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COMMISSION STAFF WORKING DOCUMENT

Impact Assessment Report

Proposal for a

COMMISSION DECISION

amending Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (Organostannic compounds)

(amendment of Council Directive 76/769/EEC)

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Accompanying the

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(amendment of Council Directive 76/769/EEC)

Lead DG: Enterprise and Industry

Other involved services: ENV, SANCO

Nota bene: **No Interservices Steering Group has been set up as the Proposal will be adopted in comitology, but DG ENV and DG SANCO have been consulted during the preparation of the impact assessment.**

Services consulted in ISC: AGRI, ENV, SANCO, JRC, EMPL, ECFIN, TRADE, JLS, MARKT, RTD, SJ, TREN, SG

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Disclaimer:

This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

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EXECUTIVE SUMMARY

Organotin compounds (OTs), also known as organostannic compounds, are composed of tin bound directly to varying numbers (1, 2, 3 or 4) organic groups and have a wide range of applications. Restrictions have already been introduced at EU level on certain antifouling applications of tri-substituted organotin compounds (which have biocidal functions) by means of amendments to Directive 76/769/EEC on restrictions of the marketing and use of dangerous substances and preparation, Regulation (EC) No (782/2003) on the prohibition of organotin compounds on ships, and Directive 98/8/EC on the placing on the market of biocidal products. However, there is still a large number of consumer products containing organotin compounds (in particular from their use as PVC stabilisers or as catalysts) not regulated by EU legislation which either lead to a relatively high level of possible exposure to organotins or are relatively commonplace and, as such, a consumer is likely to come into frequent contact with them.

Although organotins are not included in the list of priority substances under Council Regulation (EEC) No. 793/93, various concerns have been expressed over their potential risks to human health (e.g. adverse effects on the immune system). The Commission mandated several studies to conduct a targeted risk assessment to examine possible risks to human health and the environment from the use of four organotin compounds in consumer products: dibutyltin compounds (DBT), dioctyltin compounds (DOT), tributyltin compounds (TBT), and triphenyltin compounds (TPT), which were deemed to be of highest concern. This assessment identified a significant level of risk for consumers exposed to organotins from a range of sources, which should be reduced. The Scientific Committee on Health and Environmental Risks (SCHER) has confirmed the need for risk reduction measures.

The Commission then contracted another study to collect more information on existing alternatives to organotin compounds, national restrictions for certain uses of organotin compounds, and the economic and social impacts of potential restrictions on the marketing and use of certain organotin compounds at Community level. The results of the various studies were discussed extensively with the Member States and the industry concerned.

This impact assessment report analyses and evaluates the various possible measures that could be adopted in order to reduce risks to the health of consumers from products containing organotins by reducing the probability that consumers will be exposed to levels above the tolerable daily intake (TDI).

It has to be noted that a number of sources of exposure to organotin compounds are within the scope of specific Community legislation (e.g. food, food contact material, medical devices), which are not affected by the measures considered in this proposal. In particular, the exposure caused by fish consumption cannot be reduced other than by limiting consumption. However, given the positive impacts of fish consumption on human health and in the light of the economic implications for the fishing sector, this would clearly be disproportionate.

The following selected options were analysed in terms of their effectiveness, practicality, and socio-economic impacts:

1. No action (status quo could continue).

2. Voluntary action by industry.

3. Migration limits or mandatory labelling.

4. Prohibition of all uses of tri-substituted organotins, in particular TBT and TPT compounds in articles.

5. Prohibition of the use of DBT and DOT compounds in specific consumer products for which the RAR identified significant contribution to exposure, such as: T-shirts with PVC prints, PVC gloves, PVC sandals, wall and floor covering, female hygiene products, nappies.

6. Prohibition of the use of dioctyltin (DOT) and dibutyltin (DBT) compounds as stabilisers in all consumer products made of plasticised PVC.

7. Prohibition of the use of dioctyltin (DOT) and dibutyltin (DBT) compounds as stabilisers in all consumer products made of rigid PVC.

8. Total ban of TBT, TPT, DBT, DOT in all consumer products.

In the light of the analysis conducted, a combination of the options 4, 5 and 6 emerged as the most favourable measure. This would mean a restriction of the placing on the marketing and use of all tri-substituted organotins (including TBT, TPT) in all products, as well as of DBT and DOT in products made of plasticised PVC (such as gloves, sandals, bags, floor and wall covering) except for coatings of sheet metal and wire, and in some additional consumer products leading to high exposure made of other materials, such as female hygiene products, nappies and two-component silicon moulds.

This combination of options would be effective in significantly reducing the exposure for consumers from all major sources of OTs contained in consumer products. It would also be efficient as there are only very limited additional costs for industry and the administrative burden for companies and authorities is low.

There would be no impact on the EU budget. The proposal will also be notified to the WTO under the TBT agreement, which will give third countries the possibility to comment.

BACKGROUND

This impact assessment presents the possible policy options and their comparative advantages and drawbacks that could be adopted to control the risks to human health from the use of certain organostannic compounds that are concerned by the draft Commission Directive accompanied by the assessment (hereafter referred to as "the Proposal"). The proposal will be adopted by the Commission after the competent Regulatory Committee has given its opinion in accordance with Council Decision 1999/468/EC.

Organostannic compounds (hereafter referred to as 'organotins' or 'OTs') are substances composed of tin, directly bound to a number of organic groups. There is a wide range of organotins that can be manufactured and placed on the market and these are used in a variety of applications. Di-substituted organotins (usually in combination with mono-substituted organotins and, to a lesser extent, tri-substituted compounds) are used as stabilisers for PVC and as catalysts for various products. Historically, prior to the introduction of a number of use restrictions, tri-substituted organotins were used as biocides in anti-fouling paints applied to ship hulls, in consumer products, in wood treatment and in pesticides.

Organotins are not included in the list of priority substances under Council Regulation (EEC) No. 793/93 on the evaluation of the risks of existing substances[1]. Consequently, no comprehensive risk assessment has been carried out by a Rapporteur Member State and peer-reviewed by all other Member States in accordance with the provisions of that Regulation. However, due to concerns over potential risks from organotins, (e.g. as disruptors of the endocrine system, substances classified as reprotoxic Category 2 etc.) the European Commission (DG Enterprise and Industry) commissioned an external contractor (RPA Analysts Ltd.) to conduct a detailed assessment of the possible risks to human health and the environment. This assessment, concluded that there are risks to the health of consumers and that these need to be reduced.

The purpose of this impact assessment is to analyse and evaluate the various possible measures that could be adopted in order to reduce the identified risks to human health in terms of their effectiveness, practicality, and socio-economic impacts.

It has to be noted, that not all sources of exposure will be addressed by this proposal since there are other Community instruments that already cover specific sources, as illustrated in Table 1. The specific Regulations either prohibit the use of organotins or impose clear restrictions that limit human exposure from the sources concerned.

Table 1: Specific sources of exposure and coverage by legal instruments

Source of exposure:	**Community instrument:**
Biocidal products (such as wood preservatives, antifouling paints)	Directive (98/8/EC) on the placing of biocidal products on the market[2], Regulation (EC) No (782/2003) on the prohibition of organotin compounds on ships
Food packaging materials	Regulation on materials and articles intended to come into contact with food (EC) 1935/2004[3]

1 OJ L 84, 5.4.1993, p. 1.
2 OJ L 123, 24.4.1998, p. 1.
3 OJ L 338, 13.11.2004, p. 1.

Dental moulds and medicinal packaging	Directive 93/42/EEC concerning medical devices[4]
Occupational exposure	Council Directive 89/391/EEC[5] of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work and individual directives based thereon, in particular Council Directive 90/394/EEC[6] of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work and Council Directive 98/24/EC[7] on protection of health and safety of workers from the risk related to chemical agents at work. Furthermore, a study on the health effects of tributyl tin compounds on workers is currently carried out by DG Employment and expected to be finalised by June 2008.
Consumer articles	These will be addressed by the proposal accompanied by this impact assessment
Fish and seafood consumption	Exposure relates to historic use of antifouling paints containing mainly tributyltin compounds, and cannot be reduced other than by limiting fish consumption. This is not regarded to be a feasible option. Due to the global prohibition of TBT in antifouling paints the problem will gradually disappear.

Section 1: Procedural issues and consultation of interested parties

A first study was commissioned in 2002 to assess possible risks from the use of organotins in areas outside of their use as biocides in anti-fouling systems, as well as to describe the profile of the organotins industry. The Commission submitted the final report[8] (RPA & CEH, 2002) to the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) which raised some concerns regarding the assessment of risks. In view of these concerns, a second report was prepared by RPA in 2003[9] which updated the 2002 report and, where possible, addressed the concerns expressed by CSTEE. In response to further remarks raised by CSTEE, the Commission then contracted a third study to examine possible risks from the applications of four organotins: dibutyltin compounds (DBT), dioctyltin compounds (DOT), tributyltin compounds (TBT), and triphenyltin compounds (TPT) including their use as biocides in antifouling systems. These four organotins were deemed to be of highest concern.

