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COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

Proposal for a Commission Decision amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of organostannic compounds for the purpose of adapting its Annex I to technical progress

(amendment of Council Directive 76/769/EEC)

SUMMARY OF THE IMPACT ASSESSMENT

{C(2009) 4084 final}
{SEC(2009) 705}

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Lead DG: Enterprise and Industry

Other involved services: AGRI, ENV, SANCO, JRC, EMPL, ECFIN, TRADE, JLS, MARKT, RTD, SJ, TREN, SG

Agenda planning or WP reference: 2008/ENTR/026

BACKGROUND

This impact assessment accompanies the draft Commission Decision amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of organostannic compounds for the purpose of adapting its Annex I to technical progress.

Organotin compounds (OTs), also known as organostannic compounds, are composed of tin bound directly to 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. 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.

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).

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

The draft proposal on organotins was discussed with Member States at several meetings of the Commission's Working Group on Directive 76/769/EEC. Representatives of various industry associations attended these meetings including: European Stabilisers Producers Association (ESPA), European Tin Stabilisers Association (ETINSA), European Tin Catalysts Association (ETICA), European Plastics Converters (EuPC), European Silicon Producers (CES), European Adhesive & Sealant Manufacturing Association (FEICA) and European Council of producers and importers of paints, printing inks and artists' colours (CEPE). The proposed restrictions on organotins have been discussed with other Commission services, in particular with DG SANCO and DG-ECFIN.

Other related legislations were also examined to avoid any legal overlap or contradictions such as: the General Product Safety Directive (2001/95/EC), the Biocidal Products Directive (98/8/EC), the Regulation on materials and articles intended to come into contact with food (EC) 1935/2004, and the Medical Devices Directive (93/42/EEC).

2. PROBLEM DEFINITION AND OBJECTIVES OF THE POLICY INITIATIVE

Studies on the effects of OTs have consistently reported effects on thymus weight and on thymus mediated immune function. The dominant contribution to human uptake is via consumption of fish and fish products due to historic use of TBT in antifouling paints for ships (which has been eliminated by previous EU legislative actions).

The latest risk assessment report (RAR), however, concluded that risks to consumers may still arise from a wide range of products containing organotins and can be evaluated in relation to a group TDI (Tolerable Daily Intake corresponding to 0.1 μg Sn/kg bw/day), as organotins are considered to act additively with similar modes of action. The RAR identified significant contributions to the risks for children exposed to organotins from certain consumer products (for example PVC-printed T-shirts, wall and floor coverings). Other significant exposure sources include: cookies baked on silicone coated baking paper, sanitary panty liners (adults and children), food wrapped in PVC, and foot sprays (adults). These uses contribute to exposure in the range of 20 – 100% of the TDI or even more. The RAR concluded that risks from organotins to children are higher than those for adults considering that the overall exposure for 70% of young child consumers will exceed the group TDI, while this percentage is 25% for adults. It should also be noted that certain DBT compounds will soon be classified as toxic for reproduction, Category 2, which is not the case for DOT compounds. Consequently, the use of DBT compounds might lead to risks of more severe effects.

The main objective of the proposal accompanied by the impact assessment is to limit the risks to the health of consumers from products containing organotins by reducing the probability that consumers will be exposed to levels above the TDI.

The proposal will not cover the use of organotin compounds in several specific applications which are already regulated at Community level by other legislative frameworks (such as for food contact materials, medical devices and medicinal products).

3. RIGHT OF THE COMMISSION TO ACT

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 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.

4. COMPARISON OF THE VARIOUS POLICY OPTIONS TO ACHIEVE THE OBJECTIVES

Different options to achieve the intended objectives have been analysed in the Impact Assessment report. The selected options take into account the available information on current practices among the identified consumer uses of organotin compounds and the existing legislation at the EU and national levels. These options consider in particular the conclusions of the targeted Risk Assessment reports and the views of the stakeholders as currently available to the Commission concerning potential restrictions on the marketing and use of certain organotin compounds. A summary of this analysis is given in the table below:

