Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions

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

Agreed

16 March 2017

10 March 2017

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

16 March 2017

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

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

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

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

Chemical name(s): ***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***.

Contents

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

(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

See the opinon of RAC.

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 outbreak 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 lipophilicity) 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 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 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):

See the opinon of RAC.

Key elements underpinning the RAC conclusion:

See the opinon of RAC.

Information on hazard(s)

Summary of proposal:

This restriction proposal targets the placing on the market of spray products[1] 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 lipophilicity (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 lipophilicity) 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 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):

See the opinon of RAC.

[1] Aerosol dispensers, pump and trigger sprays

Key elements underpinning the RAC conclusion(s):

See the opinon of RAC.

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 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/m2 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):

See the opinon of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinon of RAC.

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 1. 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 spray, 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 1 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/lipophilicity of the solvent. Mixtures of TDFAs and solvents that are less lipophilic then 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 it must be expected that there is a 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.

TABLE 2.

Scenarios	Model	Spray type	Mean event concentration [mg/m³]	RCR (with DNEL 0.068 mg/m³)	RCR (with DNEL 0.21 mg/m³)
1) Impregnation of 3.4 m² tiles in a 10 m³ bathroom (approx. use 40 g/m²)	ConsExpo 4.1	Aerosol	0.84	12.4	4.0
		Trigger	0.15	2.2	0.7
		Pump	0.056	0.8	0.3
	SprayExpo	Aerosol	97.1	1427.9	462.4
		Trigger	39.2	576.5	186.7
		Pump	14	205.9	66.7
2) Impregnation of 3.4 m² tiles in a 10 m³ bathroom (use approx. 10 g/m²)	ConsExpo 4.1	Aerosol	0.25	3.7	1.2
		Trigger	0.046	0.7	0.2
		Pump	0.015	0.2	0.1
	SprayExpo	Aerosol	27.3	401.5	130.0
		Trigger	11.1	163.2	52.9
		Pump	3.6	52.9	17.1
3) Spraying of a 0.3 m² mirror in a 10 m³ bathroom (use approx.40 g/m²)	ConsExpo 4.1	Aerosol	0.09	1.3	0.4
		Trigger	0.016	0.2	0.1
		Pump	0.0059	0.1	0.03
	SprayExpo	Aerosol	7.5	110.3	35.7
		Trigger	2.9	42.6	13.8
		Pump	1	14.7	4.8
4) Spraying of a 0.3 m² mirror in a 10 m³ bathroom (use 10 g/m²)	ConsExpo 4.1	Aerosol	0025	0.4	0.1
		Trigger	0.0045	0.1	0.02
		Pump	0.0015	0.02	0.01
	SprayExpo	Aerosol	2.5	36.8	11.9
		Trigger	1	14.7	4.8
		Pump	0.34	5.0	1.6

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 m³ 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 characterize the risk.

RAC conclusion(s):

See the opinon of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinon of RAC.

Uncertainties in the risk characterisation

See the opinon of RAC.

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™ were likely to be fluorosilane with unknown length of the per/poly-fluoroalkyl chain. The Dossier Submitter assumed that these could be TDFAs, but could not prove its similarity. It is

argued by the Dossier Submitter that the observed cases were linked to these specific products.

Toxicity of hydrolysates is dependent on the ability of the hydrolysates 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 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.

Workers exposure

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

RAC conclusion(s):

See the opinon of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinon of RAC.

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.

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):

See the opinon of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinon of RAC.

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of RAC

Summary of proposal:

The Dossier Submitters 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.

RAC conclusion:

See the opinon of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinon of RAC.

Justification for the opinion of SEAC

Summary of the proposal:

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.

The Dossier Submitter, reported several cases involving respiratory disorders 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 among 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. The proposed restriction targets both products used for absorbing surfaces (textile and leather) and non-absorbing surfaces (tile and ceramics). 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 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.

SEAC conclusions

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 would be 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 conclusions

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. During the public consultation, no information about such products that are currently on the market was submitted. 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 the 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 present2 (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 contain TDFAs, as the chemical description on labels or in SDS are not sufficiently detailed. This is because TDFAs are not classified under CLP by some companies.

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.

[2] 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/

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

Justification for the opinion of RAC

Summary of proposal:

The dossier provides a short overview of possible EU wide legislative measures as well as 2 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.

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.

