EUROPEAN COMMISSION

Brussels, 14.4.2011
SEC(2011) 471 final

COMMISSION STAFF WORKING PAPER

IMPACT ASSESSMENT REPORT

Accompanying document to the

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 (acrylamide)

(amendment of Council Directive 76/769/EEC)

{C(2011) 2533 final}
{SEC(2011) 472 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On 1 June 2009 Directive 76/769/EEC was repealed and replaced by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation,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: Environment; AGRI, ENV, SANCO, JRC, EMPL, ECFIN, TRADE, JLS, MARKT, RTD, SJ, TREN, SG

Agenda planning or WP reference: 2007/ENTR/016

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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Note: This impact assessment has been sent to the Impact Assessment (IA) Board on 5 October 2007 which expressed its opinion on 9 November 2007 in written procedure.

This impact assessment has been revised – in particular in Section 2 (Problem Definition) and Section 6 (Analysis of impacts) – in order to take into account the comments in the opinion of the IA Board and the comments of the IA quality checklist received by DG Enterprise and Industry before the Board issued its opinion.

This Impact Assessment was a part of an interservice consultation, during which no changes have been requested.

The Bibliography included in Section 9 lists all documents that have been used in the preparation of this impact assessment. They are accessible either by internet or upon request from DG Enterprise and Industry.

BACKGROUND

This impact assessment presents the possible policy options and their comparative advantages and drawbacks that could be adopted to control the risks for human health and the environment from the use of acrylamide for specific applications that are concerned by the Proposal accompanied by the assessment (hereafter referred to as "the Proposal").

Acrylamide, (CAS No 79-06-01, EINECS No 201-173-7) was designated a priority substance for evaluation under Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances[2]. The total EU production figure of acrylamide is reported to be 80,000-100,000 tonnes/annum. The overwhelming majority of acrylamide is used by the chemical industry as an intermediate in the production of polyacrylamides for a number of various applications. About 80-90% of polyacrylamide is used in wastewater treatment, paper and pulp processing where the polymer is generally diluted to 0.05-0.5% w/w before use. Other uses include crude oil production, cosmetic additives (such as body lotion and shampoo), soil and sand stabilisation, and polyacrylamide gel electrophoresis. Acrylamide can be also used as a grouting agent to seal cracks against water penetration in tunnels, walls, sewers etc.

Acrylamide has been classified[3] as carcinogenic and mutagenic category 2, and as toxic to reproduction category 3. As a result of its category 2 classifications, sale of acrylamide to the general public as a substance, or in preparations at concentrations above 0.1% has been prohibited under Directive 76/769/EEC[4]. Only professional or industrial uses of acrylamide are therefore currently permitted.

The Member State Competent Authority designated to conduct the risk assessment (the UK Health & Safety Executive) identified risks for human health and the environment from the use of acrylamide in grouts for small and large scale applications[5]. The Risk Reduction Strategy subsequently developed for acrylamide proposed a restriction on its use in grouts and evaluated the effectiveness, practicality, economic impact and monitoring of the proposed measures. After discussions with the Member States, stakeholders and the Commission, marketing and use restrictions at Community level under Council Directive 76/769/EEC were agreed as the most efficient risk reduction measures. This decision was formalised through the adoption of Commission Recommendation 2004/394/EC[6].

The purpose of this impact assessment is to refine the above recommendations and to provide support for the legislative Proposal to implement the recommended measures.

Section 1: Procedural issues and consultation of interested parties

Possible risk management measures for acrylamide grouting applications have been discussed at a number of meetings.

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2 OJ L 84, 5.4.1993, p. 1

3 The classification of the substance is established by Commission Directive 2001/59/EC of 6 August, adapting to technical progress for the 28th time Council Directive 67/548/EEC (OJ L 225, 21.8.2001, p. 1).

4 OJ L 333, 4.12.97, p. 1

5 The Risk Assessment Report, as well as a summary thereof, can be found at: http://ecb.jrc.it/existing-substances/.

6 OJ L 144, 30.4.2004, p. 1

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. The discussions covered: (a) work practices in various types of grouting operations, (b) workers health protection and environmental exposure and (c) alternative grouting materials and their performance characteristics, especially under extreme conditions. Whereas the use of acrylamide in grouting operations was found to be no longer widespread in Europe, industry maintained that for certain extreme conditions there are still no suitable alternatives for acrylamide. It was agreed that industry should better define those extreme conditions, e.g. high water pressure, low temperature, presence of dissolved salts, and extreme pH, so that consideration could be given for possible derogations.