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 be achieved only to the extent that some Member States adopt effective measures.
Voluntary action	**Low:** Given 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 Competent Authorities to verify the compliance of the industry with such voluntary action.	**Low:** Administrative costs for industry for setting up, enforcing and monitoring a voluntary commitment could be significant.
Migration limit values or mandatory labelling	**Very low:** Not practicable to establish migration limits for the	**Very low:** Cost and resource requirements for industry and

	very broad range of different consumer products similar to what is already the case for some OT compounds in food contact materials. 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.	authorities to agree on safe maximum migration limits for each 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, the risks of which 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 DBT compounds in all consumer products and of DOT compounds in specific consumer products (PVC T-shirts, PVC gloves, PVC sandals, female hygiene products, nappies, RTV-2 silicon moulds)	**High:** By prohibiting the use of DBT compounds with their more severe hazard profile in all consumer products, and the use of DOT compounds in specific products, which according to the RAR contribute significantly to exposure, this measure is likely to be effective, in reducing consumer exposure to acceptable levels (< than TDI).	**Average to High:** No significant costs are expected for industry due to the existence of alternatives of comparative cost and technical feasibility for most applications. However, for certain applications of DBT compounds no alternatives are currently available, and time limited derogations need to be foreseen. For DOT compounds, the list of banned applications may need to be updated at intervals, if use of DOT is observed in new products.
Ban of the use of DOT and DBT compounds as	**Average:** This measure would be effective in reducing the	**Average:** Due to availability of alternatives for OTs in most

stabilisers in all consumer products made of plasticised PVC	contribution to the overall exposure considering that several placticised PVC articles contribute overall >100% of the consumer TDI. However, no distinction would be made between the more hazardous DBT compounds and DOT compounds.	plasticised PVC applications and the fact that industry is already reducing OT use for such products, such a restriction on the use of OTs can be implemented without significant costs. It is, however, possible that some companies, in particular SMEs, would incur significant costs as a result of this measure unless an appropriate transition time is foreseen. An exception from a ban will be necessary for coil and steel coating.
Ban of the use of DBT and DOT compounds as stabilisers in all consumer products made of rigid PVC	**Low to Average:** A total ban on the use of DBT and DOT compounds 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. Furthermore, no distinction would be made between the more hazardous DBT compounds and DOT compounds.	**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 compounds in all consumer products	**High:** It would provide the best possible guarantee of reducing the overall exposure to these organotins and their contribution to the TDI. However, no distinction would be made between the more hazardous DBT compounds and DOT compounds.	**Low:** Significant adverse impact on the industry, in particular for SMEs in the area of producing and transforming PVC and those producing silicon based adhesives and sealants using OT catalysts.

5. CONCLUSION

In order to reduce the exposure of consumers to organotin compounds to levels below the TDI while at the same time limiting the costs, a combination of the options that are highly effective and highly efficient is the preferred solution. This would be a combination of options 4 and 5, which means a prohibition of the placing on the marketing and use of: tri-substituted

organotins (including TBT and TPT compounds) in all articles; of DBT compounds in all consumer articles with a number of time-limited exemptions to allow for the development of alternatives; and of DOT compounds in a range of specific consumer articles with a potential for high exposure, which include printed T-Shirts, gloves, sandals, female hygiene products, nappies and two-component silicon moulds.

Overall, the combination of options 4 and 5 would eliminate organotins from all significant sources of exposure to both adults and children, 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. Furthermore, it would be ensured that DBT compounds with their more serious hazard profile will eventually be eliminated from all consumer articles.

Following recent consultation with other Commission services and Member States and in order to ensure the most efficient reduction of consumer exposure to DOT (as well as to avoid problems of legal misinterpretation in future) it is preferable to extent the scope of DOT restriction for "printed T-shirts" and "PVC sandals" to "textile articles intended to come in contact with the skin" and to "footwear or part of footwear intended to come in to contact with the skin" respectively, as the exposure scenarios would be comparable. In order to minimise exposure to children, DOT compounds should also be restricted in "childcare articles", given that their use in toys is already prohibited via the Toys Directive. No negative impacts on industry are expected from the widening of DOT restrictions as apparently the use of organotin compounds in these applications has already been phased-out. Therefore, the additional limitations will prevent any possible future re-introduction of such uses.

Considering the overall costs and benefits, this measure is proportionate. 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.

6. MONITORING AND EVALUATION

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 will ensure harmonised implementation within the internal market.

Member States have long-established mechanisms and have nominated authorities to monitor compliance with the restrictions of Directive 76/769/EEC. These same structures can be used under Regulation (EC) 1907/2006 to monitor compliance with the new restrictions of this proposal which will therefore not create a significant administrative burden. Furthermore, a Forum for Exchange of Information on Enforcement will be managed by the European Chemicals Agency and will coordinate a network of Member States authorities responsible for enforcement of this Regulation.