

**RESPONSE FROM THE EUROPEAN COMMUNITIES TO COMMENTS SUBMITTED BY
WTO MEMBERS UNDER G/TBT/N/EEC/52**

**(REGULATION CONCERNING THE REGISTRATION, EVALUATION AND AUTHORISATION
OF CHEMICALS (KNOWN AS REACH – COM((2003) 644 FINAL)**

INTRODUCTION

The European Communities thanks all those who have submitted comments individually or collectively on its draft Regulation concerning the registration, evaluation and authorisation of chemicals (known as the REACH regulation) notified under the TBT Agreement on 21 January 2004 (notification G/TBT/N/EEC/52).

This document provides the comprehensive response of the European Communities to comments submitted by WTO members and others. For the sake of clarity and precision, comments have been regrouped by subject matter.

It should be noted that this notification concerns a proposal by the European Commission that is still under discussion in the other European Community Institutions, that is, the European Parliament and Council of Ministers. It is therefore still subject to modifications and may still develop as a result of those discussions. This process also provides the European Communities with an opportunity to take into account the comments received in the context of the abovementioned notification. WTO members will be informed about major amendments to the proposal.

The European Communities recalls that the initial deadline for comments had been set 90 days from the date of notification. Following requests from some WTO members, the Commission subsequently extended the period for comments to 21 June 2004 (i.e. 150 days).

Comments have been issued by the USA, Japan, Canada, China, Brazil, Australia, Chile, Singapore, Taiwan, Thailand, Cuba, American Chemistry Council (ACC) and the Asia-Pacific Economic Co-operation Chemical Dialogue (APEC). On 30 June a series of bilateral meetings were held in Geneva between the Commission and some of the countries and organisations that have commented.

The European Communities is pleased to note that most respondents have recognised the importance of ensuring a high level of protection for human health and the environment from exposure to chemicals. A key objective of REACH is to improve the level of health and environmental protection by requiring more information on the hazards of chemicals used in the European Union, so that industry can better assess their risks, and take the necessary action to manage those risks. Indeed most responding WTO Members have implemented national or international legislation to achieve similar ends. Most respondents also recognise that regulatory action needs to be continually developed and updated in response to technological and scientific developments and pressure from society to improve standards of living and quality of life. This pressure to act is becoming greater as the use of chemicals grows.

The European Communities welcomes the dialogue that has developed with other WTO members on the REACH proposal. The European Communities has sought throughout the development of REACH to be as transparent as possible with its trading partners. In

May 2003, the European Commission published a draft legislative text on the internet and invited comments from all interested parties. Moreover, on the 20th May 2003, the European Communities communicated under article 2.9.1 of the TBT Agreement an early notice on documents concerning REACH, offering WTO Members the opportunity to become acquainted with the system considered and to participate in the internet consultation (document G/TBT/W/208). This consultative exercise generated a great deal of interest and we received over 6000 distinct responses from all over the world. These comments resulted in significant changes to the proposal before it was adopted by the European Commission in October 2003. We are pleased that some respondents have acknowledged our transparency, and willingness to take into account comments.

Moreover, since the publication of the REACH proposal, the European Commission has had numerous bilateral contacts with several WTO members, and with ASEAN and APEC.

INTRODUCTORY COMMENTS

From the bilateral exchanges and the written comments received, it appears that a number of misunderstandings about the proposal still remain. The European Communities recognises that the REACH proposal is a very large and complex one and that it takes considerable effort and time for it to be properly understood. We have done our best to explain its provisions in bilateral meetings but we see that more still can be done to enhance the understanding of those who have submitted comments of the REACH proposal. As a first step, therefore, we attach as an annex to this response a detailed explanatory document [**Enclosure 1**] which contains flowcharts explaining the various processes to be introduced by the REACH proposal. In addition, the European Commission will present the REACH proposal to WTO Members in the context of the next meeting of the TBT Committee in Geneva on the fourth of November 2004. The European Communities hopes these initiatives will assist understanding and answer many of the highly detailed questions that have been posed.

As well as questions of understanding, we have received a large number of comments on the practical operation of the system. Many of these questions are also answered by the material attached to this reply, and this letter addresses the main concerns that have been raised. However, we believe that the more specific and detailed questions that have been annexed to some responses are best resolved in a technical dialogue with stakeholders on a bilateral basis.

The European Commission has already recognised the need for clear guidance for stakeholders to ensure consistent, cost-effective and smooth operation of the system, explaining the many flexible elements in REACH available to companies. It has therefore started a major programme of work to develop such guidance, in co-operation with stakeholders. The Commission intends that appropriate guidance will be available at the time each part of the REACH system comes into force.

