

JBCE Position Paper on Draft REACH Regulation

As an association of Japanese companies, which manufacture in, and export to, the EU chemical substances as well as technology oriented equipment containing a wide variety of chemicals, the Japan Business Council in Europe (JBCE) welcomes the opportunity to submit comments on the European Commission's draft proposal for a Regulation on the Registration, Evaluation, Authorization and Restrictions of Chemicals of May 7, 2003 (draft REACH Regulation).

JBCE shares the European Commission's goal of improving the EU's chemical regulatory policy and the health and safety of EU citizens and the environment. We believe, however, that the future EU chemical regulatory framework should be based on an adequate sustainable balance between environmental and health objectives and other society interests, and thus be practical, workable, realistic, and in compliance with the law of the EU and its international obligations.

JBCE therefore wishes to make the following comments on the draft REACH Regulation, intended to assist the Commission in the preparation of its formal proposal to the Council and the Parliament. JBCE looks forward to continuing its active participation in a constructive dialogue with the Commission and other stakeholders.

I. Scope

Substances in Articles. -- **The registration requirements of the REACH Regulation should apply to substances in articles only if they are intended to be released during normal use of the article.** Subjecting all substances in articles to the requirements of the REACH regime on the basis of broad and vague criteria of potential release during normal use and disposal would impose an enormous administrative and testing burden on manufacturers of articles around the world. Manufacturers of articles are responsible for marketing only articles that are safe to the users, as laid down in horizontal legislation such as the General Product Safety directive and other product specific directives. In addition, horizontal and industry specific waste EU legislation already requires that waste from articles be adequately treated and disposed. Thus, registration requirements for substances in articles should be limited to those substances intended to be released during normal use of the article. This approach would contribute to ensuring the workability of the system as well as avoiding unnecessary trade disputes.

Substances in Preparations Regulated by Specific EU legislation. -- **The scope of the REACH Regulation should not include substances in preparations that are already regulated by specific EU legislation.** As the draft REACH Regulation acknowledges, there is EU sector-specific legislation, such as the Cosmetics Directive, regulating the risks of substances and preparations. Sector-specific legislation, by taking into account the specific characteristics of the relevant industries, provides more effective regulation than horizontal legislation. Thus,

where new regulatory measures are necessary for the protection of human health or the environment, these should be introduced by amending and extending the scope of vertical sector-specific legislation and not by integrating the specific sector in broad horizontal legislation, such as the draft REACH Regulation.

II. Duty of Care

Requirements of Chemical Safety Assessment and Chemical Safety Report. -- **The requirement to perform a Chemical Safety Assessment and perform a Chemical Safety Report should be limited to more practical levels.** It would clearly be disproportionate and too burdensome to require all actors in the supply chain to perform a Chemical Safety Assessment and to draft a Chemical Safety Report for every single chemical substance they manufacture, import or use, regardless of the substance's characteristics and quantity. Thus, the requirement to perform a chemical safety assessment should be limited to substances that are subject to registration. In addition, the requirement to supply information through the supply chain should be limited to that of existing safety data sheets.

The REACH Regulation should also clarify that no chemical safety assessment and no chemical safety report is required for the use of substances in articles if the substance is not intended to be released.

III. International Aspects

Acceptance of Testing Data Obtained Outside the EU. -- **Testing data obtained outside the EU and on the basis of methods other than those of the REACH Regulation should be accepted as largely as possible.** JBCE welcomes the Commission's intention, as stated in Annex IX, to accept test data obtained by methods other than those described in Annex X. Data obtained outside the EU and on the basis of methods other than those of the REACH Regulation should be accepted in order to avoid unnecessary testing, including animal testing, and unnecessary obstacles to trade.

Harmonization of Definition of PBT Substances. -- **The definition of PBT substances should follow existing international standards.** The definition of PBT substances contained in the draft REACH Regulation is not compatible with the internationally recognized definition included in Annex D of the Convention on Persistent Organic Pollutants. The REACH Regulation should incorporate the latter definition in order to avoid misunderstanding of the REACH regime and avoid unnecessary restrictions of trade.

Non-discriminatory Treatment Against Foreign Downstream Users. -- **The REACH Regulation should not discriminate between foreign and EU based downstream users.** The draft REACH Regulation defines downstream users, which may benefit from less stringent requirements if an actor up the supply chain has registered or obtained authorization for the chemicals they use, as persons "*established within the Community* other than the manufacturer or the importer." Thus, importers of chemical downstream uses in the form of preparations (e.g.

foods, cosmetics, personal care products) are not treated as downstream users but as importers of chemicals in preparations that are subject to full registration and authorization requirements (unless the suppliers of the substances they used in manufacturing their products obtained EU registration or authorization, which in many instances will not be the case). Such discrimination against foreign downstream users is not justified in particular when the European Chemicals Agency has already obtained data on the substances used.

IV. Data Sharing and Avoidance of Potential Supply Monopoly

The registration and authorization procedures should not be the basis for *de facto* restrictive practices and monopolies against downstream users or later registrants and authorization applicants. JBCE welcomes the draft REACH Regulation's objective of avoiding the shifting of responsibility for chemical assessments to downstream users, who are not well equipped for such exercise. There is a risk, however, that the proposed regime will create *de facto* supply monopolies and restrictions for certain substances or preparations, or specific applications thereof (since not all current suppliers will be able to support all substances and all uses of these substances). To limit this risk, costs on testing should be shared on the basis of the quantities imported, produced or used. Similarly, first registrants and authorization holders should always be required to grant letters of access for data on the basis of reasonable costs sharing and not on the basis of fixed fees that may result in a barrier to market access.

V. Confidentiality

The REACH Regulation should ensure the confidentiality of all sensitive business information. The REACH requirements on duty of care, registration, authorization, restrictions, classification, data sharing and public information should ensure that neither competitors nor the public may obtain secret information, such as details on product formulations, other secret know how, identification of suppliers or customers, and production and marketing volumes. In particular, the link between registrants/authorization holders, substances, and specific uses should never be disclosed to the public or to third parties.

VI. Need for Clearer Definitions and Terms

The REACH Regulation should ensure legal certainty by using clearly defined and unambiguous terms. Throughout its entire text, the draft REACH Regulation uses broad and undefined terms that do not provide clear guidance to chemical manufacturers, importers and downstream users of their rights and obligations under the proposed regime. Thus, for example, point 21 requires registrants to inform the Agency of "significant" changes in quantities produced or imported by them. Similarly, point 38 allows national authorities to evaluate a substance with a view to examining any information of the registration and "any other relevant information." Also point 64 requires the registration of substances in articles if they are released in "sufficiently high" amounts. The REACH Regulation should avoid as far as possible the use of ambiguous terms, which fail to provide legal certainty to all interested parties.