RAC conclusion(s):

See the opinon of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinon of RAC.

Justification for the opinion of SEAC

Scope including derogations

Summary of proposal:

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

A Restriction options

RMO1 (proposed restriction)

A ban of mixtures containing TDFAs and organic solvents in spray products for consumer use with a concentration of TDFAs equal to or greater than 2ppb 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 TDFAs in a combination with organic solvents are available at the same price according to the Dossier Submitter. RMO 1 could allow the use of polyfluoralkyl trialkoxysilanes with polyfluoralkyl chain lengths different from octyl as a drop-in alternative, provided that these drop-in raw materials do not contain TDFAs as residues.

RMO2

A ban of mixtures containing TDFAs and organic solvents in spray products for consumer use with a concentration of TDFAs equal to or greater than 800 ppb by weight.

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 because of the quantitative tests that are significantly more expensive. However, the costs for industry might be lower when compared to RMO 1 if the presence of TDFAs as impurities were below 800 ppb. As RMO2 would allow the use of polyfluoralkyl trialkoxysilanes with polyfluoralkyl chain lengths different from octyl as drop-in alternatives.

RMO3

A ban of mixtures containing TDFAs and organic solvents 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 is 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 has a higher average cost-effectiveness than RMO1, it is easier to implement as other application methods are available at about the same price, and enforcement costs are lower.

B Non-restriction options

Harmonised C&L

The Dossier submitter concludes that this risk management option has no potential to reduce or control the risks as the parent substances do not fulfil the criteria in CLP, Article 36(1) for proposing a harmonised classification. Mixtures of TDFAs and organic solvents could fulfil the criteria for classification with Acute Toxicity, Category 1 or 2, but only classification of substances can be harmonised under the CLP Regulation.

Inclusion on the candidate list and eventual inclusion in Annex XIV

This RMO is irrelevant because according to the available information the substances targeted by this proposal do not fulfil the criteria of Article 57 of the REACH Regulation.

Amendment to CLP Annex II part 3

The Dossier Submitter notes that if the Commission introduces 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" this could result in a removal of the most dangerous impregnation products from the market if they are classified correctly. However, it seems that none of the products related to the reported incidents were labelled as acute toxic to humans, and so, this RMO is considered not relevant in the context of this restriction proposal by the Dossier Submitter.

Establishment of an IOEL for the workers environment under Workers Legislation

This RMO is irrelevant as workers are out of the scope of this restriction proposal.

Product Safety Directive

The Dossier Submitter has rejected the Product Safety Directive (PSD) for a number of reasons. The first reason is that the knowledge of importers/producers about the risk combining TDFAs with organic solvents in spray products is limited. The second reason is the periodic revisions foreseen and the fact that this directive imposes a case-by-case evaluation. The third argument presented by the Dossier Submitter is that the directive should be linked to the relevant products specific legislation, which in this case is according to the Dossier Submitter the REACH regulation.

Voluntary agreements

It is claimed by the industry that 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. Therefore, there is a risk that a number of companies will be out of the voluntary agreement between some parties. Therefore, this RMO is considered likely by the Dossier Submitter to be ineffective in order to control the risks. Furthermore, the manufacturers sell TDFAs to distributors and not directly to the producers of proofing/impregnation products.

Information campaigns including labelling

The Dossier Submitter claims that information campaigns directed to consumers have very limited effect. The ground for this claim is based on experience that shows that private consumers have used the products indoors even if it is stated on the label of the spray products that the product should only be used outdoors. Additionally, for such product types to be used on furniture or in bathrooms, it is reasonable to expect that these products will always be used indoors.

SEAC conclusions

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 also agrees with the Dossier Submitter that a restriction would be the most appropriate option to reduce the risks from such spray products. SEAC finds that RMO1 and RMO2 would be more effective than RMO3 as they cover trigger and pump spray products.

SEAC finds 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 would also take into account the advice of the Forum 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 products 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.

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 the incidents that have occurred involved the use of products containing TDFAs and/or 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[3].
- 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 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):

See the opinon of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinon of RAC.

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

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of proposal:

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

- prices of some alternative substances;
- estimated cost of the 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.

No information on reformulation costs for mixtures of TDFAs and organic solvents used in spray products for consumers is available because there is no information about the number of formulas that need to be reformulated. 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. All the quantitative information was used by the Dossier Submitter to substantiate the assessment.