Acrylamide was subsequently discussed at several meetings (February, July and 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 industry representatives as well as by Member States. 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.

Several extreme conditions that would possibly require continued use of acrylamide in grouts could be: a water flow rate higher than 300 L/min, temperatures below 8°C, high salt concentration and pH etc. In particular, for the sealing of microcracks, acrylamide has been claimed to work much more effectively for technically demanding conditions such as the need for a speedy reaction or low porosity of the crack At each meeting of the LWG, industry and Member States were requested by the Commission to provide numerical values and the necessary justification for the parameters needed to define the extreme conditions for which derogations from a ban might be considered. The one Member State in which extreme salt conditions had initially been reported as an example of an extreme condition in which only acrylamide is effective, has since informed the LWG that this is no longer the case. No other information on extreme conditions has been received from Member States or industry.

Industry, however, has contested the conclusions of the Risk Assessment Report (RAR) concerning the risks to human health and has requested that the RAR be reopened to take into account additional data published in the period between completion of the RAR and May 2006. The UK Rapporteur agreed to evaluate the additional data and bring its conclusions to the attention of the Technical Committee on New and Existing Chemicals (TC NES), which is responsible for the implementation of the Regulation (EEC) No 793/93. In June 2007, following the UK's proposal, the TC NES took the decision not to reopen the RAR. The conclusions of the risk assessment and the risk reduction strategy therefore remained unchanged.

In July 2007, at a meeting of the LWG, several Member States again called for a proposal from the Commission for risk management measures under Directive 76/769/EEC concerning the use of acrylamide in grouting applications. The UK Rapporteur reported that industry has promised to provide further data on mutagenicity concerning threshold effects and the dose/response relationship which, if received by end of July, would then be forwarded for evaluation by the UK Consultative Committee on Mutagenicity on 4 October. However, it seems unlikely that the outcome of this evaluation will change the conclusion of the RAR concerning mutagenicity.

Other legislations such as the General Product Safety Directive (2001/95/EC)[7], and the Directives 67/548/EEC and 1999/45/EC on the classification, packaging and labelling of dangerous substances and preparations[8], were also examined to avoid any legal overlap or contradictions.

The proposed restrictions on acrylamide have been discussed with other Commission services, i.e. DG Environment and the European Chemicals Bureau of DG Joint Research Centre, to arrive at a general agreement for the measures in the Proposal.

Section 2: Problem definition

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. In particular, there is a risk of cancer to workers and exposure should be reduced as far as possible because it is not yet possible to establish a safe limit of exposure. There have also been incidents of contamination of drinking water supplies when grouts were not used correctly, which in turn can lead to exposure of humans.

- **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.

For particular groups of the population, the necessary risk reduction measures are already in place. Community legislation lays down minimum requirements for the protection of workers, such as Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[9] and individual Directives based thereon, in particular Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work[10], Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.[11] These are considered as appropriate and sufficient legislative instruments to eliminate and reduce the risks for workers due to acrylamide exposure. It should be noted that the Commission is currently in the process of establishing occupational exposure limits for acrylamide.

As a result of the classification of acrylamide as a carcinogen and mutagen, category 2, sale of acrylamide to the general public as a substance, or in preparations at concentrations above 0.1% has already been prohibited under Directive 76/769/EEC. Consequently, the existing

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7 OJ L 11, 15.01.2002, p.4.

8 Directives available at http://ec.europa.eu/enterprise/chemicals/legislation/markrestr/index_en.htm

9 OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

10 OJ L 131, 5.5.1998, p. 11.

11 OJ L 158, 30.4.2004, p. 50.

legislative framework (Directive 76/769/EEC in combination with Directive 2001/95/EC on General Product Safety) are considered sufficient to address the risks identified for consumers.

