used in all Member States. According to the assumptions made by the Dossier Submitter, about 20-200 kg TDFAs in approximately 6 800 – 100 000 spray product units (in combination with solvents) are sold yearly to the general public. Incidents to consumers from the use of impregnation sprays have been documented in seven EU Member States, namely Denmark, France, Germany, the Netherlands, Spain, Sweden and the United Kingdom. It is not known if these sprays contained TDFAs or not. The Dossier Submitter has therefore assessed that an EU wide restriction is necessary to minimise the risks. It is also highlighted by the Dossier Submitter that an EU wide restriction would remove any potential distorting effects that national restrictions might have on the free circulation of goods on the common market, and thereby ensuring equal market conditions and a level playing field for all the actors on the internal market."

RAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection across the EU and of maintaining the free movement of goods, RAC supports the view that any necessary action to address risks associated with (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives, (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives should be implemented in all Member States.

Key elements underpinning the RAC conclusion(s):

RAC notes that while the parent substances in proofing and impregnating sprays implicated in human incidents could not be identified, there is some evidence linking the presence of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and solvents in Magic Nano Glass & Ceramic and Magic Nano Bath & WC.

While information has been made available during the public consultation for products containing TDFA's & organic solvents this has only been with respect to professional uses.

RAC also notes that while the PSP Directive is applicable and resulted in the withdrawal of the market of Magic Nano Glass & Ceramic and Magic Nano Bath & WC [17]this was a specific product measure. There is currently no restriction under REACH on the placing on the market of mixtures of TDFAs and organic solvents in consumer products. There is also no provision in Annex II part 3 of CLP that prohibits the placing on the market, for the general public, substances or mixtures classified as acute toxic in Category 1 or 2 by inhalation in aerosol packaging.

As the acute toxicity to humans effect only occurs when both substances are used together and aerosolised into a mist with a respirable concentration <10 um this information would not always be evident to formulators based on the test data of the parent substances in the mixture. Information would have generally only been available to the importers or formulators if the mixture was tested before the product was placed on the market or if this information is contained in Section 2.3 of SDS "Other Hazards".

This proposal only targets mixtures of TDFAs and solvents. While evidence of the parent substance is not available for all incidents reported involving proofing or impregnation sprays, there is evidence that many of the proofing sprays contained solvents. As the hypothesis for

17 http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/main/?event=main.weeklyReport.Print&web_report_id=165

the toxic effect is that the solvent, depending on its lipophilicity, facilitates contact between the "proofing reaction products" and the SP-B proteins in the lung thus inhibiting the pulmonary surfactant. This hypothesis may also be relevant to other impregnating sprays. Therefore, importers and formulators of proofing sprays should consider this information when classifying mixtures that use organic solvents with other proofing parent substances in aerosol packaging to establish if those mixtures might have similar effects when packaged for use as aerosols or sprays. There is also merit based on cases with other impregnating/proofing aerosol products to consider a requirement to test the toxicity of such products prior to being placed on the market.

SEAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection of consumers across the EU and of maintaining the free movement of goods SEAC supports the view that any necessary action to address risks associated with TDFAs, (mono-, di- or tri-O-(alkyl) derivatives of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol) used with organic solvents in spray products, should be implemented on an EU wide basis.

This restriction will prevent that such spray products are placed on the Union market now or in the future. This action would also guarantee the free movement of goods within the EU to ensure that the internal market works properly.

Key elements underpinning the SEAC conclusion(s):

RAC concluded that the risks for consumers and the general public due to the use of impregnating aerosol, trigger and pump sprays containing TDFAs and 2-propanol are not adequately controlled when used under certain conditions.

SEAC recognises that action is required to avoid the risks for consumers' pulmonary distress from the use of the targeted products, since it cannot be excluded that the targeted products are (or could be put) on the EU market intended for use by the general public.

It is not known if sprays containing TDFAs and organic solvents are currently placed on the EU market in consumer products. No information was submitted during the public consultation about such products that are currently on the market for consumers. Sweden provided information that proofing/impregnation spray products based on mixtures of TDFAs and organic solvents and intended for consumer use, were registered in the Swedish Product Registry from 2010 to 2013. However, since 2014, no consumer products based on mixtures of TDFAs and organic solvents have been registered.

It is known that in Spain there are eight proofing/impregnation spray products with TDFAs and organic solvents placed on the market for professional use. It cannot be discounted that these products are also bought and used by consumers but there is no evidence either way.

According to the Dossier Submitter spray products, likely to contain mixtures of TDFAs and organic solvents linked to incidents due to exposure from proofing/impregnation sprays, have been identified in several cases in a number of Member States. When severe incidents have occurred, the products have subsequently been withdrawn from the market (RAPEX 2006 and 2010). One of the manufacturers of TDFAs submitted comments in the public consultation that they do not know of any current use of TDFAs in the targeted products. The same manufacturer also claims that the use of TDFAs in some of the spray products involved in the reported incidents has not been conclusively proven. This statement is corroborated by the information available in the dossier. RAC has stated in their opinion that it is plausible that

fluorosilanes were the active substances that have contributed to the lung injuries seen.

There are a number of proofing/impregnation sprays on the market at present[18] (Feilberg et al., 2008; Nørgaard et al. (2010)) but the composition of these spray products is not known in sufficient detail. It is not possible to identify if the proofing/impregnation sprays on the market contain TDFAs, as the chemical's description on label or in the SDS are not sufficiently detailed. This is not least because TDFAs have no harmonised classification under CLP. Furthermore, TDFAs have not been self-classified under CLP by some companies. About half of the notifiers to the CLP inventory signal no classification.

Therefore, the possible presence on the EU market of proofing/impregnation spray products, based on mixtures of TDFAs and organic solvents intended for supply to the general public cannot be discounted and should be taken into account in the SEAC assessment.

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 provides a short overview of possible EU wide legislative measures as well as two restriction RMOs that are further assessed in addition to the proposed restriction. These EU wide legislative measures are the following:

RMO1 (proposed restriction):

A ban of mixtures containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents in spray products for consumer use with a concentration of TDFAs equal to or greater than 2 ppb by weight.

The proposed restriction was considered by the Dossier Submitter to be the most appropriate EU wide measure due to its higher effectiveness, proportionality and practicality, compared to the other RMOs. Alternatives to (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives in combination with organic solvents are available at the same price according to the Dossier Submitter.

RMO2:

A ban of mixtures containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents in spray products for consumer use with a concentration of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives equal to or greater than 0.00008% (800 ppb).

Compared to the proposed restriction, the Dossier Submitter foresees that for the same capacity of risk reduction, RMO2 would bring significantly higher costs for monitoring and enforcement. However, the costs for industry might be lower when compared to RMO 1.

[18] http://universealsealants.co.uk/shop/indoors/grout-sealer/; http://www.ltp-online.co.uk/prod/ltp-grout-tile-protector; https://www.bestoninternet.com/tools-home-improvement/household-supplies/granite-countertop-sealer-reviews/

RMO 1 & 2 could actually allow the use of polyfluoralkyl trialkoxysilanes with polyfluoralkyl chain lengths different from octyl as a drop in alternative.

RMO3:

A ban of mixtures containing (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvent in aerosol dispensers for consumer use with a concentration of TDFAs equal to or greater than 2 ppb by weight.

This RMO is considered by the Dossier Submitter to have lower risk reduction capacity than RMO 1 and 2 as the risk from spray products other than aerosol dispensers are not addressed. However it is expected that the cost from this RMO is also lower as it would impact fewer actors on the market than RMO1. The Dossier Submitter considers that this restriction have a higher average cost-effectiveness than RMO1, it is easier to implement as other application methods are available at about the same price and lower costs for the enforcement.

Justification for the opinion of RAC

RAC conclusion(s):

While RAC agrees that a restriction is an appropriate EU wide measure to prevent the hazard and associated risks to consumers with the use of sprays containing TDFAs and organic solvents. While there is evidence confirming the previous presence of TDFA's & organic solvents in spray products on the market for consumer use, there is currently (since 2014) no evidence confirming the presence of such spray products on the EU market for consumers. However, as professional products still exist on the market without the proposed restriction in place, there is a potential that these could be replaced on the market for consumer use.

Key elements underpinning the RAC conclusion(s):

Incidents of respiratory illness related to exposure to spray products typically occur in outbreaks related to the release of new or reformulated products on the market. Often these products are subsequently withdrawn from the market.

In the case of the use of TDFAs with organic solvents RAC agrees that a restriction on the use of TDFAs with organic solvents is the most appropriate for the following reasons

- Animal tests have shown that when TDFAs is used in combination with organic solvent in impregnating proofing sprays the resulting hydrolysates are acute toxic by inhalation when the product is respirable.
- based on the information available, the parent substances do not fulfil the criteria in CLP, Article 36(1) for proposing a harmonised classification. Mixtures containing TDFAs and organic solvents may fulfil the classification criteria as acute toxic depending on the organic solvent and the content of TDFAs – a mixture containing 1.1% TDFAs and 2-propanol fulfil the criteria for classification with Acute Toxicity, Category 2. Producers of the spray products containing TDFAs and organic solvents should classify and label them appropriately in accordance with this. However, it seems that in none of the incidents reported, the products were labelled as acute toxic to humans. As only classification of substances can be harmonised under the CLP Regulation (cf. articles 36-38), it is not relevant to consider this risk management option for mixtures of TDFAs and organic solvent.
- the acute toxic effect is not evident from data on the individual parent substances so

in the absence of test data on proofing sprays these products are likely to be incorrectly classified under CLP.

- While an amendment to CLP Annex II Part 3 would address the packaging of all substances or mixtures classified as acute toxic by inhalation. CLP has no provision to harmonise effects relating to a mixture which is only applicable when two or more substances are used together.
- In general, test data for the purpose of classification and labelling or REACH is applicable to the individual substances rather than testing of the final mixtures. In the case of proofing sprays, as the health effect is not observed following exposure in the individual substances but following exposure to the mixture it is not possible to determine that such an effect exists without there being a requirement to test all proofing sprays mixtures containing organic solvents prior to them being placed on the market. Such a legal provision in not currently in place in the EU.
- For consumers, voluntary agreements between stakeholders and information campaigns are not considered to be sufficiently effective. The General Product Safety Directive is not considered appropriate as the knowledge by importers/producers of the risk when combining TDFAs with organic solvents in spray products may be limited (if existing).
- While a requirement for the testing of the final impregnating/proofing before it is placed on the market would be appropriate in identifying those products which do not comply with the PSD. There is no defined set of appropriate test procedures to test formulated impregnation/proofing spray products.
- There is limited information to support that TDFAs & organic solvent products are currently on the market in the EU for consumers.
- While RAC consider a restriction would be effective RAC cannot conclude, from the reported poisoning incidents whether the proposal warrants an EU wide measure as the Dossier Submitter nor RAC could confirm the presence of TDFAs and organic solvents in the reported accidents involving impregnation, proofing sprays. However RAC consider an EU wide restriction would be effective measure to address the risks (identified in animal studies) associated with the use of mixtures of TDFA and organic solvents in spray products.
- The 725 EU incidents involving these products types have been reported in 8 of the EU Member States (UK, DK, NL, SE, FR, ES, IE & DE) see BD Table 6. RAC do acknowledge that impregnation, proofing sprays are used and available for sale to consumers and the general public across the EU and that a restriction would be appropriate in preventing respiratory incidents resulting from exposure to TDFAs & organic solvents.