MAIN ISSUES RAISED

Alleged discrimination

- **Article 6 and the issue of substances in articles**

Several comments focus on Article 6 of REACH, which aims at ensuring that risks to health and the environment from exposure to substances released from articles are addressed in an equivalent way to the risks that substances pose by themselves or in preparations. It is argued by some respondents that Article 6 is discriminatory against non-EU producers of articles that are imported into the European Union. For example, it is suggested that the treatment of substances in articles is not compliant with WTO obligations because the exemption in Article 6(5) would in effect apply only to substances registered by manufacturers or importers operating inside the EU. Some comments propose that the system for articles should be limited to a list of named substances.

The European Communities believes that article 6 is not discriminatory against non-EU producers of articles that are imported into the European Union. The aim is to make sure that risks to health and the environment that may arise from exposure to dangerous substances released from articles are addressed. EU producers of articles and importers of articles produced outside the EU have the same duties. Importers, by definition, import articles made by producers located outside the EU. These articles are made from substances which may have been sourced outside the EU, and which are therefore not submitted to registration requirements under REACH. These non-EU producers are untouched by any requirements of REACH in terms of production and use of these substances. An EU producer of an article, in contrast, may use substances that are either produced in the EU, or imported, but in both cases these substances will have been subjected to the REACH registration requirements. If anything, the obligations with regard to substances in imported articles are slightly easier than in the case of articles produced in the EU, as the importer of an article only has to consider substances classified as dangerous which may be released during use. It is also important to note that Article 6 only becomes applicable 11 years and 3 months after REACH comes into force, leaving ample time for manufacturers and importers to get acquainted with the system, including the guidance on Substances in Articles that will be developed.

The proposal to limit provisions to a list of named substances would be inconsistent with the principle of industry responsibility, and it would be difficult to identify the substances in advance. Care has been taken to limit the scope of Article 6 to dangerous substances that are intended to be released and to dangerous substances that the registrant knows (or is informed) are released incidental to the use of the article. Given the quantities of substances involved, this is a proportionate approach to controlling risk.

- **REACH for EU and non-EU manufacturers**

More generally, other respondents argue that REACH is discriminatory because it will be allegedly much more difficult for non-EU manufacturers to comply with REACH than for EU manufacturers. While the European Communities is planning extensive guidance material which can be used by EU and non-EU manufacturers alike, we do not agree that REACH is discriminatory against non-EU manufacturers. All WTO members have national legislation in place which non-national manufacturers must comply with, despite

difficulties which may arise from language and comprehension. Today, the EU already has in place a network of legislation on chemicals which require non-EU companies to ensure their chemicals are classified and labelled according to EU rules, are notified if they are new substances (including those substances released from articles) and comply with certain restrictions and prohibitions. Thus, non-EU manufacturers must already now provide a considerable amount of information to their EU importers to ensure they comply with EU rules on chemicals. Although REACH extends these requirements in some areas, the same principles will remain, and at the same time a greater coherence and transparency will be introduced into the EU's regulation of chemicals.

All REACH provisions equally apply to EU and non-EU-producers and the system is expected to affect equally EU and non-EU producers in a completely non-discriminatory way.

This is equally valid for those provisions relating to the confidentiality of information. In this connection, and to assist non-EU manufacturers who may be concerned about revealing certain confidential information to their importers, Article 6a of REACH allows non-EU manufacturers to appoint a representative (referred to as an “only representative”) established in the EU to handle information and register on their behalf, if they wish to do so. We believe this demonstrates our willingness to be sure that REACH is non-discriminatory, as non-EU manufacturers, like EU manufacturers, will not be required to reveal confidential information to their customers.

In conclusion, the European Communities believes that the REACH proposal is fully compatible with article 2.1 of the TBT Agreement according to which “*products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country*”.

- **The principle of least trade restrictiveness**

Many of the respondents argue that REACH is more trade restrictive than necessary.

The REACH system aims at ensuring a high level of protection of health and the environment by imposing thorough and wide-ranging requirements which go further than most existing national and international legislation on chemicals. The European Communities considers that these objectives are legitimate and that the REACH proposal does not constitute an unnecessary obstacle to trade, with a view to achieving the level of protection deemed appropriate. In this regard, it may be worth recalling that the WTO TBT Agreement recognises, in its preamble, “*that no country should be prevented from taking measures necessary to ensure the {...} protection of human, animal or plant life or health, of the environment {...} at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement*”. This principle was strongly reaffirmed by all WTO members in the Doha declaration (paragraph 6).

A number of the comments received relate to the overall workability and perceived administrative burden imposed by REACH. In particular, uncertainties are expressed about how certain details of the system might work in practice, and assumptions are

made about how heavy a burden this might be on industry and its effects on international trade. However, those comments do not contain any clear examples that the REACH proposal is not workable. Indeed, the Community considers that REACH will be less cumbersome than the existing fragmented legislative regime currently in place.