4 OJ L169, 12.7.1993, p. 1.
5 OJ L 183, 29.6.1989, p. 1.
6 OJ L 196, 26.7.1990, p. 1.
7 OJ L 131, 5.5.1998, p. 11.
8 Report available at http://ec.europa.eu/enterprise/chemicals/legislation/markrestr/index_en.htm
9 Report available at http://ec.europa.eu/enterprise/chemicals/legislation/markrestr/index_en.htm

The third report (RPA, 2005) - hereinafter referred to as the Risk Assessment Report (RAR)[10] - identified a significant level of risk (requiring risk reduction measures) for humans exposed to organotins from a range of consumer products. The Scientific Committee on Health and Environmental Risks (SCHER)-which replaced the SCTEE- was subsequently invited by DG Enterprise and Industry to assess the overall scientific quality of the RPA report and issued an opinion in October 2006[11].

In summary, SCHER concluded that there is a high risk of individual members of the general population (greatly) exceeding the Tolerable Daily Intake (TDI) for organotins, while the health and environmental risk estimates in the RAR may not represent worst case situations. According to SCHER, the total consumer exposure to organotins from all identified pathways should form the basis of the risk assessment so that: "if the resulting total exposure exceeds the TDI, then there is a reason for concern and risk reduction measures should be considered, regardless of the number of exposure pathways involved"

Possible risk management measures to reduce the exposure of consumers to OTs were discussed at several meetings (November 2006, February and July 2007) of the Working Group of the Competent Authorities responsible for the implementation of Directive 76/769/EEC concerning restrictions on the marketing and use of dangerous substances and preparations (known as the Limitations Working Group), hereafter referred to as the "LWG". Those meetings were attended by representatives of the Member States, industry, and other stakeholders.

As information on certain issues of interest (e.g existing alternatives to OTs, current EU and national restrictions for certain uses of OTs etc.) was still missing, the Commission, at the end of 2006, decided to commit another study[12] to collect more information in order to assess the impacts of potential restrictions on the marketing and use of certain organotin compounds at Community level. The report recommended a range of marketing and use restrictions, under Council Directive 76/769/EEC.

The recommendations were discussed during the LWG meeting on 3 December 2007. Representatives of various industry associations attended this meeting including: European Stabilisers Producers Association (ESPA), European Tin Stabilisers Association (ETINSA), European Tin Catalysts Association (ETICA), European Plastics Converters (EuPC), European Silicon Producers (CES), and European Adhesive & Sealant Manufacturing Association (FEICA). In general, industry asked regulators to ensure that those applications of organotins which do not contribute significantly to the overall exposure (i.e. mainly those in rigid PVC), or for which there are no alternatives (i.e. one-component room temperature vulcanisation silicon sealants) are not restricted in their use.

A number of Member States supported elimination of the uses of TPT/TBT and restrictions of DBT/DOT only in the consumer articles for which the RAR had identified significant risks.

Other related legislations were also examined to avoid any legal overlap or contradictions such as: the General Product Safety Directive (2001/95/EC)[13], the Biocidal Products

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10 Report available at http://ec.europa.eu/enterprise/chemicals/legislation/markrestr/index_en.htm

11 Scientific Committee on Health and Environmental Risks opinion on the risks to health and the environment associated with the use of the four organotin compounds TBT, DBT, DOT and TPT. Final report adopted by the SCHER during the 14th plenary of 30 November 2006. (http://ec.europa.eu/health/ph_risk/committees/04_scher/scher_opinions_en.htm)

12 Impact assessment of potential restrictions on the marketing and use of certain organotin compounds. RPA study finalised in September 2007. http://ec.europa.eu/enterprise/chemicals/studies_en.htm

13 OJ L 11, 15.1.2002, p. 4.

Directive (98/8/EC)[14], the Regulation on materials and articles intended to come into contact with food (EC) 1935/2004[15], and the Medical Devices Directive (93/42/EEC)[16].

Based on the studies and an opinion of the Scientific Committee on Health and Environmental Risks (SCHER) it was decided not to await registrations of organotins under REACH, which would take several years during which consumer exposure would remain largely the same as today, but instead proceed already now with restrictions. Should registration under REACH lead to new information in the future, which might change the outcome of the risk assessments, the restrictions of the Proposal accompanied by this impact assessment will be reviewed.

All potential measures have been discussed involving also other Commission services such as DG Environment and DG Health and Consumer Protection to consider the different pieces of legislation covering the various uses of OTs and to arrive at a general agreement for the measures to be adopted to manage and reduce the identified risks.

A previous version of this report has been submitted to the Impact Assessment Board and has been discussed on 17 March 2008. The opinion of the Board of 19 March 2008 contained several recommendations for improvement that have been taken into account in the current report, in particular as regards the regulatory context and the relationship with other Community policies, the products covered by each option, the impacts on trade partners and an explanation of the methodology used to determine consumer exposure.

Section 2: Problem definition

This section provides information on the different uses of organotins before describing the risks that they pose for human health and the environment.
The total quantity of organotins sold in the EU is reported to be 21,000 tonnes for 2007 in the following applications:

(1) Use of organotins as PVC stabilisers:
Table A in Annex 1 summarises the main applications of OTs in rigid and plasticised PVC consumer products based on current data (2005 and 2007).

By far the largest use of organotins (>16,000 tonnes) is as stabilisers of PVC mainly in order to avoid decomposition whilst heated during processing of PVC into final products. The manufacture of rigid films (e.g. credit cards, food packaging, printed films) and rigid extruded sheets is the main use of organotin stabilisers in the EU, accounting for around 50% of the total consumption. Organotins stabilisers are also used for rigid PVC profiles (windows, furniture etc.) and pipes (high and low pressure systems, drinking and waste water pipes etc.).

(2) Use of organotins as catalysts
Organotins are used as catalysts in various reactions and applications (e.g for electrodeposition coatings, in polyurethane manufacture, in esterification reactions etc.). Table B in Annex 1 contains an overview of the most important applications.
Their major application in consumer products relates to their use as catalysts in silicones manufacture, and as catalysts in room temperature vulcanisation (RTV) to produce silicon elastomers. The most important consumer products containing organotins as catalysts include:

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14 OJ L 123, 24.4.1998, p. 1.
15 OJ L 338, 13.11.2004, p. 1.
16 OJ L169, 12.7.1993, p. 1.

RTV-1 one-component silicon sealants and RTV-2 two-components Do-it-yourself silicon moulds. Total amounts of organotins used in relation to silicon are in the order of 50 to 100 tonnes in the EU. Earlier food related applications (baking and cooking silicon moulds, baking paper silicon coating) are now regarded as historical uses which have ceased following voluntary action by the industry.

(3) Other organotin uses

According to the RAR, certain organotins are used as intermediates in chemical synthesis as well as in glass coating process, but these are industrial applications not leading to exposure of consumers, which are, therefore, not considered for further restrictions. Table C in Annex 1 contains an overview.

In addition, the following applications of tri-subsituted organotins (such as TBT, TPT) are already restricted due to various EU legislative actions:

- in antifouling paints, as previously explained;
- in pesticides (no longer authorised under Directive 91/414/EEC on plant protection products[17])
- in a wide range of biocidal applications (e.g non allergenic pillows, insoles for shoes, etc) which are no longer allowed in the EU since no tri-substituted organotin compound has been notified under the Biocidal Products Directive. However treated materials containing the compounds may still be imported from outside the EU.

According to the conclusions of the RAR which were subject to the evaluation of SCHER, the following risks were identified:

- **Risks for human health**

Studies on the effects of OTs have consistently reported effects on thymus weight and on thymus mediated immune function. It would appear that all OTs are immunotoxic, though only for TBT there are studies available to establish a No Observed Adverse Effect Level (NOAEL). Consequently, continuous exposure to organotins above the tolerable daily intake (TDI) can lead to an impairment of the functioning of the immune system and resulting diseases. However, it is important to note that the health risks identified rely solely on calculated exposures compared to effect levels where adverse health effects might appear. There is no epidemiological (e.g. from poison centres or other research) or probabilistic information available that would allow to attribute a specific number of cases of sickness or premature death of persons to exposure by organotins.

There are no quantitative studies regarding absorption of OTs following inhalation exposure, but several case studies report adverse health effects following exposure to e.g. paint containing TBTO and carpet sprays. (SCHER, 2006). Humans can be exposed to OTs by inhalation of dust particles or to the compounds themselves.

Risks to consumers may arise from a wide range of products containing organotins and can be evaluated in relation to a group TDI (Tolerable Daily Intake), as organotins are considered to act additively in similar modes of action. The RAR followed the SCTEE recommendation to use a group TDI for the four OTs investigated based upon immunotoxicity. The group TDI, corresponding to 0.1 μg Sn/kg bw/day, is assuming the same mechanism of action for the four

17 OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/52/EC (OJ L 214, 17.8.2007, p. 3)

compounds and the same potency (per μg Sn), but the mechanism of these compounds has not been investigated in a systematic way. A similar approach has been taken by the European Food Safety Authority in its opinion on organotin compounds in foodstuff (EFSA, 2004). In order to reduce the identified risks to acceptable levels, overall exposure should be brought down to levels below the TDI.

The RAR identified significant contributions to the risks for children exposed to organotins from certain consumer products (PVC-printed T-shirts, wall and floor coverings.). Other significant exposure sources include cookies baked on silicone coated baking paper (adults and children), food wrapped in PVC (adults and children), sanitary panty liners (adults) and foot spray (adults). These uses contribute to exposure in the range of 20 – 100% of the TDI or even more. In general, risks from organotins to children were found to be higher than those for adults.