Professional users covered by occupational health regulation are assumed to be provided with a sufficient level of protection if the products are properly labelled. Even if not labelled properly the product will most like be labelled according to the hazard of the organic solvent(s). This may include precautionary statements such as "Avoid breathing the dust, fume, gas, mist, vapours or spray", depending on the solvent(s). Incidents of lung injuries among professional users working with proofing/impregnation sprays have been identified. However, none of the identified cases seems to involve TDFAs and in cases are associated with the misuse of occupational controls to protect workers from exposure.

A restriction under REACH is considered an appropriate risk management measure to control the risks from the use of impregnating proofing sprays of TDFAs and organic solvents.

As the effect has been related to proofing sprays RAC suggests that COM and Member States should perhaps consider whether there is a need to require proofing spray mixtures containing organic solvents to be tested to ensure they are correctly classified, labelled and packaged. Industry would then be able to determine whether proofing products classified as acute toxic by inhalation are suitably safe for use by consumers when placed on the market in aerosol, pump or trigger spray packaging.

Justification for the opinion of SEAC

SEAC conclusion(s):

SEAC agrees with the line of argumentation presented by the Dossier Submitter with regard to the non-restriction options being less effective or even ineffective ways for reducing consumer exposure to mixtures of TDFAs and organic solvents in spray products. This includes the use of the PSD as a risk management option.

Therefore, as there are no suitable non-restriction options, SEAC concludes that a restriction would be the most appropriate option to reduce the risks from such spray products.

SEAC finds that among the restriction options, RMO1 and RMO2 would be more effective than RMO3 as they cover trigger and pump spray products[19]. Therefore, SEAC also concludes that a restriction with a specific scope as in RMO1 or RMO2 would be a more appropriate and implementable measure for the industry and enforcement authorities, as it clearly identifies the mixture, the ingredients and the application methods that lead to a risk. However, SEAC also takes the advice of the Forum into account in their evaluation of the proposal and proposes to delete the first paragraph of the Dossier Submitter proposal. The goal of this paragraph is assured by the scope of the second paragraph. Therefore, the availability of the spray products based on mixtures containing TDFAs and organic solvents for the general public in EU can be assured with a ban for placing on the EU market of such products.

In addition, the scope of the proposed restriction covers all uses of spray products based on mixtures of TDFAs and organic solvents. SEAC is not aware of other possible uses than for proofing/impregnation sprays. The information available for evaluation by SEAC only addresses the proofing/impregnation spray products. Therefore, SEAC considers that the text of the restriction proposal should only address the use of proofing/impregnation spray.

Lastly, following the Forum advice and the RAC opinion SEAC supports that professional product containing mixtures of TDFAs and organic solvents should be labelled for professional use only.

Therefore, SEAC concludes that a restriction, specifically RMO1 (as amended), is the most appropriate EU wide measure to address the concern for human exposure to spray products containing mixtures of TDFAs and organic solvents.

[19] According to the RAC opinion, there is a not controlled risk in the use of the trigger and pump sprays under specific scenarios.

Key elements underpinning the SEAC conclusions

Voluntary agreements and information campaigns could be effective as an RMO in certain cases if there is information and knowledge about the use of the substance, and there is a trade body that can facilitate and enforce/audit such agreements with all relevant suppliers. This is not the case here. Voluntary agreements should be seen as different from voluntary action, such as product removal, following undesirable incidents such as in the cases of respiratory distress previously reported.

Based on the information provided by the industry during the public consultation, as well as the information provided in the Background Document regarding the consumer use of proofing/impregnation spray products, it is clear that there have been incidents of respiratory distress caused by the use of proofing/impregnation spray products. However, according to the submitted information, it cannot be excluded that some incidents that have occurred involved the use of products containing TDFAs and organic solvents.

SEAC acknowledges that the Product Safety Directive (Directive 2001/95/EC) could be effective to handle the risks for the general public if the proofing/impregnation spray products were tested before being put on the market. However, as there is no obligation for the testing of the final proofing/impregnation spray products before their placing on the market, SEAC agrees that the Product Safety Directive is less suitable to apply as a risk management measure to address the risks for impregnating/proofing sprays containing mixtures of organic solvents and TDFAs for the following reasons:

- There are no appropriate provisions for the testing of the proofing/impregnation spray products prior to their placing on the market.
- The cost for the testing could be significant[20].
- The Product Safety Directive applies to individual products on a case-by-case basis, and is not able to prevent incidents with new products.

SEAC therefore, finds that a restriction option would be a more appropriate EU wide measure regarding its practicability enforceability and effectiveness. SEAC takes note of the RAC opinion that the risks to the general public from the use of proofing/impregnation aerosol products, trigger or pump spray products are not properly controlled, and therefore the RMO3 does not cover all the risks of concern.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

The restriction is considered effective in reducing the risks for consumers when applying mixtures based on TDFAs and organic solvents. The restriction is expected to only reduce a part of the incidences of lung injury from the spray applications of impregnating agents.

Other impregnation agents are not addressed by the proposed restriction due to the lack of convincing animal toxicity data and lack of a substantial causal relationship between the

[20] http://www.productsafetylabs.com/media/1266/price-schedule-2016.pdf, accessed at 02.01.2017

substances and the effects seen in the exposed humans. Nevertheless, implementation of the proposed restriction may have a multiplying effect on reducing the use of potentially harmful mixtures (e.g. causing lung injury) of other mixtures of fluorinated substances and organic solvents.

Introduction of a risk-based limit value of e.g. 0.00008% (0.8 mg/kg, 800 ppb, based on the risk calculation for an aerosolised NFP 1-like product (see BD B.9.1.1.2.) and an extra assessment factor of 10 for combinations of TDFAs and organic solvent) for spray products containing TDFAs and organic solvents has been considered by the Dossier Submitter (the analytical detection limit is 2 ppb). This limit would avoid that other mixtures containing other substances where TDFAs could be found as an impurity would be effected.

RAC conclusion(s):

- RAC considers that in the absence of appropriate provision for the testing of of the final impregnating/proofing before it is placed on the market, a REACH restriction is an appropriate risk management measure addressed at consumers as it will specifically reflect the particular concerns of the use of TDFAs and solvents in mixtures placed on the market in spray products. However, as the incidents and the risk assessment have related to proofing impregnation/sealing sprays the ECHA guidance on restrictions should reflect this.
- The proposal does not restrict uses of TDFAs and organic solvent mixtures by industrial and professionals. However, RAC notes that there is a need to ensure mixtures of TDFAs and organic solvents are correctly labelled as fatal if inhaled to ensure that professional and industrial users are properly informed about the hazards.

Key elements underpinning the RAC conclusion(s):

While PSD may be effective in the case of removing individual products on a case by case basis from the market there is no risk management measure currently in place that prevents the risk or specifically reflects the particular reaction product hazard when the general public use TDFAs and solvents in spray products.

The current proposed measure will address not only the placing on the market of proofing and impregnating sprays but <u>all</u> spray products placed on the market for sale to the general public and consumers.

As professional and industrial uses are not proposed for restriction there is a need to ensure communication of information in the supply chain and that all mixtures of TDFAs and organic solvents are appropriately labelled "Fatal if inhaled".

Socio-economic impact

Justification for the opinion of SEAC

<u>Costs</u>

Summary of proposal:

The Dossier Submitter submitted a qualitative assessment of the proportionality of the restriction proposal and some quantitative information on the assessment of costs such as:

- Prices of some alternative substances;
- Estimated cost of the individual laboratory tests to ensure compliance;
- A rough estimation of the annual number of units of spray proofing/impregnation products containing TDFAs used with organic solvents on the market and an estimation the consumer price per can;
- An assessment of reformulation costs per formula using the estimation presented for D4/D5 substitution as a benchmark.

Neither testing costs to ensure compliance nor reformulation costs for mixtures of TDFAs of organic solvents used in spray products for consumers are available. However, it is identified that costs are expected only for substitution to other substances than polyfluoroalkyl trialkoxysilanes, which might be more complicated and therefore would imply an increase of reformulation costs. The dossier Submitter also provided the costs for individual tests for TDFA's analysis in mixtures. All the quantitative information was used by the Dossier Submitter to substantiate the assessment.

Production and compliance costs

The Dossier Submitter has not identified any significant impacts for any of the actors manufacturing, formulating, importing, or supplying TDFAs or mixtures based on TDFAs or any other polyfluoroalkyl trialkoxysilanes.

For consumers using the spray products with TDFAs and organic solvents, no significant impacts have been identified by the Dossier Submitter as the substitution to other mixtures (polyfluoroalkyl trialkoxysilanes with different polyfluoroalkyl chain than the octyl chain), substances or alternative application methods, have not previously influenced the price of the final impregnation product. For all niche applications, it is not known whether any loss of functionality would occur.

The conclusion of the Dossier Submitter is that the compliance costs, in general, would be quite limited for the concerned actors.

Distribution of costs and impacts on sales

The Dossier Submitter has not identified any impacts on sales or distribution of costs for any of the concerned actors in the supply chain. For the four TDFAs manufacturers in the EU, it is estimated that less than 10 % of TDFAs annual production is used in proofing/impregnation spray products. From these assumptions, the Dossier Submitter estimates that only 1% is used in the products targeted by this restriction proposal. The estimated yearly volumes sold in spray products in combination with solvents to the general public are 20-200 kg. SEAC presumes that these figures include imported TDFAs with polyfluorooctyl trimethoxysilane that, according to the available information, is not manufactured in the EU. The number of cans sold yearly to the general public is estimated at 6 800-100 000 cans. With an estimated turnover of €8-12 per can, these cans represent a total annual turnover between €54 000 and €1 200 000.

According to the Dossier Submitter, the number of formulators and producers of aerosol dispensers containing TDFAs is not known. However, based on information from industry, the number of producers, including producers for professional uses of TDFAs, may likely be in the range of tens to several hundred companies.

Costs for ensuring compliance

The Dossier Submitter has not identified any costs for ensuring compliance if a substitution would occur to alternative application methodologies like brushes, rollers or cloth.