The European Communities would like to point out that in the preparation of the proposal, the issues of workability and proportionality were key concerns. The extended impact assessment carried out by the European Commission assesses the costs of REACH to industry, including importers, to be between €2.8 and 5.2 billion over 11-15 years. Given the high level of protection of health and the environment the proposal aims to achieve as indicated by the benefits, conservatively estimated €50 billion over 30 years for health effects alone, the European Communities believe that the envisaged system is proportionate and sustainable. Moreover, the European Commission is undertaking an extensive programme of work in its “interim strategy” to prepare for the introduction of REACH, including the development of guidance for industry and co-operation with stakeholders in strategic partnerships to test and establish the workability of REACH in practice. The most important partnership has been set up together with the European chemicals industry association (CEFIC) and provides for the testing of the REACH registration and evaluation procedures for 8 to 10 substances involving chemical companies and downstream users from European and non-European origin.

One of the most frequently expressed concerns is the proportionality of the impact of REACH on downstream users of chemicals, on international supply chains and therefore on world trade. The European Commission’s extended impact assessment already includes consideration of the indirect impact of REACH on downstream users as well as its direct cost to the chemical industry. Moreover, in light of the comments received from various sources, the European Commission is now engaged in a process of further impact assessment with stakeholders including representatives of third country manufacturers in Europe. The scope of the work includes further detailed analysis of the potential impact on downstream users and supply chains in global industries such as automobiles and electronics. This work includes analysis of effects on the global sourcing of chemical substances, components and articles. It will in particular focus on concerns raised about the likelihood and implications of the potential withdrawal from the market of substances due to REACH.

Concerns have been expressed by some respondents about the requirement for every manufacturer and importer to register a substance. In particular, concerns are raised about the potential for duplication of testing and risk assessments. However, this neglects the fact that registrations must be targeted at addressing the risks arising from the actual **uses** of a substance. Different registrants of the same substance may have different uses, different requirements for data and different chemical safety assessments. The data on these uses may well be confidential business information, hence the need for separate registrations. Nevertheless, there is an obligation on registrants to share hazard data derived from animal tests in order to avoid the duplication of animal testing. Furthermore registrants are encouraged to form consortia and to make joint registrations. However, this remains a commercial decision.

Some respondents have suggested a system of “one substance one registration” (OSOR). The benefits of such a system of mandatory sharing of non-animal test data and other core data are claimed to be lower costs for industry at the registration stage, a lower likelihood of duplicate testing and simpler handling of the subsequent single dossier. The

Commission is open to any changes to REACH which can reduce costs and bureaucracy while retaining its timetable, objectives and scope. However, the Commission has concerns about the workability of the OSOR proposal, particularly in relation to the compulsory requirement foreseen for industry consortia to agree core technical data.

A large number of comments have been made regarding the scope and operation of the authorisation system. While some comments do not really address WTO matters, the main thrust of the criticisms is that authorisation is disproportionate and unworkable.

A concern common to many respondents is that authorisation decisions are based on hazard rather than risk. In this context, Article 54(f)¹ is criticised as leading to uncertainty for importers.

In fact, although hazard is the basis on which the decision is made to subject substances to the authorisation system, the authorisations themselves (ie. whether or not to authorise uses) are decided strictly on the basis of a consideration of risk. Substances are not “banned” on the basis of their hazard. In cases where applicants cannot demonstrate that risk can adequately be controlled, the authorisation system also takes into account socio-economic factors and the feasibility of substitution. The possibility under article 54(f) to subject other substances, such as endocrine disruptors, to authorisation is appropriate, given the potential risk from these substances which are of “very high concern”, meaning that sufficient scientific information is available to establish their hazardous nature and implications. Proposals to include any such substance in the authorisation system will be subject to a careful, systematic scientific review and an agreement by all Member States.

In conclusion, the European Communities believes that the REACH proposal is compatible with article 2.2 of the TBT Agreement according to which “*Technical regulations shall not be more trade restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment of the legitimate objective would create*”.

- **Inconsistent application by EU Member States**

A further concern that has been raised is that EU Member States will not apply and enforce REACH consistently and that this will lead to uncertainty for importers and therefore to trade barriers.