Commission Recommendation 2004/394/EC, therefore defines a strategy in order to limit the remaining risks: (a) for humans exposed via the environment resulting from the use of acrylamide-based grouts, (b) for the aquatic environment as consequence of exposure arising from the use of acrylamide-based grouts in construction applications. The Recommendation also states that in the light of the risk reduction strategy, there is no requirement for further testing or information regarding the terrestrial ecosystem.

The magnitude of the risk from the use of acrylamide grouts in the EU is at present very small due to a move to alternatives following bad publicity from incidents during construction of tunnels in Norway (1995-97) and Sweden (1992-97) and in anticipation of a ban at EU level. In 2000, acrylamide grouts, all imported, were estimated to represent less than 1% of the total EU market in grouts, and their use has since decreased further. In the two above-mentioned incidents, workers were exposed by vapour and skin absorption, and acrylamide was washed out of the cracks into which it was injected by high water flow rates before it could set and contaminated surrounding lakes and water bore holes.

The purpose of introducing a ban at the present time would therefore mainly be to prevent reintroduction of the use of acrylamide grouts rather than to reduce an existing risk. Grouts are used by a relatively small number of large civil engineering companies (e.g. about 10 in the UK, 14 in Germany) for large tunnelling projects, but also by a very much larger number of small and medium sized enterprises in all Member States for the repair of sewers, or to treat rising damp in buildings (e.g. 24 companies in the Netherlands). The potential for reintroduction of acrylamide grouts into the EU can be seen by comparison with the situation in the United States where use of acrylamide grouts is not restricted. The US consumption figures for 1989 were about 300 tons, worth about €3 million, which represented about 50% of all grouts used, most of it for sewer repair by smaller companies.

Section 3: Right of the Commission to act

Directive 76/769/EEC relates to restrictions on the marketing and use of certain dangerous substances and preparations and is a well-established instrument to control risks from dangerous substances and preparations. Acrylamide is classified as carcinogenic category 2 and mutagenic category 2 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 the Directive, it is prohibited to use it in substances and preparations placed on the market for sale to the general public. In addition the packaging of substances and preparations containing acrylamide must be marked legibly and indelibly “restricted to professional users”. The Proposal to amend this Directive to further restrict the placing on the market and use of acrylamide will eliminate the risks identified at Community level.

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.

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)[12]. 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.

The only alternative option under REACH would be the "authorisation" procedure. However, it will take several years before all necessary steps to make the substance subject to authorisation will be completed (e.g. establishment of the candidate list of substances of very high concern, selection of substances for inclusion into Annex XIV, setting of a date by which authorisation would have to be requested, conclusion of the authorisation procedure). It is also very unlikely that acrylamide would get the highest priority to be included into Annex XIV among the first batch of substances and it is therefore uncertain, if and when this would actually happen.

Section 4: Objectives

The objectives of the Proposal are to reduce the identified risks in order to achieve a high level of protection of human health and the environment and to establish harmonised rules throughout the EU to avoid barriers to intra-Community trade in products containing acrylamide.

The objectives of the Proposal are in particular:

- to control the risks for humans exposed via the environment resulting from the use of acrylamide-based grouts
- to control the risks for the aquatic environment as consequence of exposure arising from the use of acrylamide-based grouts in construction applications.

Section 5: Policy options

Different options to achieve the intended objectives are analysed below 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 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.

No action

This would mean that the status quo (i.e. no restrictions concerning the placing of the market and use of acrylamide-based grouts) could continue.

Voluntary action by industry

A voluntary commitment, such as the substitution of acrylamide by other substances would be made by producers, distributors and importers of grouts, who would subsequently implement the measures and monitor compliance with the commitment periodically. The commitment

[12] OJ L 396, 30.12.2006, p. 1.

could be recognised by the public authorities and the results achieved would have to be assessed at regular intervals.

Mandatory specific conditions for the use of acrylamide in grouts

The establishment of specific conditions for continued use of acrylamide in grouts such as restrictions to particular conditions would be an option to reduce the potential for the incorrect use of acrylamide and to control the risks for human health and the environment.

Ban on acrylamide in grouts

A ban of the placing on the market or use of acrylamide in grouts and for grouting applications would be established.

Section 6: Analysis of impacts

The analysis of the impacts of the various policy options has been conducted taking into consideration the efficiency and proportionality of the options to reduce the identified risks. Advantages and disadvantages have been examined for each option to support the legislator in making the most appropriate and science-based decisions.