For other alternatives substances, as insufficient information is given about their use in the spray products in the Safety Data Sheets, importers, distributors and retailers may need to request further information from the producers of the spray products. The additional costs for such compliance documentation are considered to be very small by the Dossier Submitter without making any quantitative estimations of these costs.

Additional compliance checks may have to be carried out by various actors in the supply chain. It is expected by the Dossier Submitter that downstream users and dealers would rely on information from manufacturers while the costs for verification by laboratory tests would probably be relatively small. The costs for testing may be limited to around €300 per test, for a qualitative analysis aiming to indicate whether the product contains one or more substances meeting the target group formula. If a qualitative analysis is conducted aiming to identify all substances that meet the targeted group formula used in the product, the cost would be around €1 000. Actors in the supply chains for the concerned sector are used to exchange information on hazardous substances used in products.

The Dossier Submitter foresees that importers are likely to require documentation about the compliance of the imported products with the restriction. The foreign producers are expected to bear the costs for documenting compliance for imported products. The Dossier Submitter considers the administrative costs for importers to collect and verify the documentation to be insignificant.

Reformulation costs

Polyfluoroalkyl trialkoxysilanes with polyfluoralkyl chains different from the TDFAs were considered as drop-in alternatives, which could easily substitute TDFAs in proofing/impregnation spray products, without including any extra costs. The Dossier Submitter does not foresee the need for any changes to process and the prices of raw materials of the alternatives are at the same level or cheaper than TDFAs. There is no information if the substitutes will be used in the same amounts as TDFAs, but a lower performance could be expected for these substances with polyfluoralkyl chains length shorter than TDFAs. No significant reformulation costs are expected for these alternatives. However, the substitution of TDFAs in proofing/impregnation spray products by other substances than polyfluoroalkyl trialkoxysilanes might not be so easy. In the absence of other information, the Dossier Submitter has used the estimation of the reformulation costs to substitute D4 and D5 in wash-off personal care products as a benchmark for the reformulation costs of TDFAs. The Dossier Submitter concludes that the annualised costs of reformulation per formula should be 30% of the estimated value for D4/D5 substitution, which is €8 000-12 000.

SEAC conclusion(s):

The analysis of costs for this restriction proposal is mainly based on a qualitative assessment undertaken by the Dossier Submitter, whilst using some quantitative information as supporting arguments. Taking the available information in the Dossier and the information submitted in the Public Consultation into account, SEAC agrees with the qualitative approach. Only limited quantitative information was found by the Dossier Submitter after reasonable enquiries to appropriate stakeholders or was submitted in the Public Consultation.

SEAC agrees with the Dossier Submitters analysis that the costs of this restriction will not be significant for the consumers or the industry. The SEAC conclusion on costs is grounded on:

- The volume of TDFAs used in the targeted products is less than 1 % of the annual volume of TDFAs used in consumer spray products.
- The small size of the market under the restriction scope with an annual turnover in the range of € 54 000 - € 1 200 000.
- The prices of the alternative substances being available at a similar level as the targeted substances.
- The presence of existing alternative products on the market with similar prices to previous examples of assumed TDFA containing spray products (i.e. spray products not based on TDFAs, or the target mixtures in cans or bottles for alternative application techniques).
- In a worst-case scenario, where the TDFAs will have to be substituted by non-drop-in substances, the mixtures of TDFAs and organic solvents have an indicative annual cost in the range of €8 000- €12 000 per formula.
- If the targeted mixtures are no longer placed on the market, there is no additional cost for importers, formulators and aerosol producers of these spray products because of the proposed restriction.

One potential additional cost is if the presence of TDFAs as impurities in other fluorinated products would impose a need for reformulation of those spray products. In such a case, RMO1 and RMO3 could impose higher costs than RMO2, as RMO2 allows a higher concentration limit for TDFAs and avoids the need for reformulation and other costs. However, there is no information available that impurities of TDFAs occur in products placed on the market, although it is possible that they occur[21]. For further assessment of RMO1, RMO2 and RMO3, see the section for the overall proportionality and its table comparing the impacts.

Key elements underpinning the SEAC conclusion(s):

MARKET SIZE

The estimations presented in the dossier of the volumes of TDFAs used in proofing/impregnation spray products were based on the registration data and on the information provided from the industry. SEAC accepts the Dossier Submitter's assumptions and agree with the approach taken to estimate the market size of the targeted products, given the information available. There are no registered TDFAs for the moment, but there are

[21] Although information is very limited, the presence of TDFAs as impurities in other products was raised as a potential issue in the call for evidence carried out during the preparation of the restriction proposal. However, despite this being a specific question in the SEAC DO PC, no information on this issue was submitted,

two that are pre-registered and included in the list of substances to be registered by 31 May 2018: polyfluorooctyl triethoxysilane and polyfluorooctyl trimethoxysilane. For the first registered product, which is known to be manufactured in EU, the industry expects that less than 10% of the annual production is used to produce proofing/impregnation spray products. This is approximately the percentage that is sold via distributors. The distributors in their turn sell the mixtures to spray producers, among others but the final uses of the TDFAs are not known. Therefore, it is estimated that a maximum of 1-10 t/y polyfluorooctyl triethoxysilane could be used in spray products. It is not known if these products are exclusively for professional use. For the other registered substance, there are no known European producers, but the registration band for pre-registered substances are the same, 1-10 t. Therefore, the Dossier Submitter assumes that the same volume of polyfluorooctyl trimethoxysilane is used to produce spray products, an assumption that SEAC accepts. Taking into account that 90 % of the manufactured TDFAs, sold by the manufacturers and formulators, is not used in spray products, the same percentage can be assumed when estimating the TDFAs percentage sold by the distributors for estimating how much will be used to produce spray products. Therefore, SEAC accepts as plausible that the volumes of TDFAs used annually in the EU could be estimated between 20-200 kg, 1% of the annual manufacture, with a production of 6 800 and 100 000 for 250 ml units. With TDFAs concentrations between 1.0 and 1.5%, the annual turnover would be €54 000 and €1 200 000. Notwithstanding, there is no evidence to confirm the retail costs, SEAC notes that the assumption made by the Dossier Submitter for consumer prices is realistic[22]. During the public consultation and in the targeted consultation no new justified information was submitted, therefore the assumption is not disputed.

COMPLIANCE COSTS

Reformulation costs

An important part for the compliance costs are the reformulation costs. For producers that may have to develop more complex reformulations, the Dossier Submitter concludes that the annual costs of reformulation per formulation could be 30% of the estimated value for D4/D5 substitution for non-coordinated reformulation, which is €8 000- €12 000. SEAC assumes that for these type of products, produced essentially by small companies with a small market share, it is unlikely that they keep regular reformulation activities that could be coordinated with this current demand. Although the reasoning given for that range is weak, SEAC may consider this estimation of the reformulation costs as indicative. The Dossier Submitter is not able to estimate the total number of products facing reformulation, and so the estimation of the total costs of reformulation was not carried out.

[22] When searching on the site of the www.amazon.de for prices of proofing spray products SEAC found four products of different brands to be applied on stones or tiles with prices (24/10/2016) at €13, €25, €27 and €40, which is in concordance with the range of €16-24 per can estimated by the DS.

SEAC's approach to overcoming this lack of information is to apply different scenarios, and to focus on the credibility of the estimated reformulation costs to arrive at an indicative value. Therefore, SEAC assumes four scenarios to describe the general public market of the targeted products market, where there are 0, 2, 5 and 8 targeted spray products available for non-professional users, each of them with its own producer. In addition, SEAC assumes that the market shares are equal for all the companies, since the differences among the formulations of the mixtures to be used in pump or trigger or aerosols spray products from different producers, based in TDFAs and organic solvents, are irrelevant and as half of the products have the same formulation. This last assumption is underpinned by the fact that it is stated in the Background Document that it is common practice that producers of spray products obtain ready-formulated impregnating agents from large chemical producers, on which they only make some minor modifications to the mixtures (usually dilutions). These four scenarios are based on the following information:

- SEAC is not aware of if any proofing/impregnation spray products based on mixtures of TDFAs and organic solvents, intended for supply to the general public, are put on the market.
- It is known that there are eight proofing/impregnation spray products with TDFAs and organic solvents put on the market for professional use in Spain. Therefore, it is unlikely that there is a larger product diversity on the market for use by the general public.
- Information received during the public consultation from the Swedish Product Registry, verifies that mixtures containing organic solvents and TDFAs were used in two spray products for non-absorbing surfaces by consumers between the years 2010 and 2013.

For the first scenario, where it is assumed that there are no targeted spray products on the market for consumers use, RMO1 and RMO3 could be more costly for the industry than RMO2. These two options may imply a restriction for the use of mixtures with polyfluoroalkyl trialkoxysilanes with polyfluoroalkyl chain different from octyl if the content of TDFAs as impurities would occur. RMO2 does not involve any product reformulation because the limits of the TDFAs content might be sufficient to avoid the need for reformulation to comply with this RMO. However, there is no information on the content of TDFAs as impurities in such substances or even if TDFAs as impurities occur in such products.

For the scenario with eight companies sharing the market, assuming an equal share of a total annual turnover of €50 000 and €1 200 000 would roughly account for an annual turnover between €6 250 and €150 000 for each company. From SEAC's view, it is not credible that a company produces one product with this annual turnover, for sales throughout the EU.

For the scenario with five companies on the market, each of them would have an annual turnover between €10 000 and €240 000, which is more plausible but perhaps still not credible.

Finally, if there are only two companies on the market, their annual turnover would be €25 000 and €600 000. SEAC finds this to be the more realistic scenario.

According to the SEAC assumptions, industry will only have to reformulate one formula, and therefore the annual costs for reformulation will be an indicative value of €10 000 (central range estimate of the range estimated by the DS for the reformulation costs of one formula).

The price of alternatives

In the background document, there is some evidence that the alternative mixtures, not based on polyfluoroalkylsilanes, used for proofing/impregnation are available at comparable prices to sprays previously on the market. In addition, the cost of functionally similar products designed to be applied using alternative application methods like brushes, rollers or cloths, when compared to spray products is about the same. According to the information submitted by industry via the public consultation, these types of substances are expensive and polyfluoroalkyl trialkoxysilanes with a longer chain than TDFAs are even more expensive, although no precise data were made available and they are probably also covered by the PFOA restriction.

The cost of reformulation of TDFAs by other polyfluoroalkyl trialkoxysilanes, is pointed out in the background document as irrelevant because they are considered drop in alternatives at the same price or at a lower price, with a tendency to increasing prices with increasing chain length of the polyfluoroalkyl alkoxysilanes.

SEAC agrees with this analysis, but notes that the polyfluoroalkyl chain length of polyfluoroalkyl trialkoxysilanes could not be the key parameter to set the price, as the increase in the chain length does not necessarily lead to an increase of the price of the substances[23].