- **Risks for human health via the environment**

According to the RAR, the dominant contribution to human uptake is via consumption of fish and fish products. The origin for this is the historic use of TBT in antifouling paints for ship hulls that has led to contamination of sediments, fish and seafood in particular along busy shipping lanes, shores and harbours. Due to the persistent nature of TBT, the ban of TBT antifouling paints cannot reduce the contamination quickly. It will therefore take a number of years until the ban will lead to significantly lower levels of exposure from fish consumption.

Other risks for human health through uptake of organotins via the environment are limited. There are potential risks to human health via the environment close to sources of significant emissions, for example through contamination of agricultural produce grown close to production sites and processing plants (e.g. timber treatment plants). However, these risks are of a local nature (up to a distance of several hundred meters) and the scientific evidence is not conclusive. Already on a regional level, these risks become negligible, for example if milk from cows that graze close to a processing plant is mixed with milk from other areas, the resulting concentration of organotins becomes insignificant. In addition, the use of TBT for wood processing has already been phased out in Europe. Additional Community action to address this is therefore not necessary.

The RAR concluded that the overall exposure for 70% of young child consumers will exceed the group TDI, while this percentage is 25% for adults. Further details on the contributions to exposure from various products are contained in Table 2 below. Annex 2 contains a description of the methodology on how the exposure levels have been derived.

Table 2: Consumer exposure to certain organotins (TBT, TPT, DOT, DBT) from the main exposure sources

Source	% of group TDI for consumer	
	Adult	**Child**
Food & Food Packaging Fish/fishery products	71%	284%
PVC food packaging	22%	54%
Baking paper/cookies	720%	2325%

Medical applications Foot spray	49%	n.e
Dental moulding	46%	n.e
Consumer Products Printed T-shirts	25 %	189%
PVC gloves	33%	n.e
PVC bags	7%	n.e
Earplugs	<1%	n.e
Drinking water pipes	<1%	<1%
Rigid film	3%	n.e
PVC sandals	33%	33%
Female hygiene products	62%	n.e
Silicon sealant	4%	n.e
2 part silicon moulds	87%	n.e
Paddling pool	n.e	3%
Mouthing PVC toys	n.e	2%
Nappies	n.e	21%
Household dust	17%	117%
Biocidal applications Cycling shorts	18 %	n.e
Non allergenic pillows	2%	19%
Shoe insoles	26%	n.e
* The group TDI of 0.1 µg Sn/kg bw has been used as a basis for determining consumer exposure ** n.e : non-estimated		

Potential risks to the health of workers have not been investigated as these are sufficiently covered through the relevant Community legislation on the protection of workers, in particular Directives Council Directive 89/391/EEC [18] of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work and individual directives beased thereon, in particular Council Directive 90/394/EEC [19] of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work and Council Directive 98/24/EC [20] on protection of health and safety of workers from the risk related to chemical agents at work. Furthermore, a study on the health effects of tributyl tin compounds on workers is currently carried out by DG Employment and expected to be finalised by June 2008. Further action could then be initiated, as appropriate.

[18] OJ L 183, 29.6.1989, p. 1.
[19] OJ L 196, 26.7.1990, p. 1.
[20] OJ L 131, 5.5.1998, p. 11.

- **Risks for the environment**

Risks from the presence of tri-subsituted organotins have been identified for the aquatic environment for a range of organisms. In addition, in relation to the marine environment, TBT and TPT are likely to be classified as both PBT (persistent, bio accumulative and toxic) and vPvB (very persistent, very bioaccumulating) substances. Although DBT and DOT could be classified as PBT substances, they are unlikely to be vPvB substances. However, no particular risks to environmental organisms have been identified for DBT and DOT.

In commenting on the RAR, the opinion of the SCHER was that:

- Human exposure to organotins comes via one or a large number of pathways; and the most important exposure pathways are food, indoor air, household dust and dermal contact with different polymer materials;

- the total consumer exposure to organotins from all identified pathways should form the basis of the risk assessment. Any risk reduction strategy should, therefore, aim to ensure that the risk of individual members of the general population exceeding the TDI for organotins as a result of the cumulative exposure from a variety of consumer articles, products and pathways is reduced;

- It should be noted that restrictions have already been introduced at EU level on certain antifouling applications of organotins by means of amendments to the Limitation Directive 76/769/EEC (such as: Directives 89/677/EEC[21], 1999/51/EC[22] and 2002/62/EC[23]). Regulation (EC) No (782/2003)[24] of the European Parliament and the Council also prohibits the use, as from 1 July 2003, of organotin compounds as biocides in anti-fouling systems on EU ships and, as from 1 January 2008, on any ship entering EU waters.

In summary, even though the existing pieces of European legislation are assumed to gradually reduce the risks from contamination of the marine environment (and subsequent fish consumption), there is still a large number of consumer applications (in particular as PVC stabilisers or catalysts) not regulated by EU legislation. These products either lead to a relatively high level of possible exposure to organotins or are relatively commonplace and, as such, a consumer is likely to come into frequent contact with them.

Section 3: Right of the Commission to act

During the last decade, a number of European countries (e.g. Austria, Denmark, France, Germany, Netherlands) have put in place national measures to control the marketing, use and exposure to organotins, mainly related to tri-substituted OTs. These measures have been superseded by more recent EU legislation and in particular, the Biocidal Products Directive. The use of organotins in several specific applications is also regulated at Community level, in particular for food contact materials, medical devices and medicinal products. For the remaining vast range of other consumer products, there is currently no Community legislation.

Directive 76/769/EEC, which is based on Article 95 of the Treaty, relates to restrictions on the marketing and use of certain dangerous substances and preparations and is a well-established instrument to control risks from such dangerous substances and preparations. The Directive

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21 OJ L 398, 30.12.1989 p. 19.
22 OJ L 142, 5.6.1999 p. 22.
23 OJ L 183, 12.7.2002 p. 58.
24 OJ L 115, 9.5.2003 p. 1.

seeks to establish harmonised rules to achieve a high level of protection of human health and the environment throughout the Community and to avoid divergent national legislation which is liable to cause barriers to intra-Community trade.

Directive 76/769/EEC already contains provisions prohibiting the use of organotins in antifouling systems, and therefore can be used to introduce further rules on the use of organotins as PVC stabilisers or catalysts in the broad range of consumer products, that are currently not regulated at Community level. In the light of the vast variety and high numbers of products concerned, this cannot be achieved by leaving the responsibility to act solely to the Member States. This could lead to a situation, where Member States take actions of different scopes and affecting the same products in different ways. It would be difficult for industry to comply with a multitude of diverging rules and difficult for Member States to ensure enforcement. Furthermore, as the problems to human health due to exposure from certain consumer products containing organotins can occur in all Member States, action at Community level is the most efficient and proportionate way to eliminate or reduce the identified risks.

Section 4: Objectives

The objectives of the Proposal are to reduce the identified risks to human health by taking appropriate proportionate and efficient measures in order to achieve a high level of protection of human health and to establish harmonised rules throughout the EU to avoid barriers to intra-Community trade in consumer products containing certain organotin compounds.

The objectives of the Proposal are more specifically:

- to reduce risks to the health of consumers from products containing organotins by reducing the probability that consumers will be exposed to levels above the tolerable daily intake and
- to eliminate the risks for human health and the environment from products treated with biocides containing tri-substituted organotins (TBT, TPT).

Section 5: Policy options

In the following, different options to achieve the intended objectives are presented. The selected options take into account the available information on current practices among the identified uses of OTs, the existing legislation at the EU and national levels and the views of the stakeholders as available to the Commission at the time of writing this impact assessment. These options consider in particular also the conclusions of the targeted Risk Assessment reports and of the findings of the Impact Assessment study concerning potential restrictions on the marketing and use of certain organotin compounds.

Options ruled out at an early stage:

The exposure caused by fish consumption cannot be reduced other than by limiting consumption. However, given the positive impacts of fish consumption on human health and in the light of the economic implications for the fishing sector, this would clearly be disproportionate. Similarly, a recall of consumer products already in consumers' possession has not been considered as this would clearly be very difficult to put into practice and would be disproportionate. For most products, it is impossible to determine for the consumer whether they contain organotins or not. In addition, most of the products concerned have a

relatively short life span (such as T-Shirts, PVC gloves, PVC sandals etc.) and are therefore replaced regularly by consumers within relatively short periods of time.

Options that have been examined in detail:

The following options have been examined in detail. They have effects of growing stringency (i.e. more and more products listed in Table 2 would be affected) and are partly overlapping (i.e. a given product could be covered in a certain option, but it could also be affected by another, more stringent one).

Option-1: No action

This would mean that the status quo (i.e. no further restrictions concerning the placing of the market and use of certain OTs in various consumer uses, other than those currently existing in EU legislation) could continue.

Option-2: Voluntary action by industry

A voluntary commitment, such as a gradual phase-out and the substitution of certain OTs by other substances would be made by producers, distributors and importers who would subsequently implement the measures and monitor compliance with the commitment periodically. The commitment could be recognised by the public authorities and the results achieved would have to be assessed at regular intervals.

Option-3: Migration limit values or mandatory labelling

There are current regulatory approvals required for the use of DOT compounds in food packaging with specific migration limits[25] and pharmaceutical packaging. Comparable migration limits could be established for all organotins in all other products. Alternatively, it could be required that all products containing organotins would have to be labelled so that consumers would have the choice not to buy them or to be more careful when handling them.

Option-4: Prohibition of all uses of tri-substituted organotins, in particular TBT and TPT compounds in articles.