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 bilateral contacts.

No action

Although the vast majority of acrylamide (>99%) is used in the EU in the production of polyalcrylamides it can also be used in the formulation of grouting agents (~0.1%). The use of acrylamide grouts has decreased significantly compared with the past and, if at all, they are now only used for extreme conditions. Acrylamide grouts are apparently no longer produced in the EU, but could still be imported. Acrylamide grouts are still used extensively in the United States, in particular for sewer repairs, because of their very rapid setting time.

Without regulatory action, it would still be possible for companies to produce or import acrylamide from outside the EU for use in grouting applications with the resulting risks to human health and the environment. There is no information available as to the current levels of such imports.

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 acrylamide, would create obstacles to the free movement of goods in the internal market.

Voluntary action by industry

According to the information received during the latest consultations, industry in the EU already use alternatives to acrylamide in grouts (such as sodium silicates, polyurethanes, cements etc.) for the majority of applications without any formal voluntary commitment, and consequently there is little or no incentive to set one up. Quite on the contrary, some companies producing acrylamide still seem to believe that further use of acrylamide in grouts is necessary and they would therefore not be interested in participating in a voluntary commitment aiming at phasing out the substance for such use.

A voluntary scheme might also involve the application of a certification system to ensure that acrylamide based grouts would only be used by certified users with sufficient practical experience to be aware of the potential problems which may arise. However, setting up such a 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 would create a significant administrative burden to companies, the relevant industry associations but also to the monitoring authorities. Besides, the cost of implementing a certification system will be high, and may be disproportionately so for SME's but also in the light of the very low quantities of acrylamide that might still be used for grouts.

Mandatory specific conditions for the use of acrylamide in grouting applications

Establishing mandatory and suitably stringent conditions for use of acrylamide grouts should reduce the potential risks to the environment (and to human health) providing that those conditions are sufficiently targeted at the individual grouting scenarios, and are adequately supervised. Users would have to be well aware of these conditions and sufficiently qualified to respect them. It is unlikely that a single set of conditions would be suitable for the whole EU as grouting scenarios will vary considerably across regions according to local conditions (e.g hydrology and geology of the areas). Action would be required at regional and national level with good communication between all parties.

The successful implementation of locally tailored specified conditions would rely on a system controlled by numerous local supervisory bodies, which, in turn, may lead to inconsistency between Member States. Hence, the reduction in risk may not be consistent across the whole EU. Furthermore, complex interactions between hydrogeology, physical conditions (temperature, pH, etc.), and the environment more generally may mean that the supervisory bodies developing the conditions for use would bear a large amount of responsibility in ensuring that the conditions specified are sufficient. Obviously, this would be a difficult and burdensome task on large-scale projects where the geology (in particular) may not be very well known, for example, tunnels being dug through dolomite rock where the structure and soundness of the rock is not well known.

Overall, the costs and complications of setting up mandatory requirements for specific use conditions would entail burdensome administrative procedures with associated costs and would have to involve a large number of actors thus jeopardising the achievement of uniform results in terms of risk reductions. The cost, based on current practice in Germany, of training workers (14 day course) is estimated at 1500 €. The administrative cost of approval of a specific grout is estimated at 10.000 €, renewable after 5 years for 5000 €, with testing costs to the manufacturer of 5000 €. Assuming that there would be 1000 companies in the EU using grouts, with on average 5 employees, total training costs would be 7.500.000 € per year. Assuming that there would be 10 manufacturers or importers, each producing 5 grouts, this would mean a total of 10.250.000 € for first registration and 1.000.000 € per year for renewal (5.000.000 in 5 years). These costs seem disproportionate in the light of the low quantities of acrylamide potentially still used in grouts.

Total ban of acrylamide in grouting applications

As stated in the risk assessment report (RAR), the one known producer of acrylamide-based grouts in the EU stopped production at the end of 1997 and has no plans to restart production. The vast majority of European producers and importers of acrylamide into Europe no longer

supply acrylamide for use in grouting applications. Most user companies have also moved to alternatives already. Furthermore, a review of literature has indicated that, there is already a wide range of grouts based on other substances (of comparable or even lower cost) which have been used as substitutes for acrylamide grouts. The most important ones are: (a) polyurethanes (particularly water-reactive polyurethanes) for use in sewer and manhole repairs; and (b) cements, microcements and silicates for use in the construction industry (including tunnels, dams, soil stabilisation, etc.).