[23] **Santa Cruz Biotechnology (www.scbt.com) 21/10/2016**

1H, 1H, 2H, 2H, Perfluorooctyltrimethoxysilane 5g - $126

1H, 1H, 2H, 2H, Perfluorooctyltriethoxysilane 5g - $101

1H, 1H, 2H, 2H, Perfluoroodecyltrimethoxysilane 5g - $99

1H, 1H, 2H, 2H, Perfluoroodecyltriethoxysilane 5g - $95

Sinquest Laboratories (http://www.synquestlabs.com) 21/10/2016

1H, 1H, 2H, 2H, Perfluorooctylmethoxysilane 5g - $65

1H, 1H, 2H, 2H, Perfluorooctylethoxysilane 5g - $25

1H, 1H, 2H, 2H, Perfluoroodecyllmethoxysilane 5g - $48

Matrix Scientific (https://www.matrixscientific.com) 30/08/2016

1H, 1H, 2H, 2H, Perfluorooctyltrimethoxysilane 5g - $63

1H, 1H, 2H, 2H, Perfluoroodecyltriethoxysilane 5g - $58

Benefits

Summary of the proposal:

According to the Dossier Submitter, the yearly average number of EU28 consumer incidents related to spray products containing TDFAs and organic solvents are estimated to be 330-660 cases. This estimated number of incidents due to sprays containing TDFAs and organic solvents, is based on an extrapolation of the numbers of calls to the Danish Poison Control Hotline (2200 calls, central value) regarding impregnation spray products in general. The ratio of the Danish population to the total EU population was used together with the assumption that 20% to 40% of incidents are related to exposure of TDFAs in organic solvents (see Table 6 of the Background Document), to derive the number of incidents related to impregnation sprays containing TDFAs in Europe. The benefits of the proposed restriction would avoid incidents of respiratory illness. The avoided costs related to respiratory diseases are monetised at €160 000 - €460 000. That is the estimated total annual health benefits for the EU from the implementation of the proposed restriction.

The valuation of the health impacts includes the following cost elements:

- Health sector costs (hospitals)
- Medication costs (for the affected individuals)
- Productions losses (costs of lost working days)
- Welfare costs

The Dossier Submitter considers the environmental benefits of the proposed restriction to be small, as the substances concerned are expected to be substituted with other application methods of the same substances or substances with a similar environmental profile. For alternative mixtures based on polyfluoroalkyl trialkoxysilanes with shorter polyfluoroalkyl chains, the data on environmental effects are limited.

The Dossier Submitter has identified a number of alternatives to the use of mixtures containing TDFAs and organic solvent in consumer sprays, including:

a) Alternative application methods (such as brush, roller or cloth);

b) Water-based mixtures containing TDFAs (mainly for non-adsorbing surfaces);

c) Mixtures based on non-fluorinated active substances. E.g. non-fluorinated alkylsilanes and organic solvents

d) Mixtures based on polyfluorioalkyl trialkoxysilanes chain different from octyl; and

e) Mixtures based on fluorinated active substances except fluorotrialkoxysilanes.

There is a lack of information on the hazards or risks of these alternatives but it is assumed that options a), b) and c) have a much lower impact. With alternatives d) and e), the uncertainties related to impact are higher.

SEAC conclusion(s):

SEAC concludes that the benefits estimation should be based on the potential number of avoided incidents as proposed by the Dossier Submitter. SEAC also agrees with the monetised estimation of health benefits of a case.

However, SEAC disagrees with the estimation of the number of EU cases based on a simple extrapolation of the Danish data. SEAC acknowledges that it is highly likely that the number of registered incidents might not indicate the real number of incidents in the EU, thereby resulting in an underestimation of benefits. However, SEAC does not have any grounds to take the Danish data as representative for all Member States. The available information from some EU countries, presented in table 6 of the Background Document and submitted in the public consultation, points out that most of the Member States do not have any reported incidents related to the use of the targeted spray products. Therefore, SEAC concludes that the Danish data might not be representative for all the EU, and an estimation based on such extrapolation would result in an overestimation. In addition, considering the uncertainty regarding the presence of the targeted products on the market for the general public, the assumption that 40% of the estimated incidents could be related to the use of spray products based on TDFAs and organic solvent does not seem to be realistic. SEAC estimates that the number of human incidents related to the targeted products is in the range of 8.5 - 360 by year, which, using the central value estimate for the yearly average number of incidents in EU, leads to an estimation of benefits in the range of €75 000 – €110 000 per year (see estimation of number of incidents below).

Alternative techniques (e.g. application by brush or roller) or substances, with a potential lower impact are available for the majority of the uses of the restricted product.

Key elements underpinning the SEAC conclusion(s):

The Dossier Submitter in its benefits analysis, assumes 330 - 660 cases per year (average number of EU28 consumer incidents) are related to spray products containing TDFAs and organic solvents, and therefore estimates the benefits of the restriction proposal to be €160 000 - €460 000 yearly. The average number of EU28 consumer incidents is a result of an extrapolation of the number of incidents in all the EU countries using data from Poison Control Hotline in Denmark. The analysis developed by the Dossier Submitter concludes that four to seven Danish consumers suffer an incident related to the use of such products yearly. SEAC agrees with this data analysis for the Danish situation but notes that there is not any evidence that the number of Danish cases is representative for all EU countries.

<u>Health costs</u>

SEAC agrees with the approach taken by the dossier submitter to estimate the hospitalisation costs (€300 - €650 per day) which include the medication costs (€70-€320 per day), production losses (€180 per day) and welfare costs (€50 per day).

For severe incidents as they are described in the background document, SEAC agrees with the Dossier Submitter's estimate for the average number of days for treatment in hospitals (2 days), for production loss and welfare loss (4 days)[24,25,26,27].

[24] Hays, H. L. and Spiller, H., Fluoropolymer-associated illness, Clinical Toxicology Vol. 52, Iss. 8, 2014: 848-855

[25] Müller-Esch, G. and all, Pulmonary effect of inhaling leather-impregnation sprays, Dtsch med Wochenschr 1982; 107(18): 692-695

[26] Morbidity and Mortality Weekly Report, November 26, 1993 / 42(46); 885-887, Centers for Disease Control and Prevention, http://www.cdc.gov/mmwr/preview/mmwrhtml/00022198.htm

[27] Daubert, G. P. and all, Pulmonary Toxicity Following Exposure to Waterproofing Grout Sealer, Journal of Medical Toxicology, volume 5, number 3 September 2009: 125

For the monetisation of the costs of moderate incidents, the dossier submitter suggested using the value derived in the Annex XV dossier proposing restrictions on inorganic ammonium salts (€49). SEAC also accepts this approach considering the similarity of the medical care to treat moderate chemical pneumonitis.

Regarding the costs of €10 for the treatment of mild incidents, this is an assumption made by the dossier submitter without any supporting information, therefore SEAC has no means to assess the value, although the uncertainty of the figure is irrelevant for the conclusions given its magnitude.

SEAC notes that the figures to estimate the health costs are not annualised values, however, taking into account the uncertainties related to the estimated number of incidents in the EU, the correction of the annualised factor is also irrelevant for the SEAC conclusions.

Number of incidents

SEAC agrees that using the figures of the registered incidents is likely to lead to an underestimation of the benefits. However, SEAC also recognises that the estimation using the extrapolated Danish data is likely to lead to an overestimation of the benefits.

The available information does not support that the data from the Danish poison centre on human incidents due to the use of impregnation spray products are representative for EU. The analysis developed by the Dossier Submitter concludes that four to seven Danish consumers suffer an incident related to the use of such products yearly. However, the yearly average number of EU28 consumer incidents related to spray products containing TDFAs and organic solvents collected from the European Poison Centres are 8.5 cases. In addition, the assumption that 40 % of the incidents are related to proofing/impregnation spray products which contain TDFAs and organic solvents is not realistic when there are doubts whether proofing sprays products based on mixtures of TDFAs and organic solvents are available on the market for the use by the general public.

Therefore, SEAC considers that an annual figure in the range between 8.5 - 330, respectively the annual average of registered incidents and the lower bound of the dossier submitter's estimation (20% of the estimated incidents), leads to a more realistic estimation of benefits. SEAC will use the central estimated value, 161 annual incidents, to estimate the annual benefits of the proposal.

Considering these arguments and following the same reasoning as the dossier submitter (Table 16 of the background document), SEAC estimated the benefits between €76 000 and €110 000.

TABLE 4. ANNUAL HEALTH BENEFITS IN EU28 AS ESTIMATED BY SEAC

	Number of EU28 consumer incidents due to spray products containing TDFAs and organic solvents	Cost per incident, €	Cost EU28, incidents probably due to TDFAs in organic solvents, €
Severe Incidents[1] (30%)	48	1 520-2 220	72 960 – 106 560
Moderate	56.5	49	2,769

Incidents[2] (35%)			
Mild incidents[3] (35 %)	56.5	10	565
Total	161		76 294 – 109 894

[1]strong cough, dyspnoea and lung edema; [2]cough, dyspnoea, laboured breathing, bronchitis; [3]mild symptom

Other impacts

Summary of the proposal

The other impacts assessed by the Dossier Submitter regards the social impacts and wider economic impacts such as loss of export revenue and distributional impacts. None of the other impacts assessed are considered by the Dossier Submitter to be significant for the actors of concern.

Social impacts

The Dossier Submitter considers the potential loss of employment to be marginal. The Dossier Submitter has identified that the proposed restriction could result in a small distributional effect due to a change from companies specialised in the manufacture of spray products to companies producing other impregnation products. This implies a situation where a substitution is made for other application methods. If a substitution leads to the use of mixtures based on polyfluoroalkyl trialkoxysilanes with other polyfluoroalkyl chain lengths than TDFAs, it is estimated that this would have very limited effect on the employment in the EU for the manufacturers of the substances due to the very low volumes used.

The possible changes in price for the end users are not considered to be significant by the Dossier Submitter as the alternatives are not more expensive.

Wider economic impacts

Loss of export revenue

According to the Dossier Submitter, the proposal will not influence the export of the substance or the use of the same in mixtures in spray products.

The main producers of the affected products are small companies carrying their own brands supplying for a regional or local market. The Dossier Submitter has therefore not identified any impacts for producers of spray products organised in the trade associations. The consultation with industry conducted by the Dossier Submitter, assisted by ECHA, during the development of this restriction proposal also confirms this. The Dossier Submitter estimates that the exportation to non-EU countries as well as the loss of revenue due to the implementation of the proposed restriction to be marginal.

Distributional impacts

The Dossier Submitter has indicated that the proposed restriction could result in small distributional effects due to a change from companies specialised in the production of spray products to companies filling the mixtures on trigger sprays.