This option would complement the already existing ban on the use of tri-substituted OTs for biocidal purposes in the framework of Directive 98/8/EC. It would address any concerns relating to borderline products (i.e. where it is not clear whether they are affected by the Biocides Directive or not) and the importation into the EU of consumer articles treated outside of the EU, which are currently not regulated. If there are no (longer) imports of articles containing tri-substituted organotins, then the restriction would simply serve to ensure that this does not re-occur in future.

Option-5: Prohibition of the use of DBT and DOT compounds in specific consumer products for which the RAR identified significant contribution to exposure, such as: T-shirts with PVC prints, PVC gloves, PVC sandals, female hygiene products, nappies, 2 component silicone moulds.

[25] Specific migration limit means the maximum permitted rate of release of a given substance from an article, containing it, which limits the resulting exposure of the consumer. Migration rates are measured in standardized laboratory tests.

In this option, the use of DBT and DOT compounds would be restricted only in a more limited range of consumer products, which have been selected on the basis of their significant contribution to exposure as identified in the RAR.

Option-6: Prohibition of the use of DBT and DOT compounds in all consumer products made of plasticised PVC

This option would restrict the use of DBT and DOT compounds in the entire range of plasticised PVC products/applications (e.g flooring, wall covering, PVC gloves, plastic bags etc).

Option-7: Prohibition of the use of DBT and DOT compounds as stabilisers in all consumer products made of rigid PVC.

This option would eliminate the use of organotins as stabilisers in rigid PVC in all products not already regulated by specific legislation.

Option-8: Total ban of DBT and DOT in all consumer products

This option would establish a total ban for organotin compounds in all consumer products.

Section 6: Analysis of impacts

The analysis of the impacts of the various policy options has been conducted taking into consideration the criteria of effectiveness and efficiency (including practicality, economic impact and monitorability). Advantages and disadvantages have been examined for each option to support the legislator in making the most appropriate and science-based decisions to reduce the identified risks due to consumer exposure to certain organotin compounds. The marketing data and estimated costs refer to the latest information available to the Commission at the time of writing this impact assessment from discussions with all stakeholders at Working Group meetings and through further contacts with stakeholders.

It must be stressed that some of the main applications of PVC stabilised with organotins (e.g. in food contact materials, medical devices or medical applications, which account for around 60% of all organotin use in rigid PVC) are already regulated by specific legislation and therefore fall outside the scope of Directive 76/769/EEC. These are, therefore, not further considered in this report. Given that, as a consequence, the overall impacts of the envisaged measures will be limited, the analysis will be conducted in a proportionate manner, and - in the absence of quantitative information – can often only be qualitative.

Option-1: No action

According to the RAR, organotin compounds are still produced at six sites in the EU, located in: Germany (three), the Netherlands, Italy (two), and at one site in Switzerland. As described in Section 2, aggregated sales of tin stabilisers in the EU have remained fairly stable, with an average growth of about 1.5% each year over the last 6 years, in particular for use in rigid PVC. This trend can possibly be explained by substitution of other PVC stabilisers, such as cadmium and lead (phased-out voluntarily by industry or legislative action), by certain organotins, which though not being generally the first choice, maybe preferred in particular for some very demanding applications where mixed metal systems (as main alternative stabiliser systems) are not efficient. Use in catalysts is also growing (mainly in industrial applications), whereas the use in plasticized PVC seems to be declining

If the current situation would remain unchanged, it is likely that these trends would continue and therefore the identified health risks to consumers from exposure to organotins (see table 2 above) would remain stable or could even increase.

Furthermore, without action at Community level, there is the possibility that Member States would start legislating nationally, possibly applying divergent restrictive measures which, while reducing the risks from exposure to organotins, would create obstacles to the free movement of goods in the internal market. This would also lead to divergent levels of protection of human health throughout the Community.

Option-2. Voluntary action by industry

As organotins are used in a wide range of consumer articles (e.g. as PVC stabiliser, catalysts in absorbent hygiene products, silicone sealants and moulds etc.), for which various industry sectors with different interests and characteristics are involved, the impacts of this policy options should be separately considered for different categories of OTs-applications.

(a) Use of organotins as PVC Stabilisers

The sector of European PVC stabilisers is made up by 11 companies that produce more than 98% of the stabilisers sold in Europe and employ around 5,000 people. All companies participate in a voluntary scheme, known as "Vinyl 2010" that started in 2000 in order to enhance the sustainability of the products of the European PVC industry. Under "Vinyl 2010", a plan for full replacement of lead stabilisers by 2015 is being implemented, in addition to the replacement of cadmium stabilisers that was achieved in March 2001.

Considering that measures for ensuring that the phase-out of certain stabilisers is properly enforced are currently in place as part of the "Vinyl 2010 initiative", in theory these could be extended (or serve as a 'template') for a voluntary phase-out of OTs as PVC stabilisers. However, following consultation, the "Vinyl 2010" partners have informed the Commission that a voluntary self-commitment for OTs, on the basis of the existing Voluntary Commitment, is not feasible because the existing Voluntary Commitment will expire soon (in 3 years) and "Vinyl 2010" does not have know-how for controls and the prevention of imports of finished products possibly containing OTs.

Setting up a new formalised voluntary commitment, agreeing on the necessary standards, ensuring participation by all actors concerned and guaranteeing monitoring of compliance by all EU companies including small and medium-sized enterprises, producers and importers of a wide range of consumer articles would be very complicated, create a significant administrative burden to companies, the relevant industry associations but also to the monitoring authorities.

It was obvious from the consultation process, that the industry concerned did not see itself in a position to set up and enforce an appropriate voluntary commitment.

(b) Use of organotins as catalysts in various applications

Members of the European Nonwovens & Disposables Association (EDANA) have voluntarily agreed to ensure that from 2000, raw materials that come into contact with the user contain less than 2 ppb of TBT and <10 ppb for each species of organotins individually. In addition, members of the Centre Européen des Siliconés (CES), as part of an informal voluntary agreement among their members, have phased out the use of organotins for the production of silicone coated baking paper since 2002. CES has recently confirmed that the global silicone industry has now voluntarily phased out this use of organotins.

To make these initiatives more binding, the industry would need to take steps towards formalising the voluntary agreement and ensuring the recognition of the test protocols currently being used for monitoring compliance with the appropriate authorities. They would

also need to ensure that the terms of the voluntary agreement apply across the whole of their industry sector, including also importers of finished products. Setting up such a formalised commitment, agreeing on the necessary standards, ensuring participation by all actors concerned and guaranteeing compliance b all companies in the EU, including small and medium-sized enterprises would create a significant administrative burden to companies, the relevant industry associations, but also to the monitoring authorities.

Option-3 Migration limit values or mandatory labelling

Whilst the setting of migration limits for substances in plastic food contact materials is a well established practice, it is a time consuming process that poses a quite heavy administrative burden on Industry and Authorities. Migration and toxicological studies have to be performed before a substance can be authorised and adequate analytical methods need to be provided. The implementation of the relevant legislation – in particular development of the required scientific tools and evaluation of substances and materials concerned - has taken more than a decade and has involved a great number of experts in industry, the Member States, and the Commission. Work is ongoing on a continuous basis[26].

It would be totally impractical to establish similar procedures for the vast range of different consumer products where organotins can be found – if at all feasible, this would require the development of a plethora of standardised models and measuring methods to simulate all possible exposure situations. Furthermore, it would be necessary to agree on safe (maximum) limits for each product. The related costs and resource requirements for industry and authorities would be prohibitive.

Mandatory labelling of all consumer articles containing organotins as an alternative policy may well be impracticable or technically not feasible for a wide range of products containing OTs (e.g on credit cards etc.). It is also unclear that such labels would dissuade consumers from buying such articles or to change their behaviour to reduce expsoure. Furthermore, information about the presence of a substance (or even its concentration) in a product, does not really provide information about the magnitude of the resulting risks: for example, a low concentration of organotins in an article prone to easy migration or long exposure times (e.g. linings in nappies) can lead to higher exposure than a high concentration in articles less prone to migration and short exposure times (e.g. construction sheets). There would also be a high administrative burden for companies and authorities to develop, and comply with new labelling conditions, which could be disproportionate, in particular for SMEs.

Both measures would therefore not be effective, nor practicable or proportionate.

Option-4: Prohibition of all uses of tri-substituted organotins, (such as TBT and TPT compounds) in articles.

Trisubstituted organotins are typically used in products or processes subject to detailed 'approval' procedures, in particular in biocidal products. Table-3 contains an abstract from Table 2 with those consumer products that could typically contain trisubstituted organotins and their contribution to exposure.