Production and compliance costs

No significant impacts have been identified by the Dossier Submitter 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), 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 TDFAs manufacturers in the EU (<4 manufacturers), it is estimated that less than 10 % of TDFAs annual production is used in proofing/impregnation spray products. From these assumptions, DS 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 which, 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. But 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

No costs for ensuring compliance have been identified by the Dossier Submitter 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 administrative costs for importers to collect and verify the documentation are considered insignificant according to the assessment by the Dossier Submitter.

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 conclusions

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 submitted in the Public Consultation into account, SEAC agrees with the qualitative approach. Only limited quantitative information has been 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 as a result 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[4]. 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 conclusions

MARKET SIZE

SEAC recognises that the estimation of the market size presented in the background document is not very precise, but agrees with the Dossier Submitter's approach to estimating the market size of the targeted products, given the lack of available information. The approach of the Dossier Submitter to estimate the volumes of TDFAs used in proofing impregnation spray products was based on the registration data and on the information provided from the industry.

[4] 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.

There are no registered TDFAs for the moment, but there are 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, a maximum, 1-10 t/y polyfluorooctyl triethoxysilane could use in spray products. It is not known if these products are exclusively for professionals. 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, which SEAC accepts as an acceptable assumption. 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[5]. 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 this 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.

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, each of them with its own producer, available for non-professional users. Also, SEAC assumed that the market share is equal for all the companies, the differences among the formulations of the mixtures to be used in pump or trigger or aerosols spray products are irrelevant and half of the products have the same formulation. These scenarios are based on the following information:

[5] 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.

- It is known that in Spain there are eight proofing/impregnation spray products with TDFAs and organic solvents put on the market for professional use. Therefore, it is unlikely that there is a larger product diversity on the market for use by the general public.
- Information received from public consultation based on 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.

SEAC assumes that the market shares are equal for all the companies and that half of the products have the same formulation. The former assumption is based on the differences among the formulations of the mixtures to be used in pump, trigger, or aerosols spray products, and the latter is underpinned by the fact that it is stated in the background document that it is common practice that spray producers obtain ready-formulated impregnating agents from large chemical producers, on which they only make some minor modifications to the mixtures (usually dilutions).

For the first scenario, where it is assumed that no other spray products are put on the market for professional use. Therefore, it is unlikely that there is a larger product diversity on the market for use by the general public, if any products are put on the market at all.

In such a case, RMO1 and RMO3 could be more costly for the industry than RMO2, as 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.

For the scenario with eight companies sharing the market, it is expected that each of them has an equal share of a total annual turnover of €50 000 and €1 200 000 between €6 250 and €150 000. 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[6].

[6] 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 - $58OECD

Benefits

Summary of 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 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 (Table 6 of the Background Document). The ratio of the Danish population to the total EU population was used together with the assumption that 20% to 40% are related to exposure of TDFAs in organic solvents, to derive the number of reported 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 conclusions

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 ground to take the Danish data as representative for all Member States. The available information from some EU countries, presented in table 5 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 conclusions

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.

Health costs

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)[7,8,9,10].

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

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

[9] 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

[10] 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 1 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 Incidents[2] (35%)	56.5	49	2,769
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 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 by the Dossier Submitter 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. No impacts have therefore been identified by the Dossier Submitter 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 exportation to non EU countries as well as the loss of revenue due to the implementation of the proposed restriction is estimated to be marginal by the Dossier Submitter.

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 conclusions

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 conclusions

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 conclusions

If the targeted spray products are not currently placed on the market, this restriction proposal will prevent future respiratory distress incidents by preventing such products from being placed on the market. In the case 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) 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 concentration 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 4), 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.

Key elements underpinning the SEAC conclusions

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. Regarding the risk control, 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 in case if TDFAs are present as impurities in its composition. Whereas RMO2 might not imply any reformulation for spray products based on polyfluoroalkyl trialkoxysilanes other than TDFAs and could allow the use of drop in alternatives substances for the ones based on TDFAs and organic solvents, SEAC does not have any evidence that the content of TDFAs as impurity in polyfluoroalkyl trialkoxysilanes with polyfluoroalkyl chain different from octyl are below of 800 ppb.

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, but noted that 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. This could be also true for RMO2 but is less likely since this RMO allows mixtures with a high concentration of TDFAs.