SEAC conclusion(s):

SEAC concludes that the other impacts specified above are highly unlikely to be relevant and that the resulting change is likely to be distributional. SEAC arrived at this conclusion by considering: the small size of the market, the estimated costs and benefits, the availability of alternatives (products, substances, application methods) available on the market, the absence of claims in the industry consultation carried out by the Dossier Submitter, and information submitted in the public consultation.

Key elements underpinning the SEAC conclusion(s):

The Dossier Submitter provided qualitative information and analysis of the social and wider economic impacts. The information provided during the public consultation and by direct consultation with some stakeholders did not yield any further data regarding impacts for SEAC to consider.

Overall proportionality

Summary of proposal:

The Dossier Submitter concludes that the proposed restriction is proportionate to the risk as alternative application methods and other spray products without TDFAs are already available. Furthermore, the negative effects on the market are estimated by the Dossier Submitter to be marginal while potential health effects of the application of the targeted mixture in aerosol dispensers are expected to bring positive effects.

The following elements were mentioned by the Dossier Submitter to support that the proposed restriction is proportional to the risks:

- It has been demonstrated in animal studies that the reaction products of the targeted mixtures applied as aerosol cause adverse effects of the same type as reported from many incidents of a syndrome of acute lung injury. The risk assessment for spray products containing hydrolysates and condensates of TDFAs and 2-propanol shows a risk that is not adequately controlled for these reaction products applied by aerosol dispenser or trigger and pump sprays.
- For manufacturers the proposed restriction has limited impact. Manufacturers of the active substances also produce the alternatives. Furthermore, the supply to the general public is limited compared to the supply to professionals.
- Products applying alternative, less dangerous, application methods or spray products based on mixtures without TDFAs are widely available for consumers at prices comparable to the prices of the targeted products.
- Furthermore, if products for professional uses are available, consumers might in specific cases require professional assistance. The most critical use is considered to be easy-clean-applications for non-absorbing materials. In these cases more cleaning might be needed in case “protection” mixtures can not be applied.
- No other impacts are envisaged

SEAC conclusion(s):

If the targeted spray products are not currently placed on the market, this restriction proposal will prevent future incidents of respiratory distress by avoiding the targeted spray products from being placed on the market. In the case the targeted spray products are placed on the market in the future, the impacts have been identified in the proposal and evaluated in this opinion. In this case, SEAC concludes that the proposal is not disproportionate.

Assuming relevant products are currently placed on the market, as this cannot be discounted, SEAC assessed qualitatively the RMOs (RMO 1, RMO 2 and RMO 3) to identify the restriction proposal that would be most proportional or least disproportionate.

The qualitative analysis presented below (See Tables 2 and 3), however, does not allow SEAC to conclude on which RMO is the most proportional. The small differences between the three RMOs arising from the qualitative analysis are not relevant considering the uncertainties about the costs. In particular, there are major uncertainties about the reformulation and testing costs due to the lack of information about the presence of TDFAs as impurities in polyfluoroalkyl trialkoxysilanes with polyfluoroalkyl chain different from octyl.

The estimates based on monetised costs and benefit suggest that each one of the three RMOs are proportional to the risks (see Table 7), however, these estimates were (using this approach) deemed too uncertain to achieve any conclusion.

However, due to the probable low costs of the proposal it is concluded that it is unlikely that the proposed restriction would be disproportionate.

In this regard it should also be noted that, SEAC concluded that a restriction, specifically RMO1 (as amended), is the most appropriate EU wide measure to address the concern for human exposure to spray products containing mixtures of TDFAs and organic solvents.

Key elements underpinning the SEAC conclusion(s):

SEAC does not have any information whether concentrations of TDFAs as impurities occur in polyfluoroalkyl trialkoxysilanes with polyfluoroalkyl chain different from octyl. Thus, it cannot be fully excluded that a restriction for TDFAs used in a concentration of 2 ppb, like RMO1 and RMO3, will impose a ban also for polyfluoroalkyl trialkoxysilanes other than TDFAs as acknowledged by the Dossier Submitter. However, no information confirming or denying the presence of TDFA impurities was submitted in the SEAC Draft Opinion Public Consultation[28]. Regarding the risk reduction potential of the proposed restriction options, RMO 1 might not be more effective than RMO 2, as both of the two RMO impose TDFAs concentration limits, 2 ppb and 800 ppb respectively, to ensure that risks are adequately controlled for the general public. However, RMO1 and RMO3 could imply a restriction also for the use of mixtures with polyfluoroalkyl trialkoxysilanes with polyfluoroalkyl chain different from octyl, if TDFAs are present as impurities in its composition. RMO2 might not imply any reformulation for spray products based on polyfluoroalkyl trialkoxysilanes, other than TDFAs and could allow the use of drop in alternative substances for the ones based on TDFAs and organic solvents. However, SEAC does not have any evidence that the content of TDFAs as impurities in polyfluoroalkyl trialkoxysilanes with polyfluoroalkyl chain different from octyl are below of 800 ppb or even if they are present. Furthermore, SEAC does not have information about the inherent risks of the uses of such alternative substances and other less hazardous alternatives are available.

[28] It is assumed if this was a high concern to industry this would have been raised by industry in their response.

If there are no relevant proofing/impregnation spray products containing a mixture of TDFAs and organic solvents on the market, the assessment of the proportionality to the risks is of less importance. SEAC agrees that the restriction could bring positive effects in terms of preventing negative health effects. However, RMO1 and RMO3 could also have impacts on products that are used on the market that do not contain TDFAs in the formulation if there are impurities, due to the reasoning presented above. Whether TDFAs are present as impurities was however not confirmed during the public consultations.

Considering the limitations of the quantitative analysis, only a rough estimation of the reformulation costs has been made by SEAC and it is not possible to estimate the costs for laboratory test to ensure compliance, consequently it is not possible for SEAC to conclude on this basis whether RMO1, RMO 2 or RMO3 is the most cost-effective option. The quantitative analysis is therefore not sufficiently accurate to differentiate between the three RMOs in terms of them being proportionate to the risks.

SEAC found the following uncertainties and weaknesses of the qualitative analysis carried out by the Dossier Submitter:

- There is no available information on the concentration of TDFAs as impurities in polyfluoroalkyl trialkoxysilanes with polyfluoroalkyl chain different from octyl. It is however known that some distribution of relative molecular masses[29] may occur in polymerisation reaction products, as result of the different chain lengths of the synthesised polymers. Therefore, SEAC has accepted the assumption of the Dossier Submitter that RMO 1 could cover other polyfluoroalkyl trialkoxysilanes with a different chain length from TDFAs. Because of that, RMO 1 might be more effective to prevent incidents with proofing/impregnation spray products. Considering that RMO 2 might have less impact on reformulation costs, polyfluoroalkyl trialkoxysilanes with chain length different from TDFAs could be used as drop-in alternatives. However, SEAC does not have any information about the concentration of the TDFAs as impurities in such substances.

- There is no available information on the cost for testing in order to ensure compliance. SEAC is aware of that the quantitative tests to measure the TDFAs content, required by the RMO2, are at least three times more expensive than the tests required by the RMO1. In addition, there is no information on the number of the tests required on an annual basis or if contractual arrangements could be used in place of some or all testing. Therefore, it is not possible for SEAC to assess this cost for the industry. In addition to the SEAC estimation for the reformulation costs using non drop-in substances, foresees an annual cost in the range of €8 000- €12 000. Therefore, and the uncertainties mentioned above, a qualitative analysis of the differences between RMO1 and RMO2 in relation to the dimensions compliance cost it is difficult to be conducted, as it is unknown whether these test costs would be higher or lower than the reformulation costs. SEAC notes that reformulation costs could be similar to RMO 1 and RMO2 provided it is assumed that TDFAs are not present as impurities in polyfluoroalkyl trialkoxysilanes with chain length different from TDFAs.

- The enforcement of RMO2 could cost more than RMO1 if the enforcement will focus on products on the shelves, where the compliance cost regarding testing would be

[29] Bower, D. I., An introduction to polymer physics. Cambridge University Press: New York, 2002.

relevant. However, it could be expected that the enforcement will be done also through inspections undertaken by the producers of proofing/impregnation spray products, where the focus will be an analysis of the information that the companies present to attest the compliance. In the latter case, the costs are the same for the two RMOs.

Table 5 - Comparing the impacts of different RMOs using qualitative, quantitative and monetised data.

RMO	Advantages:	Drawbacks:
RMO1: (proposed restriction – ban mixtures of TDFAs and organic solvents in spray products for use by general public)	2.5-100 fewer consumers with severe incidents. 3-115 fewer consumers with moderate incidents. 3-115 fewer consumers with mild incidents.	The eventual content of TDFAs as impurities in polyfluoroalkyl trialcoxy silanes with polyfluoroalkyl chains different from octyl could make the use of these substances as drop in alternatives impossible. Therefore, higher reformulation costs per formula might be foreseen. However, there is not any information available regarding this matter. Fewer consumer benefits due to the poor performance of the alternatives products and alternative application methods. Possible social impacts in terms of unemployment. However irrelevant due to the small market of the targeted products. Administrative costs. Some distributional impacts might be foreseen but still irrelevant due to the small market of the targeted products. Blacklist effect.
RMO2: (ban of mixtures of TDFAs and organic solvent in spray products for general public uses in a concentration of TDFAs equal to or greater than 800 ppb)	2.5-100 fewer consumers with severe incidents. 3-115 fewer consumers with moderate incidents. 3-115 fewer consumers with mild incidents.	Polyfluoroalkyl trialkoxy silanes with polyfluoroalkyl chains different from octyl could be used as alternatives, which foresees lower reformulation costs – drop in alternatives. There is no information on this matter. Fewer consumer benefits due to the poor performance of the alternative products and alternative application methods. However, it is possible to keep using polyfluoroalkyl trialcoxy silanes with different chain length in sprays. Possible social impacts in terms of unemployment, however still irrelevant due to the small market of the targeted products. Administrative costs. Higher costs to ensure compliance (higher testing costs).

RMO	Advantages:	Drawbacks:
		Some distributional impacts might be foreseen but still irrelevant due to the small market of the targeted products. Blacklist effect.
RMO3: (ban mixtures of TDFAs and organic solvents in aerosol products for use by general public)	Less than 2.5 -100 fewer consumers with severe incidents. Less than 3-115 fewer consumers with moderate incidents. Less than 3-115 fewer consumers with mild incidents.	Higher reformulation costs per formula might be foreseen if the companies will not change from the aerosol production to pump and trigger sprays, provided polyfluoroalkyl trialkoxysilanes with chain length different from TDFAs could not be used as drop-in alternatives. Fewer consumer benefits due to the poor performance of the alternative products and alternative application methods. It is possible to keep using pump and trigger spray products filled with mixtures of TDFAs and organic solvents with the same level of performance. Possible social impacts in terms of unemployment, however still irrelevant due to the small market of the targeted products. Administrative costs. Some distributional impacts might be foreseen but still irrelevant due to the small market value of the targeted products. Blacklist effect.