Table-3: Consumer products affected by option 4 and related exposures		
Consumer product	**Contribution to exposure as % of group TDI**	
	Adult	*Child*

[26] http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm

Cycling shorts	18 %	n.e
Non allergenic pillows	2 %	19%
Shoe insoles	26 %	n.e
Sum***	***46 %***	***19 %***

* The group TDI of 0.1 µg Sn/kg bw has been used as a basis for determining consumer exposure** n.e: non-estimated

*** Sum of all contributions to exposure as a very rough approximation of possible worst case exposure

As explained before, their use within the EU is no longer possible due to the implementation of Directive 98/8/EC on biocides. However, there may still be importation for sale in the EU of consumer articles treated with biocidal organotins outside of the EU. The prohibition of all uses of tri-subsituted organotins in articles would therefore have the effect of:

• strengthening or reinforcing existing controls which already ban the use of these organotins as biocides (as they were not notified by any company under the Biocides Directive) and addressing any concerns relating to borderline products (e.g. those relating to products where it is uncertain whether they fall within the scope of the Biocides Directive or those of other legislation, e.g. treated socks with health claims);

• addressing the importation into the EU of consumer articles treated with biocidal products containing organotins outside of the EU. The Biocidal Products Directive does not regulate the placing on the market of materials treated with biocides - finished articles (such as textiles) containing TBT can still be imported into the EU as long as they are not making biocidal claims. This measure would, therefore, have the effect of clarifying that such treated articles cannot be placed on the market in the EU;

• preventing a potential substitution of risks where companies would move from known hazardous substances such as TBT to other tri-substituted organotins, whose risks are not fully known at present; and

• contributing to the achievement of the cessation of discharges and emissions into the aquatic environment, which is a requirement for TBT compounds, as they are included in the list of priority hazardous substances under the WFD.[27]

Given that the use of tri-substituted organotins in biocidal products is already not possible due to the Biocides Directive (unless a company requested specific authorisation), it is expected that the EU industry should be easily capable of complying with a prohibition of tri-substituted organotins and any additional administrative burden would be minimal. The measure could theoretically affect non-EU companies exporting treated articles to the EU. There is, however, no information available that would suggest that imports of such articles take place on a large scale. In addition, following detection of certain tri-substituted organotins in textiles at unacceptable levels and related media campaigns in recent years, non-EU producers have been able to quickly switch to substitutes. It is therefore unlikely that there will be significant adverse effects on foreign producers. Some benefits may therefore be accrued by EU manufacturers, particularly from the creation of a more level playing field. Furthermore, this measure is not expected to impact producers of the substances, considering that the production of TBT compounds for biocidal applications has strongly decreased and

[27] OJ L 327, 22.12.2000, p.1

the sales in the EU have stopped (exports may still be on-going). Another benefit may relate to the potential for an increase in sales of alternatives (or their raw materials). However, the scale of this is unlikely to be significant (based on recent usage, production and marketing trends in the sector).

Monitoring the implementation of a ban of the use of tri-substituted organotins should be relatively straightforward, given that suitable systems have been established through previous restrictions under Directive 76/769/EEC. In effect, the addition of these organotins to an existing range of restrictions on chemical substances being monitored is likely to be rather marginal. Additional efforts might be required by customs services (or other authorities in the Member States in charge of monitoring imports), but again, the necessary structures and practices should already be in place with regard to a number of other substances which are already restricted and have to be monitored.

Overall, the effectiveness, practicality and economic impact of this measure appear to be satisfactory, relative to its objectives. No significant impacts are expected on EU trade, competitiveness and employment as a result of this measure. This measure would ensure that no imported articles containing tri-substituted organotins could be placed on the market and would therefore lead to an equal treatment of companies inside and outside the EU and ensure the full benefits in terms of protection of human health and the environment.

Option-5: Prohibition of the use of DBT and DOT compounds in specific consumer products for which the RAR identified significant contribution to exposure, such as: T-shirts with PVC prints, PVC gloves, PVC bags, PVC sandals, PVC wall and floor covering, female hygiene products, nappies and 2-component silicone moulds

This measure will eliminate the use of di-substituted organotins in specific consumer articles, selected on the basis of their relative high contribution to exposure such as: T-shirts with PVC prints, PVC gloves, PVC sandals, female hygiene products, nappies, and 2-component silicone moulds. Table-4 contains an extract from Table 2 with all those products that would be affected by this option.

Table-4: Consumer products affected by option 5 and related exposures

Consumer product	**Contribution to exposure as % of group TDI**	
	Adult	**Child**
Printed T-shirts	25 %	189%
PVC gloves	33%	n.e.
PVC bags	7%	n.e.
PVC sandals	33%	33%
PVC wall and floor covering (exposure mainly via household dust)	17%	117%
Female hygiene products	62%	n.e.
2 part silicon moulds	87%	n.e.
Nappies	n.e	21%
Sum*	***264 %***	***360 %***

* The group TDI of 0.1 µg Sn/kg bw has been used as a basis for determining consumer exposure
** n.e: non-estimated

*** Sum of all contributions to exposure as a very rough approximation of possible worst case exposure

The socio-economic impacts of this measure for each separate category of products are as follows:

(1) female hygiene products and nappies: As previously discussed, following informal voluntary action by companies organised in EDANA, OTs are no longer intentionally used in these products and occur only as impurities. The socio-economic consequences of a prohibition would therefore be minimal;

(2) specific consumer products made with plasticised PVC: For printed T-shirts, socio-economic impacts should be minimal as these are generally not produced in the EU, but are imported. Member companies of ESPA intend to ensure that such use ceases in the EU. For PVC gloves and sandals, the impact should also be minimal as industry is already moving towards alternatives. With regard to wall coverings and flooring, ESPA companies are currently working with their customers to change to alternative stabiliser systems with the aim of phasing out this use by the end of 2007. The measure could theoretically affect non-EU companies exporting such articles to the EU. There is, however, no information available that would suggest that imports of such articles made of plasticised PVC and containing OTs take place on a large scale. Producers in third countries should be able to move to the same alternatives as is happening within the EU. Furthermore, the Proposal will also be notified to the WTO under the TBT agreement, thus giving third countries the possibility to comment.

In summary, for most of the consumer goods in question, industry has already started phasing out the use of OTs (i.e. female hygiene products, PVC printed T-shirts, PVC gloves and sandals, wall and floor coverings). This indicates that there are available alternatives and that any increases in costs are either minimal or can be passed through the supply chain.

It is also important to note that OTs, in general, account for less than 0.1% by weight of the final products that they go into. The costs of the OT as an input to production within the share of total production costs are also expected to be minor, so that no significant price effects on consumers or relating to imported goods are expected.

With regard to the related downstream markets for the end consumer goods (e.g. PVC printed T-shirts, etc.), the question becomes one as to whether or not other related markets are affected and whether these impacts should be considered in the assessment. The ban on the use of OTs is not expected to lead to either a shift in the supply or demand of goods in the downstream markets as there are substitutes available. As a result, the change in producer surplus can be expected to be greater than any change in consumer surplus (given the existence of substitutes and the fact that OTs are only one factor of production in the end product).

(3) RTV silicone applications According to the available information, introduction of alternatives is easier in RTV-2 DIY silicone moulds compared with RTV-1 silicone sealants. In RTV-1 silicone sealants, though alternatives (such as titanates and zirconates) already appear to have a significant market share, the catalyst manufacturers claim that organotins are the established catalysts of choice. In terms of cost, titanium and zirconium are more expensive compared with tin (approximately 5 times higher). The high catalyst loading makes the cost of the catalyst a major contributor to overall formulation costs. Additional problems associate with reduced performance and applicability of these alternatives as opposed to

organotins. For RTV-2 DIY silicone moulds, addition curing catalysts such as platinum complexes appear to be the leading alternatives to organotin catalysts. These have both advantages (no shrinkage, generally skin-safe) and disadvantages (higher cost, less easy to use, adverse effects from the presence of certain substances) compared to organotin catalysts.

Concerning the criticality of RTV-1 silicone sealants in a variety of demanding applications (e.g construction and movement joints, in bridges, roads etc.), the associated industry (CES, FEICA) claim adverse impacts through increased costs of alternatives, the colour of the produced sealant and the expected shelf-life of alternatives. A report[28] mentions a sold quantity of 114.400 t silicone sealants in Europe in 2006, of which: 7.3% are claimed to go to consumers, 20.2% to industrial uses, 28.9% to construction 3.6% to automotive, and 40% to glazing & insulated glazing. According to the European Silicon Producers (CES) more than 12,000 small and medium sized companies in the EU, applying 230,000 tons/y of silicone sealants in the construction sector, would be strongly affected by restrictions of DOT/DBT in these applications. CES claims that if organotins would no longer be available for the silicone sealants applications, such measure would have significant repercussions on >95% of these SMEs. Therefore, RTV-1 silicon sealants should be exempted form the proposed prohibition.

Adequate time is needed to allow the rather fragmented industry to adapt. With respect to RTV-2 DIY moulds, CES members are prepared to accept a regulatory decision to phase out the use of organotins for the DIY market. It should be noted that dental moulds fall out of the scope of the Limitation Directive, as being regulated by the Directive on Medical Devices.

Monitoring the implementation of restrictions on the use of organotins in these products should be relatively straightforward, given that suitable systems have been established through previous restrictions under Directive 76/769/EEC. In effect, the addition of these organotins to an existing pool of a wide range of restrictions on chemical substances being monitored is likely to be rather marginal. Additional efforts might be required by customs services (or other authorities in the Member States in charge of monitoring imports), but again, the necessary structures and practices should already be in place with regard to a number of other substances which are restricted.

Overall, this option would accelerate current trends, cover all producers and importers and serve to prevent re-occurrence of past uses. Restrictions on DBT would also reduce the amount of TBT which is present as an impurity - and, therefore, help in achieving the targets of the Water Framedwork Directive. Also, because industry has found alternatives to organotins in most of the targeted applications, such restriction can, therefore, be implemented quickly, with the exception of RTV-1 sealants. The effectiveness of this measure in reducing the contribution to the overall exposure is high considering that several plasticised PVC articles contribute >100% of the TDI. However, the list of banned applications may need to be updated at intervals, if use of DOT/DBT is observed in new products that would not be listed in the ban.

