WORLD TRADE ORGANIZATION

G/TBT/N/EEC/52/Add.3/Rev.1
9 February 2007

(07-0565)

Committee on Technical Barriers to Trade Original: English

NOTIFICATION

Revision

The following communication, dated 9 February 2007, is being circulated at the request of the Delegation of the European Communities.

Further to its communication of 17 August 2006 (G/TBT/N/EEC/52/Add.2), the European Communities would like to inform the members of the Committee that:

1. Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

and

2. Directive 2006/121/EC of the European Parliament and of the Council amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency

were adopted on 18 December 2006. Both texts were published in the Official Journal of the EU L 396 of 30 December 2006. The texts of the Regulation and of the Directive are available at:

http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2006:396:SOM:EN:HTML

The REACH Regulation 1907/2006 will enter into force on 1 June 2007. The Directive 2006/121/EC shall apply from 1 June 2008.

For further information on REACH please see also:
http://ec.europa.eu/enterprise/reach/index_en.htm and
http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

The Appendixes to this addendum contain a note concerning the further developments since the adoption of the Common Position adopted by the Council in June 2006.

The European Communities underlines again that at all stages of the procedure it has taken great care to ensure that the WTO rules are respected. In the final text there is no discrimination between EU producers and exporters sending substances or articles to the EU. In addition, the requirements have been designed to take into account the specific risks derived from substances and are the least burdensome measures that would achieve the objectives sought to protect human health and the environment.

REACH has been developed in a climate of transparency and consultation. Stakeholders had opportunities to express their views and an Internet consultation was held on the draft proposal. The EC has also had an open and constructive dialogue with 3rd country representatives on REACH.

APPENDIX 1

NOTE

MAIN CHANGES FROM COMMISSION PROPOSAL

SCOPE

It has been made clear that waste is exempted from the REACH requirements. In addition, it has also been explicitly confirmed that the Member States may also exempt substances used in the interests of defence. The Commission will review the scope of the regulation five years after entry into force.

A number of "natural substances" such as ores, ore concentrates, minerals and cement clinker are excluded from registration if they have not been chemically modified. In addition, the Commission will review the exemptions from registration contained in Annexes IV and V within 12 months after entry into force of REACH.

Changes have also been made to the definitions including that of existing substances ("phase-in substances"), to cover all substances listed in the European inventory of existing commercial chemical substances (EINECS), and a definition of alloys has been added. Tonnage for phase-in-substances will be calculated as a three-year average as long as they have been manufactured or imported for 3 consecutive years.

REGISTRATION

Substances on their own or in preparations

A number of modifications to the Commission Proposal have been introduced to improve the workability of REACH, whilst ensuring that enough information is generated by industry to allow a substance to be used safely and information to be made available to the authorities and downstream users.

In this context, to reduce the impact on producers or importers of small volumes of substances, particularly SMEs, the requirements for registration of substances in quantities of 1 to 10 tonnes have been changed. A prioritisation system has been introduced where, for non-phase-in substances and for phase-in substances of very high concern or phase-in substances that are potentially dangerous to health or the environment and are used in dispersive ways, a defined set of information (set out in Annex VII), along with any additional relevant information that is relevant and available, must be submitted. For other substances at this tonnage level, only a set of physicochemical information and any additional relevant information that is available must be submitted.

The information requirements for substances manufactured or imported in quantities of 10 to 100 tonnes have been reduced; the most significant change being the reproductive toxicity requirements. No significant changes to the information requirements for substances manufactured or imported in quantities of 100 tonnes or more have been introduced but the Commission will, within 18 months of entry into force, adopt criteria defining what constitutes adequate justification for omitting certain tests based on the exposure (waiving). In addition, the first registration deadline has also been extended to 3.5 years after entry into force.

REACH allows manufacturers and importers to benefit from extended registration deadlines if they pre-register their phase-in substances in 12 to 18 month after entry into force. To ensure substances of the highest concern are registered first, pre-registered substances manufactured or imported in volumes at or above 1000 tons; pre-registered substances classified as carcinogenic, mutagenic or

toxic for reproduction; and potential PBTs[1] and vPvBs[2], i.e. those classified as N:R50-53, manufactured or imported above 100 tonnes; are required within 3.5 years of entry into force. For other pre-registered substances, the obligation to register is staggered with further deadlines of 6 and 11 years after entry into force, which will ensure that chemical operators have sufficient time to adapt to the REACH requirements. For substances that are not pre-registered, the registration requirement applies as from one year after into force of the Regulation.

