The SEA in the Restriction proposal on **TDFAs**

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L'analisi socio-economica nel Regolamento REACH

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IAPMEI

Parcerias para o Crescimento

REPÚBLICA PORTUGUESA

ECONOMIA

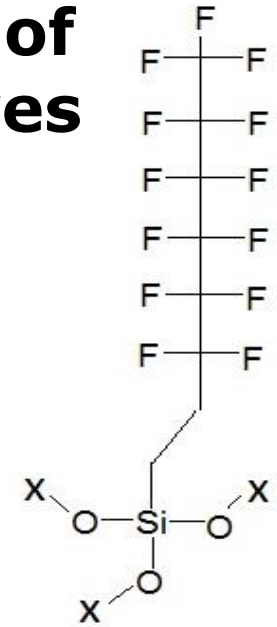
Presentation structure

- Introduction of the proposal
- Context and issues
- Impacts evaluation and Conclusions
- Proportionality
- State of play

Substance name

(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

= **TDFAs**



TDFAs belong to the group of polyfluorooctyl trialkoxysilanes

TDFAs in proofing/impregnation products

The main use of mixtures containing TDFAs and solvent applied by aerosol dispensers, hand pump or trigger spray is to provide water and oil repellence properties to different non-absorbing surfaces such as stone, ceramics, glass and enamels.

Conditions of the proposed restriction – RMO 1

- Shall not be used in mixtures with organic solvents in spray products for supply to the general public
- Shall not be placed on the market in mixtures with organic solvents in spray products for supply to the general public in a concentration equal to or greater than 2 ppb by weight
- A transition period of 18 months

Other restriction options proposed in the dossier

- RMO 2: Risk-based ban of mixtures containing TDFAs and organic solvent in spray products for consumer use in a concentration of TDFAs equal to or greater than 0.00008 % (0.8 mg/kg, 800 ppb). In order to address that the TDFAs may be present as impurities.

- RMO 3: Ban of mixtures containing TDFAs and organic solvent in aerosol dispensers for consumer use in a concentration of TDFAs equal to or greater than 2 ppb by weight.

Main points of the restriction proposal

- The aim of the proposal is to avoid all incidents related to exposure to spray products based on mixtures of TDFAs and organic solvents

- The ground of the restriction is based on reported incidents of human lung injuries from the use of proofing/impregnation spray products, supported by scientific studies with mice

- The role of the SEA, in this case, was to underline the low economics impacts of the restriction, through qualitative arguments anchored by some quantitative data, and highlight the benefits through the monetised health costs.

Overall impression

- Relatively short core report, complex and not always clear

- Weak/rough analysis, poor accuracy, lack of quantitative elements

Key issues -1

- Should all organic solvents be included in the restriction?

✓

The reported incidents and the experts opinion are sufficient to keep all organic solvents in the restriction scope, despite almost all scientific studies presented are based in mixtures of TDFAs and alcohols

Key issues -2

- Should the restriction only cover the use of the mixtures in proofing/impregnation spray products?

✓

The scope should cover only proof/impregnation spray products, since all the information in the dossier are related with proofing/impregnation spray products

Key issues -3

- Rough estimates on human health. Are the Danish incidents data representative for all Member-States?

It was not found evidences that Danish incidents are representative for EU 28

Key issues -4

- Uncertainties regarding the availability of some of the alternatives:

  TDFAS water based products for non-adsorbing surfaces ✗

  or

  use of polyfluoralkyl trialkoxysilanes with polyfluoralkyl chain lengths different from TDFAs **?**

- Lack of data on societal costs.

- Lack of data to estimate the compliance costs.

Main evaluations for this restriction case

- Justification if action is required on a union wide basis
- Justification whether the suggested restriction is the most appropriate EU wide measure
- Effectiveness in reducing the identified risks:
  - Socio-economic impacts
  - Costs
  - Benefits
  - Other impacts
  - Proportionality

Justification if action is required on a union wide basis

- **Uncertainties:**
  - Weak evidences regarding the presence of TDFAs in the products related with reported incidents
  - It is not known if sprays containing TDFAs and organic solvents are currently placed on the EU market in consumer spray products

Justification if action is required on a union wide basis

- **Key elements:**

  - RAC Opinion - RAC concluded that the risks for the general public not adequately controlled when used under certain conditions

  - Outcome of the Public Consultation -Targeted products were registered in Sweden from 2010 to 2013

Justification if action is required on a union wide basis

- **Conclusions:**
  - The possible presence on the EU market of the targeted products cannot be discounted and should be taken into account.
  - Therefore, 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, any necessary action to address risks associated with TDFAs used with organic solvents in spray products should be implemented on an EU wide basis.

Whether the suggested restriction is the most appropriate EU wide measure

- **Other non-restriction RMOs considered:**
  - Voluntary agreements
  - PSD - Product Safety Directive (Directive 2001/95/EC)

- **Disadvantages:**
  - ✓ Often spray producers are not organised in trade associations and producers are not aware of the exact compositions of the mixtures that they use
  - ✓ No obligation to test products before placing them in the market and also applies to individual products on a case-by-case, therefore PSD is not effective to prevent incidents with new products

Whether the suggested restriction is the most appropriate EU wide measure

- **Conclusion:**

  A restriction would be the most appropriate option to reduce the risks from spray products based on mixtures of TDFAs and organic solvents.