Option-6: Prohibition of the use of dioctyltin (DOT) and dibutyltin (DBT) compounds as stabilisers in all consumer products made of plasticised PVC

By prohibiting the use of DBT and DOT in products made of plasticised PVC, a number of the specific products identified in the RAR (e.g. T-shirts, PVC gloves, sandals etc.) as contributing significantly to the TDI as well as other plasticised PVC products that contain these OTs would no longer be on the market, thereby reducing consumer exposure and

[28] Frost & Sullivan, 'European flexible sealants market', 2007

enhancing protection. Table 5 contains an extract from Table 2 with all those products that would be affected by this option. As can be seen, effect of this option and option 5 are parlt overlapping.

Table-5: Consumer products affected by option 6 and related exposures		
Consumer product	**Contribution to exposure as % of group TDI**	
	Adult	**Child**
Printed T-shirts	25 %	189%
PVC gloves	33%	n.e
PVC bags	7%	n.e
Earplugs	<1%	n.e
PVC sandals	33%	33%
Paddling pool	n.e	3%
Mouthing PVC toys	n.e	2%
PVC wall and floor covering (exposure mainly via household dust)	17%	117%
Any other consumer product made of plasticised PVC	n.e.	n.e.
Sum***	***117 %***	***344 %***
* The group TDI of 0.1 µg Sn/kg bw has been used as a basis for determining consumer exposure ** n.e: non-estimated *** Sum of all contributions to exposure as a very rough approximation of possible worst case exposure		

Information from industry indicates that organotin stabilisers are already rarely used in plasticised PVC, with the liquid mixed-metal systems being the favoured stabiliser type. Industry has, however, underlined the continuous need for use of OTs in coil (or steel) coating – for example coated garden fences – as there are no appropriate alternatives. Strictly speaking, this is not really a consumer use, and according to the RAR this use is unlikely to present a significant risk to consumers.

The socio-economic impacts of the measure should be limited in the sense that:

- plasticised PVC accounts for less than a third of the total PVC in the EU;
- organotins are today already rarely used in plasticised PVC applications (whether from the stabiliser or plasticiser components), where the liquid mixed metal systems are usually the stabilisers of choice.
- the European producers are currently in a process of phasing them out in a number of remaining consumer applications.

Therefore, no significant adverse effects and/or disproportionate impacts have been indicated or are generally expected on the downstream markets or on the manufacturers of plasticized PVC. It is, however, possible that some companies would incur significant costs as a result of the measure, considering also that the available alternatives (Ba/Zn, Ca/Zn, liquid mixed systems) are comparatively more expensive than OTs, though the price increase of the final

products was estimated to be minimal (see table 6). In particular SMEs of this sector may need some time to confirm that the new formulations are fully workable in their plants and do meet their customer's specifications. However, based on the results of the consultation and studies made in preparation of the proposal, it was not possible to quantify how many companies would be in such a situation.

Table-6 Direct Cost Comparison of Alternative Stabilisers

(* price comparison is relative to organotins)

Alternative stabiliser	**Applications**	**Price of stabiliser relative to OTs**	**Price increase in the final product** (0.1% in OTs)
Liquid Ca/Zn	Plasticised PVC	50% more expensive	0.05% more expensive
Liquid Ba/Zn (1)	Plasticised PVC, including flooring	Similar	Similar
Liquid Ba/Zn (2)	Plasticised PVC	50% more expensive	0.05% more expensive
Ba/Ca-Zn stabilisers	Plasticised PVC, including flooring	20% more expensive	0.05% more expensive

The measure could theoretically affect non-EU companies exporting such articles to the EU. There is, however, no information available that would suggest that imports of such articles made of plasticised PVC and containing OTs take place on a large scale. Producers in third countries should be able to move to the same alternatives as is happening within the EU. Furthermore, the Proposal will also be notified to the WTO under the TBT agreement, thus giving third countries the possibility to comment.

In terms of practicality and monitoring the implementation of restrictions, this measure should be relatively straightforward as already explained for options 4-6.

Overall, this measure would accelerate current trends, cover all producers and importers and serve to prevent re-occurrence of past uses. Restrictions on DBT would also reduce the amount of TBT which is present as an impurity - and, therefore, help in achieving the targets of the Water Framework Directive.

As industry has found alternatives to organotins in most plasticised PVC applications, such restriction can be implemented quickly, with the exception of coil or steel coating. The effectiveness of this measure in reducing the contribution to the overall exposure is high considering that several plasticised PVC articles contribute >100% of the TDI in children consumers.

Option-7: Prohibition of the use of dioctyltin (DOT) and dibutyltin (DBT) compounds as stabilisers in all consumer products made of rigid PVC

As already mentioned before, food and pharmaceutical packaging currently account for around 60% of all organotins use in rigid PVC. These products have their own regulatory frameworks for approvals, which take full account of the possible risks to human health.

Additional restrictions in the framework of Directive 76/769/EEC would, therefore only affect the remaining 40%, which still constitute the main non-regulated uses of these compounds. Table 7 contains an extract from Table 2 with all those products that would be affected by this option (except food packaging). As can be seen the contributions to exposure from DBT and DOT compounds contained in non-food rigid PVC applications are relatively small, (e.g. overall <4% of TDI for adults) compared to the exposure resulting from other products. Consequently, this option would not lead to a significant reduction in the exposure of consumers to organotins.

Table-7: Consumer products affected by option 7 and related exposures

Consumer product	Contribution to exposure as % of group TDI	
	Adult	**Child**
Drinking water pipes	<1%	<1%
Rigid film	3%	n.e
Sum*	***< 4 %***	***< 1 %***

* The group TDI of 0.1 µg Sn/kg bw has been used as a basis for determining consumer exposure

** n.e: non-estimated

*** Sum of all contributions to exposure as a very rough approximation of possible worst case exposure

On the other hand, a ban of OT's in all rigid PVC (which constitutes the main use) would significantly affect the producers of the compounds, but also the companies that use them as an input for their products. Several parameters will influence the costs to a given company.

The substance and product portfolio will be a critical factor to be considered, in particular for companies manufacturing organotins. If a company manufactures only DBT and DOT the impacts of a restriction would be significantly higher than those for a company which also manufactures the alternatives (such as calcium or organic stabilisers). In the latter case, any losses from a restriction on organotins are likely to be compensated by an increase in sales of these alternatives (the market of which is growing quickly). During the consultations, a number of companies manufacturing organotins indicated that the impact of broad restrictions of DBT/DOT on all consumer products made of rigid PVC would be significant by reducing their turnover and could ultimately result in the closure of their units, involving direct job losses in excess of 300 workers.

For users of stabilisers, the key alternatives to DBT/DOT stabilisers in rigid PVC are calcium-based stabilisers. In general, calcium/zinc stabilisers are more expensive than the organotin-based stabilisers. Newer forms of calcium-organic stabilisers (OBS) are more complex and expensive due to a use of specialised co-stabilisers while their rate of introduction is slowed down by the extensive evaluation work required and the need for acceptance by customers with very specific performance requests. In addition, processability may be an issue and re-tooling costs may accompany the OT substitution by the calcium organic stabilisers. For example, for profile applications where extruders would require tool tuning, a retooling cost of 7,000 € has been identified per company affected, but no numbers could be obtained for how many companies would be affected by such retooling. For a number of products, in particular transparent rigid films, no suitable alternatives are yet available.

Furthermore, for companies, using OTs in PVC applications, their level of preparedness to move to alternative stabilisers is another important factor. Not all companies have anticipated the need to substitute organotins in unplasticised applications. Where changes to other

technologies and products require substantial investment and there is insufficient time to react, the viability of manufacturing at certain sites may be lost.

According to information provided by the European Association of Plastic Converters (EuPC), the turnover of the whole chain of OT-stabilised PVC products, is 8.9 billion EUR. The whole chain of the organotin using PVC industry employs 73.100 people in ~ 1200 companies (40% of which are SMEs, with an average of 120 workers/SME). In the absence of any precise data, a rough estimation can be made for rigid PVC applications, by using the proportion of 95% (as calculated by table-A, Appendix 1, for rigid PVC uses) and considering that about 40% of these concern non-food applications. Therefore, a turnover of ~3.4 bilion EUR is estimated for the rigid PVC applications, which could be affected by this option, and this could concern 450 companies which employ ~ 28.000 people.

More specifically, according to the European Rigid PVC Film Association (ERPA), if the whole industry has to shift to the use of alternative stabilisers, they would have costs of reformulation of around €10,000 per company and €150 million for the EU PVC rigid films industry. In addition to this, a much larger impact is to be expected on downstream user's small calandering plants. According to ERPA, if industry cannot replace DOT in PVC films by another stabiliser system, they would have to shut down their calendaring production plants (which cannot be used for other polymers) with the costs of this action estimated at around €3 billion.

In analogy to the situation for plasticized PVC (which is examined in Option 6), the content of the stabilisers in the final products is very low. This means that even though available alternatives (solid mixed metal systems) are comparatively more expensive than OTs, the price increase of the final products is expected to be minimal (<0.1%).

Monitoring the implementation of DOT/DBT restrictions in articles made of rigid PVC should be relatively straightforward, given that suitable systems have already been established to monitor restrictions on a range of other substances.