As stated in the RPA (2000) report[13], silicate, cement and microcement-based grouts are less expensive than acrylamide grouts. However, the cost of the grouting product represents only part of the cost of the grouting operation. Acrylamide gouts have the advantage of setting rapidly which means the operation can be completed rapidly thereby minimising the contractors labour costs and the amount of water pumping required, which is why acrylamide was used extensively in the past despite the availability of cheaper alternatives. The additional labour costs associated with the use of alternatives increases the overall total cost of the grouting operation. Moreover, if the alternatives are less effective, repairs may have to be carried out at more frequent intervals, although this would be a cost to the owner of the infrastructure, not to the contractor, who would actually benefit from more work becoming available. Since the Swedish and Norwegian incidents, large civil engineering project have specified that acrylamide should not be used, or that it is used only under strictly controlled conditions. In such cases, tendering contractors will pass on the additional costs in their quotations.

Overall total costs associated with a ban on acrylamide and NMA (n-methyloacrylamide) grouts were estimated at approximately £5 million (€ 8 million) per year. The value has been calculated on the basis of estimated sales volume of acrylamide grouts in the EU multiplied by the additional costs to move to alternative polyurethane grouts. This calculation is actually based on a figure from the US EPA ($16.11 incremental $/mixed gallon of grout, equivalent to £10 or €16 Euros) mainly due to additional equipment and training costs. It should be also noted that some workers productivity may also be lost when using certain types of polyurethane grouts, accounting for an additional loss of 160.000 € per year. However, it was noted that these figures could well be an over-estimate as they were based on usage at the time of the incidents at Hallandsås in Sweden and Romeriksporten in Norway and consultation has indicated that there had already subsequently been a move away from these grouts. These cost estimates also have to be compared to the potential benefits of avoiding incidents such as that at Hallandsås, where the total financial value of claims paid out was SEK 26 million (£1.9 million or €3 million). This excludes the environmental and ecological costs associated with the incident, however, and so underestimates the total damages caused.

Furthermore, as compared to the situation in the year 2000, the majority of companies have already moved to alternatives and do not sell these products in the EU market anymore, the introduction of a total ban on the marketing and use of acrylamide grouts today is not expected to cause significant additional costs to companies. Furthermore, this option would ensure that no imported grouts containing acrylamide 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. As the use and trade in acrylamide in the EU has been very low for a number of years, the impact on trade

[13] RPA report (2000): Risk Reduction Strategy and Analysis of Advantages and Drawbacks for Acrylamide (http://www.defra.gov.uk/environment/chemicals/pdf/acrylamide_rrs.pdf)

with third countries will be negligible. In any case, the proposal will also be notified to the WTO under the TBT agreement, which will give 3rd countries the possibility to comment.

For regulatory purpose a limit value of 0.1% of acrylamide 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 7: Comparing the options

OPTION	**Effectiveness**	**Efficiency**
No action	**Very low:** Grouts containing acrylamide would 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.
Voluntary action	**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.
Mandatory specified conditions for use	**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.

Total ban on the use of acrylamide grouts	**High:** Acrylamide-based grouts would no longer be available for use in the EU and the associated risks to human health and the environment would be reliably eliminated.	**High:** Limited additional cost for those few remaining companies still using acrylamide grouts. Alternatives to acrylamide for grouting applications exist (even at lower costs). Low administrative burden for companies and authorities.

In 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. There would be no impact on the EU budget.

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 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.

Section 9: References

– EU Risk Assessment Report on acrylamide Published on 2002; http://ecb.jrc.it/existing-chemicals/

– Commission recommendation of 29 April 2004 (L144/72) on the risk reduction strategies for various substances (including Acrylamide).

– Risk Reduction Strategy and Analysis of Advantages and Drawbacks for Acrylamide. Prepared for the Department of the Environment, Transport and the Regions of UK. (http://www.defra.gov.uk/environment/chemicals/pdf/acrylamide_rrs.pdf)