Table 6 - Comparing the main impacts of different RMOs using a qualitative scale. Using a qualitative scale to compare the net result of costs and benefits, where the relative severity of the impacts could be a positive impact among the three RMOs. (+): Showing a positive impact. (-): Showing negative impact.

	Health impacts	Impacts on reformulation	Administrative costs including tests	Change in consumer benefits	Total
RMO1	+++ Avoids incidents with proofing/impregnation spray (aerosol, trigger and pump sprays) products based on organic solvents and TDFAs or other polyfluoroalkyl trialkoxysilanes.	-- May not be possible to use drop in alternatives due to the content of TDFAs as impurities. Could also involve the reformulation of proofing/impregnation spray products based on alternative polyfluoroalkyl trialkoxysilanes, due to the content in such products of TDFAs as impurities.	- Qualitative control tests should be applied to proofing/impregnation spray products based in organic solvents and TDFAs or other polyfluoroalkyl trialkoxysilanes (€ 300/test).	-- Proofing/impregnation mixtures with TDFAs are high-end products and will be restricted. Other high performance spray products based on mixtures with alternatives such as polyfluoroalkyl trialkoxysilanes could also be restricted.	-2
RMO2	+++ Avoids incidents with spray (aerosol, trigger and pump sprays) proofing/impregnation spray products based on organic solvents and TDFAs.	- Allows the use of drop in alternatives, unless the residues (if any) are >800 ppb. It is not expected to involve the reformulation of spray products based on alternative polyfluoroalkyl trialkoxysilanes. Allows a higher concentration limit for TDFAs, allow the content of TDFAs as impurities in these products and avoid the need for reformulation and inherent costs.	--- Quantitative control tests should be applied for proofing/impregnation spray products based on organic solvents and TDFAs (> € 1000/test).	- Proofing/impregnation mixtures with TDFAs are high-end products and will be restricted. However, consumers could choose other high performance spray products based on alternatives such as polyfluoroalkyl trialkoxysilanes.	-2
RMO3	+ The same as RMO1 but only avoids incidents with aerosol spray products.	- The same as RMO1 but only affects the reformulation of aerosol products.	- The same as RMO1 but only affect the control of aerosol products	- Can be used for trigger or pump proofing/impregnation sprays products based on mixtures with	-2

				polyfluoroalkyl trialkoxysilanes that includes TDFAs.	

Table 7 - Comparing the main impacts of different RMOs using qualitative, quantitative and monetised data.

	Health impacts (per year)	Reformulation costs (per year)	Administrative costs include tests
RMO1	€75 000 - €110 000	€8 000 – 12 000	€ 300/test
RMO2	€75 000 – €110 000	Drop in alternatives at the same price level – irrelevant reformulation costs	More than € 1000/test
RMO3	Fewer benefits than RMO1 and RMO2	Reformulation costs between RMO1 and RMO2	€ 300/test

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

RAC

The proposed restriction is considered effective in reducing the risks for these mixtures in particular although other impregnation agents are not addressed by this proposal. This proposal avoids the issue that at the present, there is a lack of standardised test methods to quantify 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives.

The restriction requires that 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives is prohibited from being formulated along with organic solvents in the production of spray products intended for supply to the general public in the EU. This message is easy to communicate down the supply chain and the restriction can be enforced.

A standardised method would ensure reproducible enforcement. A combination of two methods for analysing the targeted substances were suggested, the technical devices can be purchased. The detection limit of these methods is 1-2 ppb.

SEAC

As the proposed restriction includes a ban on the use of TDFAs in mixtures used in spray products it is considered effective in reducing only the risks for these mixtures in particular because other impregnation agents are not addressed by this proposal. This proposal also avoids the issue that there is a lack of test methods to quantify TDFAs.

For the proposed restriction, the drop-in alternatives available for TDFAs might not be allowed to be used as alternatives, mainly because it is not known if there are no polyfluoroalkyl trialkoxysilanes exclusively with polyfluoroalkyl chain different from octyl polyfluoroalkyl silanes available on the market. The content of TDFAs in these substances as impurities seem likely to occur. However, the Dossier Submitter notes that there are alternatives such as silicones and other alkyl siloxanes available that could provide the same protection however with inferior quality. In addition, different application methods of mixtures of TDFAs and organic solvents as well water based mixtures could be used as an alternative instead of the

organic solvents. However, further information provided after the submission indicates that the water based mixtures would not be applicable for non-absorbing surfaces. The Dossier Submitter therefore concludes that substitution is both technically and economically feasible for these products. The Dossier Submitter also concluded that the proposal is implementable and manageable.

Formulators of products that currently contain TDFAs may need to reformulate their products prior to the deadline, i.e. by the end of the transition period or to change the application method. They may also need to seek confirmation from their supplier about the content of TDFAs in the polymers or mixtures they purchase. The retailers of aerosol and spray producers may request a declaration from their suppliers that none of their products contains TDFAs. The authorities may as the main instrument for enforcement request information about the content of product composition from the suppliers of the consumer products.

Compliance tests are expected to be undertaken as spot test campaigns and even to assess the level of compliance. The Dosser Submitter claims that at present there are no EU standards neither adequate nor analytic standard method available. The Dossier submitter has proposed to use a combination of direct infusion ESI-MS and APCI-MS in their proposal. In addition, it was considered that the TOP Assay method, which is currently being implemented by a commercial laboratory for analysing PFOA and PFOA precursors, could be adapted to analyse the targeted substances with a limit of detection of 2 ppb. However, further information provided after the submission indicates that the TOP assay method might not be applicable to use for running TDFAs analysis, as it has not been tested for such a use.

RAC conclusions:

- RAC agrees the message that 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives must not be used in mixtures along with organic solvents in spray products intended for supply to the general public is clear message that can be communicated in Annex XVII REACH.
- RAC agrees that the proposed legal text by the Dossier Submitter is not exclusive to cover proofing impregnating products but would also apply to any spray product supplied to the general public and consumers containing an organic solvent and TDFAs.
- RAC has suggested some rewording to try and make it clear that the restriction only applies to sprays products when 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents are used together in the one mixture.
- Enforcement of the 2 ppb requirement would require confirmation from formulators and importers of spray products that 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives in combination with organic solvents are not present in consumer spray products.
- The limit of 2 ppb allows industry and enforcement authorities to determine that no relevant concentration of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives is present in the spray product and thus the product is in compliance with the requirement for the absence of TDFAs and organic solvents in the mixture.
- For products containing (water-based) 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives above 2 ppb information on the lack of organic solvents must be generated. In addition standard methods on residual

solvents are established (Headspace method USP 467[30]) and can be conducted by enforcement authorities.

- RAC agrees with Forum's advice that formulation of mixtures containing organic solvents and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives alone shall not be included in the restriction based on the lack of evidence on the risk related to formulation as such.
- RAC agrees that manufacture of spray products containing organic solvents and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives that will be used in the EU (and their imports) should be restricted. However it is to note that manufacture of products to be exported are not covered by a restriction measure under REACH.
- RAC notes that further validation through COM on standardisation of analytical methods is needed.

Key elements underpinning the RAC conclusion(s):

The incidents of concern identified is in proofing sprays and the risk assessment has been based on proofing sprays. Information from poison centres continues to be reported for impregnation products however there is still no evidence available that these products contain mixtures of TDFAs and organic solvents. The dossier highlights that those formulating and importing these products are not aware of the risk so by focusing the restriction on these products it may be better at raising awareness in the sector. The current wording would mean that all consumer sprays containing organic solvents would have to be checked that they do not contain 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives.

Forum raised the question whether the sampling of liquids and pressurised fluids fit with the proposed methods which were not yet tested for TDFAs analysis. The Dossier Submitter clarifies that TDFAs are to analysed in the released spray. Spray products generating a single peak of TDFAs in the spray mist that exceeds 2 ppb are within the scope of this restriction.

As the TOP Assay which was initially proposed as a commercially available test method has not been tested for suitability to detect TDFAs, the Dossier Submitter considers to replace the TOP Assay method with the combination of direct infusion ESI-MS and APCI-MS for the analysis (Norgaard et al., 2010b and 2010c) which is also commercially available. The low temperature plasma (LTP) ionisation has been recommended to detect 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives in their unreacted state. However, this method is not commercially available. Both methods (with a LOD of 1-2 ppb) will be able to detect 2 ppb.

The Forum recommends to use the limit of quantification which according to good science practice should be 10 times greater, however the Dossier Submitter insists on a limit value based on a non-detectable content of TDFAs. RAC understands that 2 ppb is not a risk based value, rather the restriction proposal intends to ban TDFAs in the organic solvent mixture.

In principle, other spray products containing polyfluorinatied trialkoxysilanies may be affected when TDFAs occur in trace levels. The Dossier Submitter indicates that the existence of TDFAs as impurities is unknown to the Dossier Submitter, in such cases the spray products will also be covered by the restriction.

A ban on the formulation of mixtures containing TDFAs is a not necessary condition from the

[30] USP 467 Residual Solvents https://hmc.usp.org/sites/default/files/documents/HMC/GCs-Pdfs/c467.pdf

Forum's view. A ban on the formulation of TDFAs and organic solvents was included by the Dossier submitter to ease the enforcement. The Dossier Submitter explained that this relates to manufacture of impregnating sprays in the EU which is something that can be checked by inspectors through inspection of practices and documentation on sites where such spray products are manufactured in the EU without the need to undertake any chemical analysis.

A previous producer of the formulation for spray products for the supply to the general public and for professional applications can still use the formulation for the professional products. Forum and the Dossier Submitter agreed that the labelling of mixtures for professional use only may be helpful.

The Forum considered that the proposed restriction wording would require modification and an appropriately available test method to be enforceable. The Dossier Submitter clarified these elements the following the Forum advice.