In summary, this option would be easy to monitor, would not lead to significant price increases for consumer products, but would have only limited effectiveness as it would not lead to a significant reduction in exposure of consumers to organotins. In contrast, it could have significant adverse socio-economic effects on a large number of companies producing organotins and using these compounds as stabilisers in PVC.

Option-8: Total ban of TBT, TPT, DBT, DOT in all consumer products

This option would provide the best possible guarantee of reducing the overall exposure of consumers to organotins. Therefore, it would respond more effectively than any other examined policy option to the conclusion of SCHER that if the total exposure to organotins exceeds the TDI, "there is a reason for concern and risk reduction measures should be considered, regardless if this exposure comes via one or a large number of pathways". It would, in fact, cover all products mentioned in Table 2 (except food and food packaging) and the respective contributions to exposure.

Certain DBT compounds (dibutyltin chloride, CAS: 683-18-1, and dibutyltin hydrogen borate, CAS: 75113-37-0) will soon be classified by the 30th ATP and 31st ATP, respectively, of Directive 67/548/EEC as reprotoxic category 2, and it will subsequently be prohibited to sell the substances and preparations containing to consumers[29]. However, the

[29] This is a quasi 'automatic' consequence as foreseen in point 30 of Directive 76/769/EEC

exposure of consumers from the use of the substances or preparations containing them is not directly comparable to the exposure resulting from their use as stabilisers in articles made of PVC. There is, therefore, no immediate justification to extend the ban of the sale of the substances and preparations containing them to all articles.

Furthermore, a total ban of DBT and DOT compounds in all consumer applications may raise issues of proportionality in the light of the significant adverse socio-economic impacts. These have been previously discussed during the presentation of options 5, 6 and 7. Therefore, there is no further need to comment in this section.

Overall, this measure will have a high effectiveness, considering that at the same time: (a) it would ensure that no articles containing tri-substituted organotins could be placed on the market; (b) a total ban on the use of DBT and DOT in PVC products would result in significant reductions in the exposure of humans and the environment to organotins. However, significant adverse socio-economic impacts would result due to the lack of alternatives of comparative costs and technical feasibility, in particular for certain applications (transparent PVC rigid films, silicon sealants etc.). A total ban would impact upon a range of stakeholders, apart from the manufacturers of organotins, the downstream users of these products and potentially the consumers, too.

Section 7: Comparing the options

OPTION	**Effectiveness**	**Efficiency**
No action	**Very low:** As the use of OTs in consumer products for which risks have been identified would continue, the potential risks for human health would not be reduced. Member States could adopt diverging rules, which could impact adversely the Internal Market.	**Very Low:** No extra costs for industry, but the objectives would not be achieved only to the extent that some member states adopt effective measures.
Voluntary action	**Low:** Considering that participants in an existing scheme (i.e. "Vinyl 2010") considered voluntary action impractical, there would be difficulties to set up a new voluntary agreement with all actors and to monitor small and medium sized enterprises and also imports. Difficulties for the Member States and Competent Authorities to verify the compliance of the industry with such voluntary action.	**Low:** Administrative costs for industry and local supervising bodies for setting up, enforcing and monitoring voluntary commitments can be significant.
Migration limit values or mandatory labelling	**Very low:** Not practicable to establish OT migration limits for the very broad range of different consumer products (as	**Very low:** Cost and resource requirements for industry and authorities to agree on safe maximum limits for each

	in food related applications). Mandatory labelling of all consumer articles containing organotins will be impracticable or technically not feasible for a wide range of OTs applications (e.g on credit cards etc.). It is also unclear that such labels would dissuade consumers from buying such articles or to change their behaviour in order to reduce exposure.	consumer products would be very high. High administrative burden for companies and authorities to develop, and comply with new labelling conditions, which would be disproportionate, in particular for SMEs (high reformation/rebranding costs)
Ban of all uses of Tri-substituted OTs (TBT and TPT)	High: This measure would ensure continued elimination of consumer exposure from articles treated with biocidal products containing OTs, including from those produced outside of the EU, as well as, prevent a substitution of risks, where companies move from known hazardous substances such as TBT to other tri-substituted OTs, whose risks may not be fully known at present.	High: No impact on EU industry, as the production of TBT compounds for biocidal applications has strongly decreased and the sales in the EU have stopped. Some benefits may be accrued by EU manufacturers, from the creation of a more level playing field. Producers in third countries should have no difficulties to move to alternatives in a similar way as done by EU manufacturers.
Ban of the use of DOT and DBT in Specific Consumer Products (PVC T-shirts, PVC gloves, PVC sandals, female hygiene products, nappies, RTV-2 silicon moulds)	**High**: By targeting the specific products, which according to the RAR contribute significantly to exposure, this measure is likely to be effective, at least initially, in reducing consumer exposure to acceptable levels (< than TDI).	**Average to High:** No significant costs are expected for industry, due to existence of alternatives of comparative cost and technical feasibility for these applications. However, the list of banned applications may need to be updated at intervals, if use of DOT/DBT is observed in new products.
Ban of the use of DOT and DBT as stabilisers in all consumer products made of plasticised PVC	**High** The effectiveness of this measure in reducing the contribution to the overall exposure is high considering that several placticised PVC articles contribute overall >100% of the consumer TDI.	Average: Due to availability of alternatives to OTs in most plasticised PVC applications, and industry is already reducing OT use, any restriction on the use of OTs can be implemented quickly and without significant costs. It is, however, possible that some companies, in particular SMEs, would incur significant costs as a result of

		the measure. An exception from a ban will be necessary for coil and steel coating.
Ban of the use of DOT and DBT as stabilisers in all consumer products made of rigid PVC	**Low to Average** a total ban on the use of DBT and DOT in rigid PVC products is likely to result in limited reductions in the total exposure of consumers to organotins as rigid PVC applications are already covered to 60% by existing food contact legislation and remaining products of rigid PVC do not contribute significantly to exposure.	**Low:** Significant adverse effects on producers of organotin stabilisers, some of which might have to close. A very high number of PVC producers and transformers could be affected with significant costs and genuine difficulties in finding the appropriate alternative for a given product or in retooling a plant or processing system Some SME producer companies may have significant difficulties, in particular if their portfolio is based exclusively on DOT/DBT stabilisers.
Total ban of TBT, TPT, DBT, DOT in all consumer applications	**High:** It would provide the best possible guarantee of reducing the overall exposure to these organotins and their contribution to the TDI.	**Low:** Significant adverse impact on the industry, in particular for SMEs in the area of PVC or silicon catalysts sector.

In order to reduce the exposure of consumers to less than the TDI while at the same time limiting the costs, a combination of the options that are highly effective and highly efficient is regarded as the preferred option. This would be a combination of the options 4, 5 and 6, which means a prohibition of the placing on the marketing and use: of tri-substituted organotins (including TBT, TPT) in all products, as well as of DBT and DOT in products made of plasticised PVC (which includes already printed T-Shirts, gloves, and sandals), except for coatings of sheet metal and wire, and in some additional consumer products leading to high exposure made of other materials, such as female hygiene products, nappies and two-component silicon moulds.

It has to be noted that the list of products affected by options 5 and 6, respectively, are to a large extent overlapping. Table 8 provides the consolidated list of products affected.

Table-8: Consumer products affected by the combination of options 5 and 6 and related exposures

Consumer product	**Contribution to exposure as % of group TDI**	
	Adult	**Child**
Printed T-shirts	25 %	189%

PVC gloves	33%	n.e
PVC bags	7%	n.e
Earplugs	<1%	n.e
PVC sandals	33%	33%
Paddling pool	n.e	3%
Mouthing PVC toys	n.e	2%
PVC wall and floor covering (exposure mainly via household dust)	17%	117%
Any other consumer product made of plasticised PVC	n.e.	n.e.
Female hygiene products	62%	n.e.
2 part silicon moulds	87%	n.e.
Nappies	n.e	21%
Sum***	***265 %***	***365 %***

* The group TDI of 0.1 µg Sn/kg bw has been used as a basis for determining consumer exposure ** n.e: non-estimated
*** Sum of all contributions to exposure as a very rough approximation of possible worst case exposure

The sum of the exposure contributions affected is slightly higher compared to option 5 alone and this effect would be bigger, when considering that there could be further consumer products made of plasticised PVC containing organotins that have not been evaluated. A combination of options 5 and 6 will also reduce the need for amendments of the restriction to update the list of products concerned (i.e. each time when new information emerges that would demonstrate the need to restrict the use of oragnotins in another product made of PVC not already included in the list). However, when considering only the known contributions to exposure, the difference between option 5 alone and a combination of options 5 and 6 is only marginal.

Overall, this combination of options 4, 5, and 6 (as demonstrated by combining tables 3 and 8) would eliminate organotins from a range of products that could lead to exposure of up to 311% of the TDI for adults, and 384% of the TDI of children. All significant sources of exposure as listed in Table 2 would be addressed, except for food, food packaging, and medical applications (which are outside the scope of Directive 76/769/EEC). This combination of options would also be efficient as there are only very limited additional costs for industry and the administrative burden for companies and authorities is low.

There would be no impact on the EU budget. The proposal will also be notified to the WTO under the TBT agreement, which will give third countries the possibility to comment.