Considering the limitations of the quantitative analysis, i.e. only an estimation of the reformulation costs has been made by the Dossier Submitter and the fact that it is not possible

to estimate the costs for laboratory test to ensure compliance, it is not possible for SEAC to conclude on this basis whether RMO1 or RMO2 is the most cost-effective option. Taking into account that it is possible that polyfluoroalkyl trialkoxysilanes with different chain length have TDFAs as impurities in its composition, although there is no evidence of this, SEAC notes this leads to further uncertainty. 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 impurity in polyfluoroalkyl trialkoxysilanes with polyfluoroalkyl chain different from octyl. It is however known that some distributional molecular weights may occur in polymerisation reaction products in general (as also in the short-chained fluorine chemistry), as result of the different chain lengths of the synthesised polymers. Therefore, it is common that a polymeric product contains a mixture of polymer chains with different chain lengths. Therefore TDFAs could appear as impurities of other polyfluoroalkyl trialkoxysilanes, but SEAC has no information confirming this statement or 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. On the other hand, 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, a qualitative analysis of the differences between RMO1 and RMO2 in relation to the dimensions compliance cost could not be conducted, as it is unknown whether these costs would be higher or lower than the reformulation costs. SEAC notes that RMO2 could provide the chance for the companies to choose what to do in order to assure compliance on a case by case basis.

- 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 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 2 - 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. 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. Fewer consumer benefits due to the poor performance of the alternative products and alternative application methods. But 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. 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 3 - 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. (0): Showing no impact or change.

	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 polyfluoroalkyl trialkoxysilanes that includes TDFAs.	-2

Table 4 - 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

Summary of proposal:

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.

RAC conclusions:
See the opinon of RAC.

Key elements underpinning the RAC and SEAC 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 initialy 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.

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 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.

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

Justification for the opinion of SEAC

Summary of the proposal:

As the proposed restriction includes a ban on the use of TDFAs in mixtures used in spray products it is considered effective in reducing 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 impurity seems 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. Also, 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. But it is not clear if the water based mixtures would 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 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, the TOP Assay method, 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.

SEAC conclusions

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 and also in the Annex XVII of REACH. As alternative application methods, could be used and similar products without TDFAs exist on the market, SEAC finds it possible to replace TDFAs with the alternatives that seems 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 packaging or product data is not likely to be communicated via the labels. Sampling will be feasible for inspectors as the samples typically will be spray product.

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 of the restriction text and improved availability of methods for determination of regulated substances. SEAC has further suggested some rewording in order to clarify that the restriction only applies to proofing/impregnation sprays products when TDFAs and organic solvents are used together in the mixture. The suggested change of wording by SEAC also clarify 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 addressed 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 to 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 months' 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 to develop 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 conclusions

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 if at all enforceable due to the lack of clarity of the scope and the lack of available methods for determination of regulated substances. At present, it seems that the TOP assay method is not considered to be 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 don't know exactly which polyfluoroalkyl that 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 1-2 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

Summary of proposal:

The Dossier Submitter has proposed that the restriction can be monitored at two levels: The restriction may be monitored by use of information from national systems for monitoring of poisonings and the EU Rapid Alert System for Non-Food Products (RAPEX).

RAC conclusion:

See the opinon of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinon of RAC.

Justification for the opinion of SEAC

Summary of the proposal:

The Dossier Submitter states that the proposed restriction could be monitored either by monitoring of the number of poisoning incidents or 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.

SEAC conclusion

SEAC agree 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. It will, therefore, be difficult to identify and monitor what other products that contain mixtures of TDFAs and organic solvents.

Key elements underpinning the RAC and SEAC conclusions

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 doesn’t seem to exist in most Member States.
- The exact composition of the impregnating agent is often not known, while the monitoring has to be 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 occurring doesn't 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 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):

See the opinon of RAC.

Key elements underpinning the RAC conclusion(s):
See the opinon of RAC.

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.
- 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, respectively.
- The estimation of the reformulation costs using D4/D5 case as a benchmark.
- To what extent the proposed action would target aerosolised spray products based on polyfluoroalkyl trialkoxysilanes with polyfluoroalkyl chain length different from TDFAs due to trace levels of TDFAs in the mixtures.
- 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 conclusions

The public consultation as well the targeted consultations did not bring additional information in order to minimise the uncertainties specified above. 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 bring 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 conclusions

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%.

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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