



REACH REGULATION PUBLIC INTERNET CONSULTATION

A - Contact details

(Please enter your contact details)

Name: Dr Mike Jeffs
Organisation: ISOPA (European Diisocyanate and Polyol Producers Association)
Address: Av. E. Van Nieuwenhuysse Laan 4
Post/zip code: 1160
City/Town: Brussels
Country: Belgium
Telephone: 02 676 7476
Fax: 02 676 7479
E-mail: mike.jeffs@isopa.org

B - Confidentiality

- I would like my identity to be kept confidential**
(please leave this box blank if you agree that your name and organisation will be identified on the Commission's website for public access)

C - SME

- Are you a small or medium sized enterprise?** ([EC legal definition](#))
please specify the number of members:

D - Description of your primary activities

(please select only one of the following)

Industry

- Manufacturer**
 Importer
 Downstream user
 Distributor
 Trade association
 Other

NGO

- Environmental group**
 Animal welfare group
 Trade union
 Consumer organisation
 Other



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Public authorities

- EU Member State government
- Other national government
- International organisation
- National or regional authority

Other

- Academic or technical institute
- Worker in chemicals or downstream industry
- EU citizen
- Other

Please structure your response according to the following topic areas and provide comments or proposals for amendments to the legislation. Please comment on those topics that are relevant to you.

**When finished, please send your document to the following address:
entr-env-ec-reach@cec.eu.int.**

Thank you in advance for your contribution.

SHORT INTRODUCTION TO ISOPA AND THE POLYURETHANES INDUSTRY

The members of ISOPA manufacture aromatic diisocyanates and polyols in the European Union. Because of their versatile chemistry, these substances and polymers are extensively used throughout industry to make polyurethane-based products for a wide range of everyday applications. The products include energy saving rigid insulating foams, flexible foams providing comfort, high performance elastomers, adhesives and binders for numerous applications and coatings for enhancing the life-times of other materials. The main application sectors dependent on these products are the cold food chain including refrigerators and freezers, building and construction, furniture and bedding, cars/buses/trucks and footwear.

Through the supply chain originating with diisocyanates and polyols, these sectors employ about 750,000 in the EU and generate €105 billion in market value. All the actors in the supply chain operate in a highly competitive market with many non-EU enterprises. More than 95% of the downstream enterprises are SMEs.

ISOPA is an affiliate of Cefic and its members of ISOPA are BASF, Bayer, Dow, Huntsman, Repsol and Shell.

E - Topics:

1. Duty of care &
2. Chemical safety assessment

Volume 1; Title II; Points 3 and 4 (Duty of Care) – The requirement to prepare Chemical Safety Reports for all substances, irrespective of the tonnage or if the substance is subject to registration or not, is too far-reaching and will lead an impracticable system. For preparations the composition has to be disclosed because point 3 requires that all substances in a preparation have to be assessed by preparing a Chemical Safety Report. The details of the composition are important confidential information.



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To make the system practicable, the information flow through the supply chain should be managed by the use of Safety Data Sheets (SDSs). In case of preparations, only the components relevant for the safe use should be considered.

For sake of workability the duty of care principle, as set out in Point 3 should not be part of the regulation itself. It should rather be part of a preamble.

COMMENT CATEGORY – EFFICIENCY OF PROCEDURES

3. Information flow

Volume 1; Title III; Point 6; paragraph 2 (Information through the Supply Chain) – Prescribes that the information laid down in paragraph 1 should be communicated at the time of the first delivery of substances or preparations following the entry into force. That means that Chemical Safety Reports or short versions thereof have to be prepared before the new legislation enters into force. Only for point 4 is there a transitional period of one year (see point 117). This requirement will burden the industry as a whole, especially SMEs.

To make the new system workable, the information requirements should be restricted to the dissemination of SDSs.