For regulatory purpose a limit value of 0.1% of tin in the regulated products would be established - below this limit, substances are usually considered as impurities or trace contaminants that have not been deliberately added. This option would ensure the fully harmonised management of this substance within the internal market. The administrative burden in terms of market surveillance and compliance monitoring would be low.

Section 8: Monitoring and evaluation

Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on marketing and use of certain dangerous substances and preparations establishes a framework to control and limit the risk of certain dangerous substances as such or contained in preparations during specific uses and applications. This legal instrument permits to have harmonised rules throughout the European Union and to control the market in terms of production, import, distribution and use.

Member States have put into place long-standing mechanisms and have nominated authorities to monitor compliance with the restrictions of Directive 76/769/EEC. These same structures can be used to monitor compliance with the new restrictions of this Proposal which will therefore not create a significant administrative burden. Although the Directive does not contain any mechanism or indicators for progress achieved, a satisfactory level of feedback is obtained through cases registered by the poison centres, recommendations/complaints by the Member States and by industry.

Regulation (EC) No 1907/2006 will repeal Directive 76/769/EEC (REACH)[30]. on 1 June 2009. The Regulation has established a European Chemical Agency for the purposes of managing and carrying out technical, scientific and administrative aspects of the Regulation and to ensure consistency at Community level in relation to these aspects. In particular a Forum for Exchange of Information on Enforcement will be part of the Agency and will coordinate a network of Member States authorities responsible for enforcement of this Regulation.

As from 1 June 2009, the restrictions imposed under Directive 76/769/EEC will be incorporated into Annex XVII of Regulation (EC) No 1907/2006 (REACH)[31]. In view of the limited remaining lifetime of Directive 76/769/EEC, transposition by the Member States of the measures in the Proposal would serve no useful purpose. The restrictions are therefore more efficiently introduced into the Annex to Directive 76/769/EEC using a Decision rather than a Directive. The measures will enter into force on 1 June 2009 as part of REACH. If further information on risks stemming from products not covered by the preferred options were to emerge in the coming years from the implementation of REACH (in particular from registration), it will be examined if additional restrictions are deemed necessary.

Section 9: References

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[30] OJ L 396, 30.12.2006, p. 1.
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Section 10: Glossary of acronyms

AHPs - Absorbed hygiene products

ESR - Existing Substances Regulation

CES - European Silicon Producers

CHE - Centre for Ecology and Hydrology

CSTEE - Scientific Committee on Toxicity, Ecotoxicity and the Environment

DBT - Dibutyltin

DOT - Dioctyltin

EDANA -Members of the European Nonwovens & Disposables Association

EFSA - European Food Safety Authority

ERPA - European Rigid PVC Film Association

ESPA - European Stabilisers Producers Association

ETINSA - European Tin Stabilisers Association

ETICA - European Tin Catalysts Association

EuPC - European Plastics Converters

FEICA - European Adhesive & Sealant Manufacturing Association

LWG - Limitations Working Group

MDD - Medical Devices Directive

NOAEL - No Observed Adverse Effect Level

OBS - Organic-based Stabilisers

PBT - Persistent, Bioaccumulative and Toxic substance

PNEC - Predicted No-effect Concentration

PVC - Poly Vinyl Chloride

RAR - Risk Assessment Report

REACH - Registration Evaluation and Authorization of Chemicals

RPA - Risk Policy Analysts

RTV - Room Temperature Vulcanisation

SCHER - Scientific Committee on Health and Environmental Risks

SMEs - Small Medium Enterprises

SMLs - Specific Migration Limits

TBT - Tributyltin

TBTO - Tributyltin Oxide

TDI - Tolerable Daily Intake

TPT - Triphenyltin

WFD - Water Framework Directive

ANNEX 1

Uses of Organotins

Table A: Use of Organotin Stabilisers in Rigid and Plasticised PVC (Data from RPA reports)					
	Applications	**2005 tons p.a. (%)**		**2007 tons p.a. (%)**	
Rigid PVC					
Rigid films and sheets	• Food packaging • Pharmaceuticals packaging • Non-food packaging • Credit cards • Rigid construction sheets including foamed sheeting	13,067	87	13,463	85
Pipes, fittings and profiles	•Pipes for draining sewage and waste water • Pipes for drinking water • Conduit and duct pipes for protecting electrical cables • Other pipes • Fittings, window profiles	556	4	993	8
Bottles		278	2	243	2
Totals		***13,901***	***93***	***15,009***	***95***
Plasticised PVC					
Coatings and flooring	• Flooring • Wall covering • T-shirt stamps	628	4	417	2
Steel (coil) coating		314	2	80	1
Miscellaneous	• Bath sandals Rubber boots • Gardening hoses • Car interiors • Meat wrap films (etc.)	157	1	342	2
Totals		***1,099***	***7***	***840***	***5***

Table-B: Use of Organotin Catalysts (Data from RPA reports)		
	Quantity (tons p.a.) in 2002	**Quantity (tons p.a.) in 2007**
Catalysts	1,300 to 1,650	~2,000
• Plasticisers	150 - 350	
• Silicones	50 - 100	
• Electrodeposition coatings	700 - 800	950

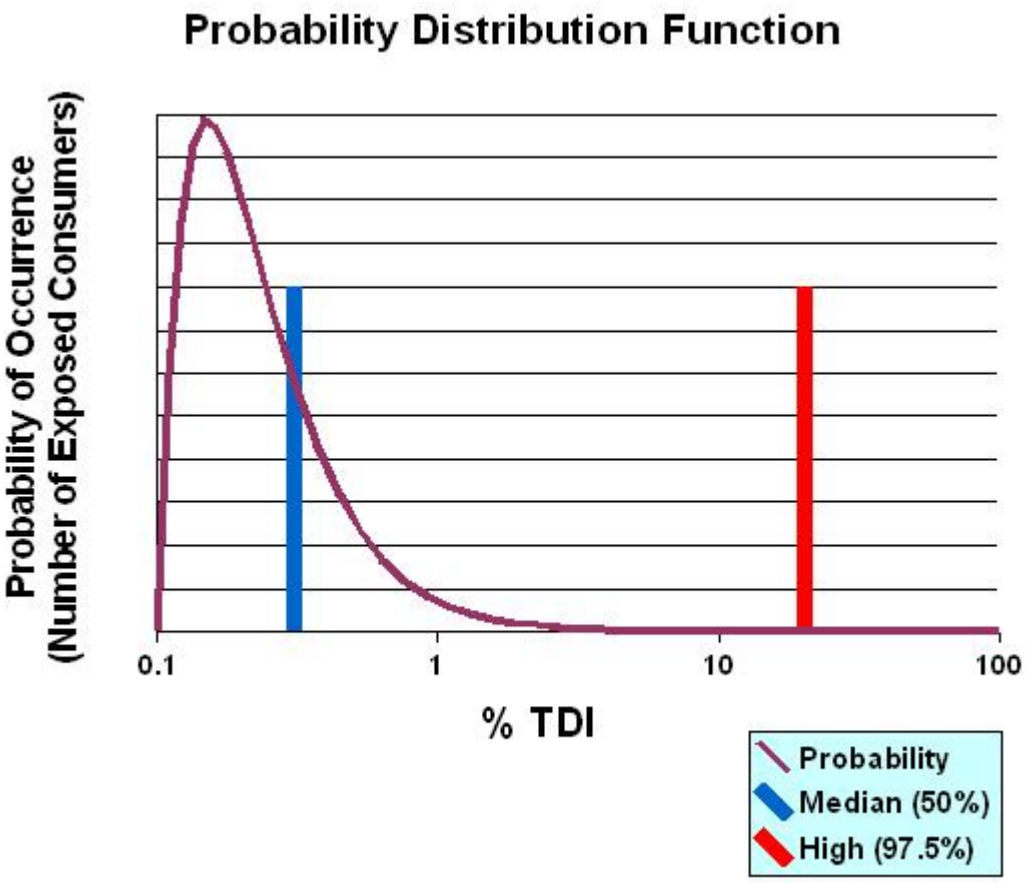
• Polyurethanes	400	750

Table C: Others uses of organotins (Data from RPA reports)		
Application	**Quantity (tpa) in 2002**	**Quantity (tpa) in 2007**
• Glass coating	760 to 800	Same
• Biocide in anti-fouling paints	1,250	Phased out globally
• Synthesis	< 150	~500
• Biocide (other)	< 100	Close to zero
• Pesticide	100	Unknown

ANNEX 2

Methodology for calculating exposure levels in Table 2

For any of the uses of organotins listed in Table 2 of the report, there will be a distribution of exposures. These will have the from of 'probability distribution functions'. An example is shown below.



Most consumers are exposed to low levels of organotins with, in this example, a median (50%) value of around 0.3% of the TDI (shown by the blue line). However, in the 'worst case' analysis (as represented by the 'high' or 97.5% red line), consumers are exposed to about 20% of the TDI.

In order to evaluate the overall exposure to consumers across the EU, a Monte Carlo simulation was used. For the Monte Carlo analysis, probability distribution functions (similar to that outlined above) were generated for every use. Assuming that exposure to the various uses were independent of each other, the Monte Carlo analysis was used to generate sample exposures (based on the probability of their occurrence) across all the uses and summed to give an estimate of the overall exposure. For the Organotins Risk Assessment Report (2005), this was repeated 2,500 times to generate another 'probability distribution function' of the combined exposure. For adult consumers, the overall median (50%) exposure was found to be about 65% of the TDI, with 25% of adults exposed to more than 100% of the TDI.