In addition, the use of 'use and exposure categories', in terms of generic exposure scenarios is specifically allowed, and the application of Good Laboratory Practice (GLP) has been limited to toxicological and eco-toxicological tests and analyses.

To reduce costs for industry and the authorities, registrants are required to jointly submit information on the hazards of a substance and its classification, and can, if they agree, also jointly submit the chemical safety report. In particular, this information must be submitted by one company (the lead registrant) on behalf of the others; the other registrants having to submit other information individually, such as their company details and their production volume. However, manufacturers and importers are allowed to opt out of the joint submission of registration dossiers if this would result in excessive cost, if they disagree with the lead registrant on the interpretation of information, or if disclosure of confidential information would cause substantial commercial damage. In addition, several changes have been made with a view to reducing animal testing to an absolute minimum necessary, including the quick implementation of new alternatives to animal tests.

Substances in articles

Substances that are intentionally released from articles will in principle be treated like all other substances and must be registered according to the periods of 3.5, 6 and 11 years that apply to substances on their own or in preparations. In addition, all substances of very high concern (on a list of candidate substances for authorisation that will be produced by the Agency) present in articles above a concentration limit of 0.1% weight by weight and present above 1 tonne per year must be notified to the European Chemicals Agency, except where exposure to humans and environment can be excluded throughout the life-cycle.

As a safety net, the Agency can require a registration of a substance in an article at any time when it considers that its release poses a risk to human health or the environment.

Finally, upon request by consumers, safety information should be provided for articles containing substances of very high concern, including as a minimum the name of the substance.

DATA SHARING

The rules on data sharing set out to reduce testing on vertebrate animals and to reduce costs to industry, have also been changed. Mandatory data sharing does not apply any more only to data from animal tests but also to data from non vertebrate animal studies that must be shared on the request of a potential registrant.

In addition, one pre-registration period of 12 to 18 months after the entry in force has been introduced, the amount of information to be submitted for the purposes of pre-registration has been reduced, more flexibility has been introduced in the functioning of the Substance Information Exchange Fora ("SIEF"), and a mechanism has been set up to make it easier for downstream users to find alternative suppliers that can pre-register their substances when their original suppliers have decided not to pre-

[1] Persistent Bioaccumulative and Toxic Substances.
[2] Very Persistent and very Bioaccumulative substances.

register.

INFORMATION IN THE SUPPLY CHAIN

The communication requirements of REACH have been clarified in that Safety Data Sheets are now required for substances that are PBTs[3] or vPvBs[4], and preparations containing them and has also clarified the duties of distributors.

DOWNSTREAM USERS

It has been clarified that downstream users can participate in SIEFs and that they can apply a system of brief general descriptions of uses to identify their uses to the supplier. In addition, an exemption from the obligation to have uses covered by a chemical safety report has been introduced for substances under 1 tonne per year.

EVALUATION

The Agency has been given a more central role than foreseen in the Commission proposal, in that responsibility for dossier evaluation, i.e. checking that registration dossiers are correct and whether further testing is necessary, has been transferred to the Agency while substance evaluation will be carried out by Member State competent authorities based on a single EU-wide rolling plan prepared by the Agency, with input from Member States. In addition, whilst assessing whether further testing is necessary, the Agency will also invite third parties to submit information that would avoid the need for vertebrate testing.

AUTHORISATION

A number of changes to authorisation have strengthened the incentive to substitute dangerous substances. It has been clarified that adequate control is not a sufficient ground for granting authorisations in the case of substances that are PBTs, vPvBs, including those that are identified as substances of equivalent concern, or where it is not possible to determine a safe threshold. Six years after the entry into force of the regulation, the Commission will review whether endocrine disrupters should also be excluded from the adequate control route.

To make the system more transparent and facilitate planning within industry, a list of substances eligible for being subject to an authorisation requirement ("candidate list") will be published by the Agency. Substances in the candidate list will be inserted in Annex XIV (i.e. substances for which an authorisation is required) on the basis of a recommendation from the Agency, taking into consideration comments from interested parties.

Applications for authorisations should always include an analysis of possible alternatives by the registrant. If this analysis shows that suitable alternatives are available then the application must also include a substitution plan. If not, information on relevant research and development activities must be provided, if appropriate.

Furthermore, the criteria to identify substances of equivalent concern, on a case-by-case basis, were also changed to require scientific evidence of a probable serious effect to human health or the environment. The European Commission will develop guidance to clarify the criteria in close co-operation with industry, Member States and other relevant stakeholders.

