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EUROPEAN COMMISSION

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COMMISSION STAFF WORKING PAPER
SUMMARY OF THE IMPACT ASSESSMENT

Accompanying document to the

Proposal for a COMMISSION DECISION Amending Directive 76/769/EEC as regards the restrictions to the marketing and use of acrylamide for the purpose of adapting its Annex I to technical progress (amendment of Council Directive 76/769/EEC)

{C(2011) 2533 final}
{SEC(2011) 471 final}

Warning: This Commission staff working document has been prepared in order to accompany the Proposal for a Commission decision Amending Directive 76/769/EEC as regards the restrictions to the marketing and use of acrylamide for the purpose of adapting its Annex I to technical progress.

On 1 June 2009 Directive 76/769/EEC was repealed and replaced by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)¹. Therefore the draft Commission Decision amending Directive 76/769/EEC was replaced by the draft Commission Regulation amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Acrylamide). Reference to Directive 76/769/EEC should be read as reference to REACH.

¹ OJ L 396, 30.12.2006, p. 1.

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: 2007/ENTR/016

BACKGROUND

This impact assessment² accompanies the draft Commission Decision amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of acrylamide for the purpose of adapting its Annex I to technical progress.

Acrylamide is classified as carcinogenic category 2 and mutagenic category 2 under Directive 67/548/EEC, and as a consequence the substance is already restricted under Directive 76/769/EEC. In accordance with the provisions of Points 29 and 30 of Annex I to Directive 76/769/EEC, it is prohibited to place it on the market as a substance and in preparations for sale to the general public.

A risk assessment conducted by the UK within the framework of Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances, identified risks for human health and the environment from the use of acrylamide in grouts for small and large scale applications. The Risk Reduction Strategy, adopted in Commission Recommendation 2004/394/EC, proposed a restriction on the marketing and use of acrylamide in grouts.

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

On 22 November 2005 the Commission organised a consultative forum attended by industry, academics and Member States to discuss a variety of technical issues of relevance to possible risk management measures. Possible restrictions on the marketing and use of acrylamide have subsequently been discussed at several meetings 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. Most Member States consistently spoke in favour of a general ban on the use of acrylamide in grouting applications, whereas some industry representatives maintained that there were no suitable alternatives for certain applications or under extreme conditions. Despite repeated requests to industry and the Member States, no information on extreme conditions that may justify derogations has been specified to the Commission so far, and the latest available information seems to confirm that there is no need for continued use of acrylamide in grouts. The proposed restrictions on acrylamide have been discussed with other Commission services, in particular with DG Environment and the European Chemicals Bureau of DG Joint Research Centre.

Other legislations such as the General Product Safety Directive³, the Worker protection legislation^{4,5,6} and Directives 67/548/EEC and 1999/45/EC on the classification,

² The full version in English is available at the website :

http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/studies/index_en.htm

³ OJ L 11, 15.01.2002, p.4.

packaging and labelling of dangerous substances and preparations, were also examined to avoid any legal overlap or contradictions.

2. PROBLEM DEFINITION AND OBJECTIVES OF THE POLICY INITIATIVE

In the conclusions of the comprehensive EU risk assessment under Regulation (EEC) No 793/93 for acrylamide, risks were identified for human health and the environment.

The particular problems to be solved are:

- Risks for human health: The risk assessment concluded that there are risks to workers and to humans exposed via the environment because of concerns for neurotoxicity, reproductive toxicity, mutagenicity and carcinogenicity as a consequence of exposure resulting from the use of acrylamide-based grouts in large scale construction applications.
- Risks for the environment: The risk assessment concluded that there are risks for the aquatic ecosystem as a consequence of exposure arising from the use of acrylamide-based grouts in construction applications, and to indirect exposure of other organisms through contaminated water from the same use.

The objective of the Proposal is to reduce or eliminate the identified risks.

It should be noted that the existing legislative framework (Directive 76/769/EEC in combination with Directive on General Product Safety and the Worker protection legislation) is considered sufficient to address the risks identified for consumers and workers.

3. RIGHT OF THE COMMISSION TO ACT

Council Directive 76/769/EEC 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. This cannot be achieved by leaving the responsibility to act solely to the Member States. As the problems identified for acrylamide can occur in all Member States, action at Community level is the most efficient and proportionate way to eliminate or reduce the identified risks. Article 95 of the Treaty is the appropriate legal base for the Proposal.

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

Different options to achieve the intended objectives have been analysed concerning the use of acrylamide in grouts. The selected options take into account the existing market situations for acrylamide for use as a grouting agent, and the latest information from

⁴ OJ L 183, 29.6.1989, p. 1.

⁵ OJ L 131, 5.5.1998, p. 11.

⁶ OJ L 158, 30.4.2004, p. 50.

industry and from the Member State competent authorities as available to the Commission at the time of writing this impact assessment report. These options consider in particular also the conclusions of the EU Risk Assessment and the related Risk Reduction Strategy published in the Official Journal of the EU.

Option	EFFECTIVENESS	EFFICIENCY
<u>No action</u>	Very low: Grouts containing acrylamide could still be used in EU, in particular for small-scale applications under extreme conditions. The potential risks for human health and the environment would not be reduced. Member States could adopt diverging rules, which could impact adversely the Internal Market.	Low: No extra costs for industry, but the objectives would not be achieved.
<u>Voluntary action</u>	Very low: Difficulties to set up a 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, in particular when considering the low quantities of acrylamide still used in grouts.
<u>Mandatory specified conditions for use</u>	Average: A decrease of risks can result due to a reduction of the potential for unsafe use. However, there will also be practical problems associated with divergent standards in the conditions of use adopted between Member States.	Low: Additional costs for local authorities (or other supervisory bodies) who would be required to define conditions of use and be responsible if problems arise. High administrative burden for companies and authorities to develop, and comply with specific conditions, which would be disproportionate in particular in the light of the low quantities of acrylamide potentially still used in grouts.
<u>Total ban on the use of acrylamide grouts</u>	High: Acrylamide-based grouts would no longer be available for use in the EU	High: Limited additional cost for those few remaining companies still

	and the associated risks to human health and the environment would be reliably eliminated.	using acrylamide grouts. Alternatives to acrylamide for grouting applications exist (even at lower costs). Low administrative burden for companies and authorities.
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5. CONCLUSION

The most effective and proportionate option would be a total ban of the placing on the market and use of acrylamide in grouts for all applications. This measure would be effective in eliminating the risks for human health and the environment; 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. Considering the overall costs and benefits, this measure is proportionate. There would be no impact on the EU budget.

6. MONITORING AND EVALUATION

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. 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.