In fact, several features of the Commission’s proposal contribute to assure consistent interpretation across the Community. First, the proposed legal instrument is a regulation, which is directly applicable in all Member States. Secondly, the future European Chemicals Agency would take decisions directly in some areas (e.g. Registration), while in other areas it would have powers to ensure consistent decision-making (e.g. Evaluation). Thirdly, the guidance referred to above will promote consistent

¹ substances, such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) and (e) and which are identified as causing serious and irreversible effects to humans or the environment which are equivalent to those of other substances listed in points (a) to (e) on a case-by-case basis in accordance with the procedure set out in Article 56.

interpretation of REACH. Fourthly, the Forum for Exchange of Information on Enforcement would also have a role to play in promoting consistency. And fifthly, stakeholders have numerous possibilities for appeal to the Agency and to the European Court of Justice in cases where they might feel that the regulation had not been consistently applied, as well as to Member State national courts, which have the possibility to request a preliminary ruling of the Court of Justice in accordance with Article 234 EC. In addition the Commission has the possibility to start infringement proceedings (ECT article 226).

As a result, one can reasonably conclude that REACH will significantly improve the consistency within the EU, and therefore facilitate trade flows, rather than the contrary.

- Other concerns raised

1. Compatibility with international efforts

Concerns have been raised that REACH is not compatible with international efforts to control chemicals, such as the International Council of Chemical Associations (ICCA) the High Production Volume (HPV) initiative and the Globally Harmonised System for classification and labelling (GHS), and indeed may even work against those initiatives.

The European Communities notes that the REACH proposal is complementary to ongoing international efforts, providing a significant input to some, making best use of the information made available in others, and avoiding duplication. Specifically, the REACH proposal does not negatively affect the OECD Screening Information Data Set (SIDS) programme and the USA's HPV programme. The proposal just requires registrants to demonstrate that they have the right to use studies that have been generated under these programmes, rather than simply submitting robust study summaries potentially copied from SIDS dossiers.

It has been erroneously suggested that REACH does not take account of existing analyses performed under other programmes or that quantitative structure activity relationships (QSARs) may not be used under REACH. REACH Annex I, section 0.4 specifically allows the use of available information from assessments carried out under other international and national programmes, and REACH Annex IX, section 1.3 sets out how QSARs may be used and their use is encouraged (article 12(1)).

A related concern is that data not generated by good laboratory practice (non-GLP data) will not be accepted under REACH and that this will have a disproportionate effect on developing countries, which may not have GLP in place. In fact, REACH allows the use of non-GLP data in certain circumstances (see Annex IX, section 1.1 of the proposal). Furthermore, there is no requirement for all data to be generated from EU laboratories.

In the view of the European Communities, REACH is fully compatible with the EU's current classification and labelling system, which is largely untouched by the REACH proposal, and GHS. In fact, the European Commission is preparing complementary proposals for the implementation in the Community of the GHS alongside REACH.

2. Effects on innovation

Concerns have been raised that REACH will be bad for innovation. While noting that this particular aspect does not fall under the competence and remit of the WTO and is therefore not subject to its rules, the European Communities would wish to take this opportunity to provide some brief comments. The European Communities considers that REACH could potentially affect innovation in a number of ways, both positive and negative, as noted in the extended impact assessment. The ongoing complementary work on impact assessment will look into this in more detail. Measures have been introduced into REACH which we believe will encourage innovation (e.g. Product and Process Orientated Research and Development exemptions from registration, removing the current distinction between new and existing substances, raising the tonnage thresholds for registration from 10 kg, currently in place for new substances, to 1 tonne). The reference to the European Inventory of Existing Commercial Chemical Substances (EINECS) in Article 3(20) ensures that the discrimination between new and existing substances is removed as soon as possible, since this is a current barrier to innovation.

3. Protection of confidential information

Concerns have also been raised that REACH would not provide adequate protection of confidential information submitted to the Agency. However, we believe that REACH does provide adequate protection of confidential information (Article 116) and finds the correct balance between the need to protect property rights and to allow access to information on health and environmental risks. Certain information will always be considered confidential, whereas information related to health and environmental risks will always be publicly available. All other information held by the Agency and Member State authorities may be requested and a decision on whether to release that information will be taken after consultation with the submitter of the information, in accordance with current EU rules.

4. Technical assistance and capacity building for developing countries

The European Communities recognises its obligations under Article 11.3 of the TBT Agreement to provide adequate assistance to allow developing countries to comply with legislation such as REACH. In addition to the provision of extensive guidance material (as mentioned above), we aim to do our best to help developing countries to familiarise themselves with REACH and comply with it. This will be achieved in part through technical assistance and capacity building but also through training and provision of information by the proposed Chemicals Agency.

CONCLUSION

In conclusion, the reactions and questions that have been posed are consistent with the comments that have already been made over the past years through various channels of communication such as the internet consultation. We have not detected any potential problems. The European Communities considers therefore that REACH is WTO-compatible.

Nevertheless, in addition to the preparation of guidance documents for EU and non-EU enterprises, the European Commission is willing to continue its efforts to explain the

REACH proposal to WTO members, and continue to pursue bilateral and multilateral dialogues with our trading partners.