[3] Persistent, Bioaccumulative and Toxic substances.
[4] Very Persistent and very Bioaccumulative substances.

In setting the length of a review period, it has been clarified that the Commission will take into account relevant information, including the risks of the substance and of alternatives, socio-economic benefits, analysis of alternatives and any substitution plan. If suitable substitutes have become available by the time of the review, the Commission may amend or withdraw the authorisation, even one granted under the adequate control route.

RESTRICTIONS

A transitional period has been introduced to facilitate the transition from the national measures implementing the Community restrictions on the marketing and use of chemicals to the restrictions provisions of the REACH Regulation, which are directly applicable. In addition, it has been clarified that a substance that has been prohibited or restricted under Regulation (EC) n° 850/2004 on persistent organic pollutants (POPs) cannot be authorised under REACH.

EUROPEAN CHEMICALS AGENCY

As already mentioned above, the European Chemicals Agency will have a greater role to play in the evaluation of substances. In addition, a number of structural changes have been introduced, such as increased Member State representation on the Management Board and independent representatives nominated by the European Parliament.

CLASSICATION AND LABELLING INVENTORY

The types of substances that can be given EU harmonised classifications have been extended to include other substances justified on a case-by-case basis besides the substances that are already included, i.e. category 1, 2 and 3 CMRs and respiratory sensitisers.

ACCESS TO INFORMATION

The rules on access to information have been modified with a view to bringing its provisions in line with Regulation (EC) N° 1049/2001 regarding public access to European Parliament, Council and Commission documents. It provides that the detailed rules for access to information held by the Agency should be drawn up by the Agency's Management Board in accordance with the provisions of the Aarhus Convention and with Regulation (EC) No 1049/2001.

The Agency is required to publish non-confidential information on its website but allows industry to justify why some of the potentially non-confidential information should not be published.

OTHER ISSUES

REACH will enter into force on 1 June 2007 and the European Chemicals Agency will become operational 12 months later, in time for the first registrations of substances.

Workability, cost-effectiveness and a smooth operation of the REACH system is of key importance for the European institutions. Guidance material for manufactures and importers is currently being prepared with the participants from trading partners in stakeholder experts groups.

Up to date information will be available on the European Commission’s website and the help-desk of the new European Chemicals Agency will also provide relevant assistance. The Agency may also be asked to provide technical assistance to the developing countries concerned when appropriate.

APPENDIX 2

NOTE

MAIN CHANGES FROM COMMON POSITION

SCOPE

There have not been changes on the scope but the Commission will review the scope of the Regulation five years after entry into force. In addition, the definition for tonnage has been changed for phase-in-substances and it now will be calculated as a three-year average as long as they have been manufactured or imported for 3 consecutive years.

REGISTRATION

Substances on their own or in preparations

The first registration deadline has been extended to 3.5 years after entry into force. In addition, several changes have been made regarding the welfare of animals used in experiments, including the quick implementation of new alternatives to animal tests. A mechanism has been set up to help downstream users find alternative suppliers that are able to pre-register their substances where their original suppliers fail to do so.

Substances in articles

Information on safe use of articles containing substances of very high concern will be made available to consumers on request.

DATA SHARING

More flexibility has been introduced in the functioning of the SIEF (in particular, there is no deadline by which SIEF members must identify their information needs). In addition, it has been clarified that downstream users and other third parties that submit relevant information are SIEF members but that only potential registrants are entitled to request information. Finally, the period of data protection for studies and tests develop to meet the obligation under REACH has been extended to 12 years.

EVALUATION

When assessing whether further testing is necessary, the Agency will also invite third parties to submit information that would avoid the need for vertebrate testing.

AUTHORISATION

PBTs, vPvBs and substances of equivalent concern have been specifically excluded from the the adequate control route. Six years after the entry into force of the regulation, the Commission will review whether endocrine disrupters should also be excluded from the adequate control route.

If the applicant's analysis of alternatives shows that suitable alternatives are available then the application must also include a substitution plan. If not, information on relevant research and development activities must be provided, if appropriate.

In setting the length of a review periods, it has been clarified that the Commission will take into account relevant information, including the risks of the substance and of alternatives, socio-economic benefits, analysis of alternatives and any substitution plan.

If suitable substitutes have become available by the time of the review, the Commission may amend or withdraw the authorisation, even one granted under the adequate control route. In such cases the Commission will require the holder of the authorisation to present a substitution plan.

EUROPEAN CHEMICALS AGENCY

In addition, to the structural changes introduced in the Common Position the representation on the Management Board has been increased to include representatives of the European Parliament.