COMMENT CATEGORY – EFFICIENCY OF PROCEDURES

Volume 1; Title XIII; Point 102 (Confidentiality) – The procedure of assessing which information will be classified as confidential is extremely bureaucratic and could prejudice commercial confidentiality. In the polyurethanes sector the knowledge in formulations (preparations) is of vital commercial importance to formulators, whether large multinationals or SMEs.

The identity of substances and their relative proportions should be deemed as confidential.

COMMENT CATEGORY – EFFICIENCY OF PROCEDURES

4. Registration procedure

Volume 1; Title IV; Chapter 2; Point 9 (f) (Registration) – there should be clarification to include the exemption of substances for application research in addition to the research categories already listed. For the chemical manufacturers and downstreamers in the polyurethane sector much of the innovation is in this category. This comment is also reflected under “other” referring to the definitions (Volume 1; Title1; Chapter 2; paragraph 24).

COMMENT CATEGORY – TECHNICAL SOUNDNESS

5. Polymers

Volume 1; Title IV; Chapter 3; Point 16 paragraph 2 (Registration) – The proposal to classify in accordance with the Dangerous Substances Directive (Directive 67/548/EEC) is not practical for several classes of polymers in the polyurethanes industry. This would require separation for registration of oligomeric fractions of low molecular weight (less than 1,000 Daltons) as substances. As a consequence, the prescribed method will lead to an over-classification of polymers and thus an unjustified stigmatisation.

ISOPA supports the Cefic position for the exemption of polymers.



COMMENT CATEGORY – SCIENTIFIC AND TECHNICAL SOUNDNESS/EFFICIENCY OF PROCEDURES

6. Intermediates

Volume 1; Title IV; Chapter 4; Point 18 (Registration) – Some manufacturers may only use an intermediate under the provisions of Points 18 and/or 18a whilst others may place the same intermediates on the market (substances). Provided that the activities of the former manufacturers remain as defined under Points 18 and 18a they should follow the registration requirements defined in those points and not the general requirements for the registration of substances.

COMMENT CATEGORY – EFFICIENCY OF PROCEDURES/OTHER

7. Data requirements

Volume 2; Annex I; Section 7 (Chemical Safety Report Format) – The Chemical Safety Report demands far-reaching descriptions of the whole processing chain of a substance. In most cases such knowledge is confidential business information.

To simplify the report it should be permitted to communicate safe exposure levels for a substance. For example, this could be done via a SDS. This would be more practicable and would reduce the workload for all actors in the supply chain.

See also comments on Duty of Care (Volume 1, Points 3 & 4) and General Provisions for Downstreamers (Volume 6; Annex XI).

COMMENT CATEGORY – EFFICIENCY OF PROCEDURES & SCIENTIFIC AND TECHNICAL SOUNDNESS

Volume 2; Annex IX; Section 1.3 (Structure-activity relationship) – SAR or QSAR (Quantified Structure Activity Relationship) is a well established and widely used methodology which can significantly reduce the requirement for animal testing and save costs and time for developing meaningful data. The text gives only grudging support for the use of this tool and imposes several conditions for its use.

It is proposed that there should be clarification of what would be acceptable in terms of adequate and reliable documentation.

COMMENT CATEGORY – EFFICIENCY OF PROCEDURES & SCIENTIFIC AND TECHNICAL SOUNDNESS

8. Data sharing/consortia formation

NO COMMENTS

9. Procedures for downstream users

Volume 6; Annex XI (General Provisions for Downstreamers) – The present proposal is unworkable because, in the polyurethanes industry, most downstream users are SMEs and, consequently, very few of them have the resources and capacity to prepare Chemical Safety Reports. A significant degree of resource will be required to compare and develop hazard scenarios and carry out a risk characterisation. For small users it will be uneconomic to continue many niche applications where the revenue does not justify the cost of the added controls and management. This will result in the loss of jobs; income to the EU and unfair competition from imported articles.



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Innovation will be stifled if a CSR is required for each and every new application.

This degree of detail would not add to the safety of the consumer.