SOCIO-ECONOMIC IMPACTS: COSTS

- **Uncertainties:**

  - Volumes of TDFAs used in spray products
  - Reformulation costs
  - Number of tests to ensure compliance
  - Presence of TDFAs as impurities in other polyfluoroalkyl trialkoxysilanes

SOCIO-ECONOMIC IMPACTS: COSTS

- **Key elements:**

  - Small volume of TDFAs used, it is estimated only 1% of the total tonnage of TDFAs
  - Small size of market, annual turnover in the range of € 54 000 - € 1 200 000
  - Prices of alternatives at the same level
  - No relevant reformulation costs if other polyfluoroalkyl trialkoxysilanes are used for substitution of TDFAs

SOCIO-ECONOMIC IMPACTS: COSTS

- **Key elements (cont.):**

  - For other substances SEAC estimates an indicative annual reformulation costs between € 8 000 and € 12 000
  - Mixtures could be continued marketed as solutions to be applied with brushes, rollers or cloth
  - Small distributional impacts
  - Production and compliance costs: no significant impacts

SOCIO-ECONOMIC IMPACTS: COSTS

- **Conclusion:**

  - The qualitative approach taken by the Dossier Submitter is sufficient to conclude that the costs of this restriction will not be significant for the consumers or the industry

SOCIO-ECONOMIC IMPACTS: Benefits

- **Major uncertainty:**

  - Estimation of the average number of incidents in EU caused by exposition to proofing/impregnation sprays based on TDFAs and organic solvents

SOCIO-ECONOMIC IMPACTS: Benefits

- **Key elements:**

  - Use of the estimation of avoided incidents to estimate the benefits of the restriction proposal
  - Estimated health costs per avoided incident €1520 – € 2220
  - 330-660 cases per year, Dossier Submitter estimation based on Danish Poison Control data
  - 161 cases per year (central value), SEAC estimation taking into account also the registered incidents in the European Poison Centres – 8.5 cases by year.

SOCIO-ECONOMIC IMPACTS: Benefits

Annual health benefits in EU 28 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(30%)	48	1 520-2 220	72 960 – 106 560
Moderate Incidents(35%)	56.5	49	2,769
Mild incidents(35 %)	56.5	10	565
Total	161		76 294 – 109 894

SOCIO-ECONOMIC IMPACTS: Benefits

- **Conclusions:**

  - 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) it is correct.
  - The average annual human incident cases estimated by the DS was considered an overestimation.
  - The benefits estimated by SEAC are in the range of €76 294 – €109 894 by year.

SOCIO-ECONOMIC IMPACTS:
Other impacts

- **Key elements:**

  - Social impacts: marginal potential loss of employment, no significant changes in price for end users
  - Wider economic impacts: none or marginal loss of export revenue, no relevant effects for producers of spray products
  - Distributional impacts: small effects

SOCIO-ECONOMIC IMPACTS:
Other impacts

- **Conclusion:**

  - Other impacts are highly unlikely to be relevant and that the resulting change is likely to be distributional

SOCIO-ECONOMIC IMPACTS: Proportionality to the risks

- **Uncertaities:**

  - Current presence of the products on the market
  - Estimation of the benefits
  - Estimation of the costs
  - Risks inherent in the use of spray products based on other polyfluoralkyl trialkoxysilanes different from TDFAs.
  - Impact of the proposed restriction in spray products based on polyfluoroalkyl trialkoxysilanes with polyfluoroalkyl chain length different from TDFAs

SOCIO-ECONOMIC IMPACTS: Proportionality to the risks

- **Key elements:**

  - Prevents negative health effects
  - Limited impacts on the manufacturers
  - Limited impacts on producers
  - Alternatives - technical and economical feasible
  - Low expected compliance costs
  - Some loss of consumer benefits

SOCIO-ECONOMIC IMPACTS: Proportionality to the risks

Comparing the main impacts of different RMOs using a qualitative scale.

	Health impacts (per year)	Reformulation costs (per year)	Administrative costs include tests	Change in consumer benefits	Total
RMO1	+++	--	-	--	-2
RMO2	++	-	--	-	-2
RMO3	+	--	-	-	-3

SOCIO-ECONOMIC IMPACTS: Proportionality to the risks

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

	Health impacts (per year)	Reformulation costs (per year)	Administrative costs including 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

SOCIO-ECONOMIC IMPACTS: Proportionality to the risks

- **Conclusion:**
  - The qualitative analysis does not allow to conclude on which RMO is the most proportional. The small differences among the three RMOs arising from the qualitative analysis, are not relevant considering the uncertainties.
  - The estimates based on monetised costs and benefits suggest that each one of the three RMOs are proportional to the risks, however, these estimates were deemed too uncertain to achieve any conclusion.
  - **Therefore, due to the probable low costs of the proposal it is concluded that it is unlikely that the proposed restriction would be disproportionate**.

State of play

The SEAC draft opinion is currently in public consultation in

https://echa.europa.eu/pt/restrictions-under-consideration/-/substance-rev/13918/term

Thank you

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