- The proposed test method is a combination of direct infusion ESI-MS and APCI-MS for the analysis of the parent substances which has a LOD of 1-2 ppb.
- The proposed limit of 2 ppb applies to any individual TDFAs or related intermediate TDFAs detected in the spray and does not require quantification of TDFAs in a chemical mixture (i.e. no LOQ is required for enforcement) as the quantification is complex and an expensive task.
- Mixtures that contain other polyfluoroalkyl trialkoxysilanes with TDFAs in trace levels above the limit value exist should be considered as coming within the scope of the restriction.
- The scope of the restriction is intended to apply to individual substances and not to the cumulative level of all TDFAs substances. The justification is that an impregnation mixture should contain between 0.5 and 2 % TDFAs. If a mixture contains more than one substance belonging to the group of TDFAs they will react with the solvent to create the same intermediate TDFAs if the solvent is an alcohol. In this case it is the sum that is actually measured.
- The intention behind prohibiting the formulation of TDFAs and organic solvents in spray products on the EU market intended for sale to the general public is to assist enforcement (enforcement can be done upon site inspection by checking inputs to production).
- It is not intended to prohibit the formulation of such products for export outside the EU. The restriction should apply to all consumer spray products for the purpose of impregnation or sealing of the surfaces/materials of concern.
- According to the background document the detection limit (LOD) for ESI-MS and APCI-MS depends on the Mass Spectrometry (MS) equipment and that for modern equipment a LOD of 1-2 ppb can be achieved for the parent silanes. The limit proposed is 2 ppb.
- According to Nørgaard et al. 2010: *Characterisation of nanofilm spray products by mass spectrometry* it is possible to distinguish between polyfluorooctyl trimethoxysilane and polyfluorooctyl triethoxysilane. Some peaks in the MS will, tough, overlap (be the same). However, if the mixture contains an alcohol (e.g. 2-propanol) that can react with the alkoxy part of TDFAs it is the MS-spectrum of this new intermediate TDFAs (e.g. polyfluorooctyl triisopropoxysilane) that will be seen.
- Information from the public consultation has not identified any spray products

containing TDFAs and organic solvents for consumers since 2014. It did yield information relating to 8 products for professional use containing TDFAs, 4 of which are water-based and for absorbing surfaces with the other 4 products being organic solvent based.

SEAC conclusion(s):

SEAC finds that the proposed restriction is implementable and manageable with the changes it has made.

This restriction can be communicated down the supply chain. As alternative application methods are available (similar products without TDFAs exist on the market), SEAC finds it possible to replace TDFAs with the alternatives that seem to be both technically and economically feasible. However, SEAC does not exclude the possibility that replacing TDFAs in the proofing/impregnation spray products might result in some product performance loss, but still SEAC concludes that the restriction proposal is implementable and manageable.

SEAC finds that the enforceability of the restriction could be problematic as no standardised test methods are yet available. SEAC notes that further work on standardisation of analytical methods is required. The Dossier Submitter proposed to apply a combination or two methods for qualitative analysis of the targeted products. The detection limit of these methods is 1-2 ppb.

SEAC has proposed some changes in the wording of the restriction text in order to improve the practicality and enforceability. Furthermore, SEAC agrees with Forum and RAC that a label indicating that the product can only be placed on the market for professional use would improve the practicality of the restriction.

Targeting and detection of non-compliance in end products will be difficult as detailed product data are not likely to be communicated via the labels. Sampling will be feasible for inspectors as the samples typically will be spray products.

The Forum considers that the restriction is not enforceable with the wording proposed by the Dossier Submitter. However, Forum finds that the proposed restriction could be enforceable with some adaptations made on the restriction text and the improved availability of methods for the determination of the regulated substances. SEAC has further suggested some rewording in order to clarify that the restriction only applies to proofing/impregnation spray products when TDFAs and organic solvents are used together in the mixture. The suggested change of wording by SEAC also clarifies that the restriction does not ban the formulation of the mixtures by the companies but only the placing on the market of such mixtures as the basis of proof/impregnation spray products for supply to the general public. With these considerations taken and changes made as presented above, SEAC agrees and finds that the proposed restriction could be implementable, enforceable and manageable.

There is very little discussion about the justification for the transition period in the proposed restriction. When describing the reformulation process, the Dossier Submitter states that there are no major impacts and therefore that no consideration needs to be taken regarding the time for reformulation. SEAC notes the lack of information about the specific length of time required to perform a reformulation to remove TDFAs, and thus cannot conclude on whether it is manageable for the involved actors to reach compliance within the proposed 18 month compliance period or not. Additionally, there is no information of the relation between the compliance period and the development of any analytical test. If the targeted products are not put on the market, the assessment regarding reformulation is irrelevant. Notwithstanding, there is no discussion of the relation between the compliance period and the development of any analytical test or the development of a standardized method to enforce

the restriction. SEAC has therefore no ground to justify or reject 18 months of compliance period but agrees that it could be sufficient to deplete stocks.

Key elements underpinning the SEAC conclusion(s):

SEAC notes that it seems difficult to detect the content of TDFAs even qualitatively, in some mixtures, because of the low concentrations and because of the available analytical techniques, which do not allow identification with sufficient detail of the type of polyfluoroalkyl silanes presented in some mixtures. In its advice, Forum pointed out that the restriction proposal is difficult to enforce due to the lack of clarity of the scope and the lack of available methods for the determination of regulated substances. At present, it seems that the TOP assay method is not considered applicable to use as a tool for this restriction. The background document will therefore only address the ESI-MS and APCI-MS tests for TDFAs' analyses.

SEAC notes that additionally, enforcement authorities will have to deal with the deficient information regarding the identification of TDFAs along the supply chain. According to the Dossier Submitter it is common that formulators do not know exactly which polyfluoroalkyl is being used in their formulations. The Dossier Submitter does not discuss the necessary steps for ensuring compliance for the different actors (manufacturers, importers, formulators, producers, retailers). Therefore, SEAC is not able to assess whether this information in the supply chain will be achieved and able to use for enforcement purposes. However, it is expected that the current situation would change with the implementation of this restriction, which could allow the enforcement via the analysis of the information in the supply chain.

The Dosser Submitter claims that at present there are no EU standards neither adequate nor analytical standard method available. The TOP Assay method is currently being implemented by a commercial laboratory for analysing PFOA and PFOA precursors. This method could, according to the information in the dossier be adapted to analyse the targeted substances, with the limit of detection of 2 ppb. However, further information provided after the submission indicates that the TOP assay method might not be applicable to use for running TDFAs analysis.

As RAC, SEAC also notes that enforcement of the 2 ppb would require a confirmation from formulators and importers of spray products that TDFAs in mixtures with organic solvents are not present in consumer spray product.

Furthermore, the Forum and the Dossier Submitter have agreed that the labelling of mixtures for professional use would be helpful. The Dossier Submitter concludes that enforcement can also be carried out upon site inspections by checking inputs to production.

Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter states that the proposed restriction could be monitored either by monitoring of the number of poisoning incidents or by the monitoring of non-compliance. To monitor the non-compliance, the Dossier Submitter identifies that the RAPEX system can be used to monitor the compliance with the restriction at an EU level. In addition, national control campaigns could be coordinated by Forum to further monitor the compliance.

RAC conclusion(s):

RAC consider that, unless dedicated inspections are undertaken at the manufacturers of impregnation, proofing etc. sprays or testing is conducted on the final or imported products, determining compliance using RAPEX may not be effective since RAPEX alerts are not an instrument to systematically monitor the presence of new series of incidents and are unlikely to be able confirm the presence of TDFAs in the product.

Key elements underpinning the RAC conclusion(s):

Enforcement can be undertaken at the production sites or when imported. At the formulation site the ingredients can be checked on-site. The label can be checked for "professional use only" and the SDS can be checked for the presence of 'Fatal if inhaled'. In addition the formulation can be tested for the lack or presence of 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents.

A comprehensive monitoring system covering all poisoning incidents does not exist in most Member States. Even if such a system were to exist it would be impeded as the active substances of the spray products are usually not indicated on the packaging. The chemical identification of the active substances would therefore not be recorded. In addition RAPEX notification do not reflect the availability of spray products containing TDFAs and organic solvents in a systematic or representative approach on a national or EU level.

Poisoning incident monitoring information would potentially only provide statistics of the number of incidents involving the use of proofing/impregnation products. The data may also provide information on the presence or absence of organic solvent-based spray products, but up to date will in most case not be able to inform about the active ingredients.

The current proposed wording by the Dossier Submitter covers all spray products sold to the general public and not just impregnating proofing sprays it may be difficult for Member States to identify what other products contain TDFA's and organic solvents.

RAC consider unless market surveillance is undertaken or testing is conducted, determining compliance using RAPEX will likely only be based on reported incidents to the national poison centres. Such notifications are unlikely to be able to confirm the presence of TDFAs in the product.

SEAC conclusion(s):

SEAC agrees that the restriction is monitorable to some extent. The scope of the proposed restriction by the dossier submitter covers all spray products sold to the general public and not only impregnating and proofing sprays. Therefore, it will be difficult to identify and monitor other products that contain mixtures of TDFAs and organic solvents.

Key elements underpinning the SEAC conclusion(s):

The Forum has not considered monitorability of the proposed restriction in its draft advice.

The Dossier Submitter suggests that even with the considered constraints the monitorability of the proposed restriction is still possible. However, the Dossier Submitter points out the following pitfalls:

- Comprehensive monitoring systems covering all poisoning incidents does not seem to exist in most Member States.
- The exact composition of the impregnating agent is often not known.
- The monitoring is based on reported incidents of respiratory illness resulting from all types of impregnating agents applied by spray.

- A small number of reported incidents.
- A high annual variation of the number of reported incidents.

As a comprehensive monitoring system covering all poisoning incidents does not exist in the Member States, SEAC questions how effective the monitorability of the restriction would be based on national poison centre data and notifications to RAPEX. The RAPEX notification does not reflect the actual use of spray products containing TDFAs and organic solvents neither on a national nor on an EU level. These monitoring systems can only provide statistics of the number of incidents from the use of proofing/impregnation products but not give information about the active ingredients or actual use of TDFAs.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of proposal:

Several of the uncertainties are related to lack of information and lack of knowledge on downstream uses in the industry. The proposal is based primarily on the basis of effects seen in experiments with mice exposed to aerosolised mixtures containing TDFAs and organic solvent. The results are compared to incidents reported to poison centres using certain proofing impregnation spray products.

While it is not possible to confirm the human incidents with the actual composition of the spray products, as data on the products composition does not exist. The substances are only referred to as "fluorinated substance" or "polyfluorinated substance" to the end-producers; this implies that the actual substances are not known; concentrations of parent substances are so low that the producers do not classify the final products. There were 154 incidents in 2006 in Germany involving two aerosol products Magic Nano Glass & Ceramic" and "Magic Nano Bath & WC" which were most likely based on a fluorosilane, Koch et al. (2009). The polyfluoroalkyl chain length of the fluorosilane is not known, but it could though very well be TDFAs.

It is also not possible to confirm if as a result of the poisoning incidents and the requirements of the PSD whether the market has already changed. Following the incidents with Magic Nano consumer products were still available on the market in Sweden until 2014.

It is also not clear to what extent the propsed restriction proposed would affect mixtures based on other polyfluorinated trialkoxysilanes due to trace levels of TDFAs in the mixtures. The present scope is rather narrow and limited to TDFAs while additional incidents exist from uses of products containing less defined fluorinated polymers or other ingredients will not be covered by the restriction proposal. Uncertainties about the effectiveness in reduction of incidents remain.