A much simpler system is required to make the proposal workable, for example, the communication of safe exposure levels for a substance via a SDS.

PROCEDURES FOR DOWNSTREAM USERS – EFFICIENCY

10. Evaluation procedure

Volume 1; Title VII; Chapter 1; (Evaluation) – There is considerable concern in the industry with respect to the ability of member states to both cope with the quantity of evaluations and with their ability to carry out evaluations in a uniform manner across the EU. Experiences with the RAR process on a very limited number of substances have highlighted these concerns.

The evaluation should be undertaken by the central agency to ensure a uniform and fair process.

COMMENT CATEGORY – EFFICIENCY OF PROCEDURES

Volume 1; Title VII; Chapter 2; Point 38, paragraph 1(d) (Evaluation) – The aggregation of tonnage enables the evaluating authority to extend the information requirements for a substance. For a producer/importer of a substance in a low tonnage level this an economic uncertainty because he can be forced to fulfill the information requirements for high tonnage substance

COMMENT CATEGORY – EFFICIENCY OF PROCEDURES

11. Authorisation procedure

Volume 1; Title VIII; Chapter 1 and Volume 6; Appendix XIII (Authorisation) – Taking Point 44 (f) together with Point 47, there is the provision for member states, at any time in the future, to propose that a substance which falls outside the criteria for inclusion in Point 44 (a) to (e) may be brought into the Authorisation process. This provision is open to potential abuse by any Member State and would cause substantial uncertainty to and affect the competitiveness of industry.

Any change in Appendix XIII should be subject to a decision of the European Commission following a consultation process with all stakeholders. The Authorisation process should be run by the Central Agency.

COMMENT CATEGORY – EFFICIENCY OF PROCEDURES AND SCIENTIFIC SOUNDNESS

12. Restrictions procedure

NO COMMENTS

13. The Agency

NO COMMENTS



14. Other

Volume 1; Title I; Chapter 2; Point 2, paragraphs 11 to 13 (Definitions) – there needs to be clarification that a transport haulier is neither a downstream user, nor a distributor. Such hauliers act as carriers of chemicals for manufacturers or importers and should clearly not be subject to the provisions of REACH in their activities on behalf of others.

Idem; paragraph 14 – the definition of isolated intermediates transported restricts the number of recipient sites to two. There is no rationale for this restriction if an intermediate is supplied under well controlled conditions. Therefore the restriction of the number of sites should be deleted.

Idem; paragraph 20 – the definition of phase-in substances is very narrow and restricts the phase-in status to those substances that a company has imported and produced in quantities above 1 ton in the time period 10 years preceding the entry into force of the regulation. To ensure a compliant transition to the new legislation, especially for SMEs, the transitional provisions laid down in Point 22 should apply to all substances listed in EINECS/ELINCS and to the No Longer Polymer (NLP) list plus other ‘substances’ recognised as NLPs.

Idem: paragraph 24 – the definition of scientific research and development should include application research and development (see comment on Point 9(f)).

COMMENT CATEGORY – EFFICIENCY OF PROCEDURES

Volume 1; Title X (Articles) – Points 63 and 64 are not well developed. There are millions of articles produced in the EU and/or imported into the EU and several thousand of these are based on polyurethanes. The proposal contains a requirement on producers and importers to notify substances which are emitted and could have an adverse effect on health or the environment. A large proportion of these actors will not have the capability to manage the issues nor is there capacity in EU laboratories to carry out the necessary tests. Guidance from the Agency is promised at least three months before the application of the provisions but this time limit is far too short given the comments above. The application of the provisions of this Title has to be delayed for at least three years after elucidation of the guidance for the necessary information to be developed.

Furthermore, an importer would be allowed to import an article into the EU which was made with substances whose use in the EU has been excluded by the Authorisation process. This is unfair competition to EU producers

COMMENT CATEGORY – EFFICIENCY OF PROCEDURES