RAC conclusion(s):

- RAC agrees that the toxic substances in the Magic Nano Glass & Ceramic and the Magic Nano Bath & WC were likely to be fluorosilanes with unknown length of the per/poly-fluoroalkyl chain.
- RAC agrees that parameters such as the application pressure, type of nozzle and volatility of the mixture influence the droplet/particle size. In spray products with a higher percentage of particles less than 10 µm increase the ability and likeliness of the

substances to reach the alveoli and thus the toxicity of the product.

- RAC agrees that sprays generated from organic solvents may result in particle sizes becoming smaller over time by the evaporation of organic solvents, such that these particles can easily penetrate the alveolus. While no assessment of the variation in volatility of solvents used in aerosols was undertaken in the dossier even if the solvent is replaced with a less toxic solvent that is more volatile, the inhalation exposure will be increased.
- RAC agrees similar effects as seen for the Magic Nano aerosol products are to be expected in aerosol products containing TDFAs & organic solvents.

  Spray products containing TDFAs in mixtures with organic solvents are normally used for non-absorbing surfaces. While it cannot be ruled out that some users could use organic solvent-based agents for absorbing surfaces these products are not marketed for such applications and such use would constitute a foreseeable misuse.
- RAC cannot confirm if the risks are properly controlled from all pump and triggers sprays. However, there is evidence to support that pump and particularly trigger sprays produce aerosols in the range < 10 µm.
- In the absence of Forum review on updated information on testing RAC agrees that the proposed test method of using a combination of direct infusion ESI-MS and APCI-MS may be a suitable test method to determine compliance.
- Inhalation toxicity testing of each individual compound is not sufficient to assess the hazard of formulated products of TDFAs and organic solvents.
- At present no specific (TDFAs-related) consumer incident information on pump and trigger sprays is available. Taking the recent information from commercially available impregnation pump sprays into account that identified particle sizes <11 µm or in the nanometer sizes in pump sprays (Kawakami et al. 2015, Losert et al., 2015), the generation of respirable particles <10 µm cannot be excluded. As no firm information exist on the threshold concentration that does not cause harm, there is a potential risk for pump and trigger spray applications.
- The Dossier Submitter assumed in the original exposure assessment that all generated aerosols have relevant fractions of MMAD < 10 µm but data from the Koch study (2009) does support this for aerosol products (with more than 20% of particles < 10 µm) and a lower particle concentration of respirable fraction for pump sprays (less than 0.9%). Therefore the dossier submitter's original exposure assessment may have overestimated the risk.
- RAC agrees there are greater uncertainties with the applicability of the ConsExpo model compared to SprayExpo. RAC considers that the input parameters for the exposure modelling for pump and trigger spray have greater uncertainty.

Key elements underpinning the RAC conclusion(s):

RAC in noting that the Dossier Submitter could not prove the similarity of the products on the market responsible for human incidents considers that the toxic substances in the Magic Nano Glass & Ceramic and the Magic Nano Bath & WC were likely to be fluorosilane with unknown length of the per/poly-fluoroalkyl chain.

While it could be argued there is no need for further action because the PSD was effective in addressing the issue, as the Magic Nano specific products were withdrawn from the market PSD is a product specific piece of legislation and will not address the use of TDFAs and organic

solvents under other product brand names**.**

The test data on aerosolised mixtures of perfluorinated silanes and 2-propanol confirmed lung toxicity in a mouse model. A study by Yamashita et al[31] which tested 4 identical waterproofing sprays with different mist particle sizes supports that the toxicity of waterproofing sprays is influenced by mist particle size generated. RAC agrees if a similar aerosol product containing a mixture of these substances were on the market, similar effects as seen for the Magic Nano aerosol products are to be expected.

There are no human cases involving pump and trigger sprays containing 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its TDFA derivatives and organic solvents. The Norgaard particle size distribution provides information on nebulised TDFAs and organic solvents where concentrations of 16.1 mg/m^3 (particles <10 µm) resulted in no lung effects in mice. Therefore considering a theoretical concentration of particles less than <10 µm (after correction for this fraction of 3% in trigger sprays and 0.9% in pump sprays) then it is unlikely that human cases would appear for exposures using pump sprays. This raises some uncertainties regarding the risks from pump and trigger sprays.

It is questionable how effective the monitorability of the restriction will be from national poison centre data due to existing difficulties confirming the presence of TDFA's in the product or from notifications to RAPEX because a comprehensive monitoring system covering all poisoning incidents does not exist in most (if any) Member States.

The Dossier Submitter has indicated the detection limit (LOD) for ESI-MS and APCI-MS depends on the Mass Spectrometry (MS) equipment and that for modern equipment a LOD of 1-2 ppb can be achieved for the parent silanes. The limit proposed in the dossier is 2 ppb.

The Dossier Submitter does not suggest quantification of TDFAs in a chemical mixture (i.e. no LOQ is required for enforcement) as this is complex and expensive task. Mixtures based on other polyfluoroalkyl trialkoxysilanes that contain TDFAs in trace levels above the limit value exist they will be covered by the restriction.

According to Nørgaard et al. 2010: *Characterisation of nanofilm spray products by mass spectrometry* is possible to distinguish between polyfluorooctyl trimethoxysilane and polyfluorooctyl triethoxysilane. Some peaks in the MS will, tough, overlap (be the same). However, if the mixture contains an alcohol (e.g. 2-propanol) that can react with the alkoxy part of TDFAs it is the MS-spectrum of this new intermediate TDFAs (e.g. polyfluorooctyl triisopropoxysilane) that will be seen.

SEAC

Summary of proposal:

The major uncertainties of importance for the socio-economic assessment identified by the Dossier Submitter are the following:

- The number of the reported poisoning incidents for which the targeted mixtures have been the cause.
- The annual number of poisoning incidents and the trend in incidents caused by the targeted mixtures in spray products. It is uncertain to what extent the market has already changed as a reaction to the reported poisoning incidents and the research regarding the effect of the substances.

[31] Yamashita M., Yamashita M., Tanaka J., et al. (1997b) Toxicity of waterproofing spray is influenced by the mist particle size.VetHum Toxicol39, 332-33

- The total number of spray products with targeted mixtures sold annually within the EU.
- To what extent the active substances and mixtures for impregnation products that are not based on TDFAs are manufactured within the EU or imported into the EU.
- The estimation of the reformulation costs using D4/D5 case as a benchmark.
- To what extent the proposed action would target polyfluoroalkyl trialkoxysilanes with polyfluoroalkyl chain length different from TDFAs due to trace levels of TDFAs in its composition.
- The threshold of 2 ppb is derived from the so-called TOP assay that is expected to be used for enforcement of the PFOA and PFOA precursor restriction. This method has not yet been applied for fluorinated silanes, silanols and siloxanes.
- The risks for spray products based on other polyfluoralkyl trialkoxysilanes different from TDFAs.
- Test costs to ensure compliance.

SEAC conclusion(s):

The public consultation as well the targeted consultations did not bring any additional information in order to minimise the above uncertainties. Therefore, SEAC had to deal with these uncertainties in the estimation of costs and benefits which made the cost-benefit analysis inconclusive. Even in terms of qualitative analysis, the basic uncertainty of the existence of the target products on the European market made it difficult to achieve solid conclusions.

SEAC notes that regarding the overall proportionality, as there is no information available to what extent substances with polyfluoroalkyl chain lengths different from TDFAs may result in the same pulmonary effects as seen for TDFAs, the risk reduction that could be achieved by this restriction proposal is uncertain. However, there are other alternatives available. Other uncertainties that could affect the proportionality are uncertainties about the market size, the number of producers or importers, the number of formulas and the costs to ensuring compliance. There are also uncertainties in the estimation of the number of incidents related to the use of this type of products in general and specifically to the ones targeted by this restriction proposal. No information has been provided that brings evidence of the presence of the targeted products on the market for the use by the general public at the present but it cannot be excluded. If the restriction proposal is aiming to prevent the future use of such products the uncertainties in relation to the proportionality is of less importance if such an approach is accepted.

Key elements underpinning the SEAC conclusion(s):

The key elements underpinning the SEAC conclusions are discussed in parts of the opinion where relevant.

Appendix 1

TABLE 2-5 RATIO OF FINE PARTICLES (%) OF 13 TRIGGER SPRAYS AND 3 PUMP SPRAYS (FROM TABLE 2 IN KAWAKAMI ET AL., 2015)

Product Name	Usage	Country	Type of Spray	Ratio of fine particles [%]	
				< 9 µm	< 11 µm
A1	Fabric	UK	Trigger	0.1	0.4
A2	Facric	UK	Trigger	0.2	0.5
A3	Leather and fabric	Japan	Trigger	0.8	1.4
A4	Leather and fabric	UK	Pump	0	0.1
A5	Ceramic products, bathroom	Unknown	Trigger	0	0
A6	Kitchen and bathroom	Japan	Trigger	0	0.2
A7	Kitchen and bathroom	Japan	Trigger	0.3	0.6
A8	Kitchen and bathroom	Unknown	Pump	0.4	0.8
B1	Iron	South Korea	Trigger	0	0
B2	Iron	South Korea	Trigger	0	0
B3	Clothing care	Unknown	Trigger	0.6	1.2
B4	Clothing care	Unknown	Trigger	1.7	2.7
B5	Preventing pollen adhesion to masks and clothing	South Korea	Trigger	0	0
B6	Preventing pollen adhesion to masks and clothing	Japan	Trigger	2.1	3
B7	Preventing pollen adhesion to masks and clothing	Japan	Trigger	1.6	2
B8	Preventing pollen adhesion to masks and clothing	Japan	Pump	0.2	0.4

Table 2-5 shows that the aerosol particles sprayed from five trigger spray products (A5, A6, B1, B2 and B5) contained few or no particles with a initial diameter smaller than 11 µm. In five trigger spray products (A3, B3, B4, B6 and B7) the ratio of particles with diameter <9 µm exceeded 0.6% (the critical % <10 µm that corresponds to a DNEL of 0.068 mg/m^3 and the ratio of particles with diameter <11 µm exceeded 1%.

For three trigger spray products (A1, A2 and A7) the ratio of particles with diameter <11 µm were below or equal 0.6%. The product A1 with a droplet/particle size distribution estimated to MMD of 81.5 µm and a GSD of approximately 2.1 reasonably well represents these three trigger spray and will be used for the exposure concentration calculations. The product B3 with a droplet/particle size distribution estimated to MMD of 65 µm and a GSD of approximately 2.2 is chosen for the RWC calculations as this represents the group of products with the ratio of particles with diameter <9 µm exceeding 0.6%.

REFERENCES

Koch W., Behnke W., Berger-Preiß E., Kock H., Gerling S., Hahn S., Schröder K. (2012) Validation of an EDP assisted model for assessing inhalation exposure and dermal exposure during spraying processes, available from: http://www.baua.de/en/Publications/Expert-Papers/F2137.pdf?__blob=publicationFile&v=9