WORLD TRADE ORGANIZATION

G/TBT/N/EEC/52/Add.2
17 August 2006

(06-3943)

Committee on Technical Barriers to Trade Original: English

NOTIFICATION

Addendum

The following communication, dated 10 August 2006, is being circulated at the request of the Delegation of the European Communities.

The European Communities would like to inform the members of the Committee that the Common Position on the REACH proposal was adopted by the Council on 27 June 2006. The text of the Common Position is available at:

http://ec.europa.eu/enterprise/tbt/nview.cfm?p=EEC_52_EN.

For further information on REACH please see also:

http://ec.europa.eu/enterprise/reach/index_en.htm.

The Appendix to this addendum contains a note concerning the main changes in the Common Position regarding the Commission proposals.

The European Communities underlines that at all stages of the procedure, both in the initial proposal and in the advice to the Council, the European Commission has taken great care to ensure that the WTO rules are respected. In the Council's text there is no discrimination between EU producers and exporters sending substances or articles to the EU. In addition, the requirements take into account the need to address the risks from substances and are least burdensome taking into account the objectives sought to improve health and the environment.

REACH has been developed in a climate of transparency and consultation. The European Commission often met with stakeholders, and an Internet consultation was held on the draft proposal. The European Commission has had an open and constructive dialogue with third country representatives on REACH.

The view of the European Commission is that the Council's Common Position on REACH is WTO compatible but, of course, the European Commission will maintain its vigilance on this matter during the second reading.

APPENDIX

NOTE

Main changes in Common Position from Commission proposal

SCOPE

In its Common Position, the Council has made explicit some exemptions from the REACH requirements as a whole that the Commission had seen as implicit, i.e. for waste and, if the member States desire it, for substances used in the interests of defence. In addition, the exemptions relating to different Titles of REACH - Registration, Information in the Supply Chain, Downstream Users, Evaluation, Authorisations and Restrictions - have been consolidated in title I.

The Council also made changes 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 added a definition of alloys.

The Council also decided to exclude from registration a number of "natural substances" such as ores, ore concentrates, minerals and cement clinker. In addition, the Common Position requires the Commission to review the Registration exemptions, contained in Annexes IV and V, within 12 months after entry into force of REACH.

In addition, it is now possible for a manufacturer, importer or downstream user to appoint a third party to represent them in discussions with other companies for the purposes of registration and data-sharing.

REGISTRATION

Substances on their own or in preparations

The Council's Common Position has introduced a number of modifications to the Commission Proposal that is aimed at making the system more workable, 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 SMEs, the requirements for registration of substances in quantities of 1 to 10 tonnes have been changed by the Common Position. A prioritisation system has been introduced where, for non-phase-in substances, substances of very high concern, and 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 other available information must be submitted. For other substances at this tonnage level only a set of physicochemical information and any available information need to be submitted.

For substances manufactured or imported in quantities of 10 tonnes or more per manufacturer or importer and year, the Common Position now requires only one test for reproductive toxicity. The Common Position did not introduce significant changes to the information requirements for substances manufactured or imported in quantities of 100 tonnes or more but did require, within 18 months of entry into force, the Commission to adopt criteria defining what constitutes adequate justification for omitting certain tests based on the exposure (waiving).

To ensure substances of the highest concern were registered first the Council decided to require the registration of potential PBTs[1] and vPvBs[2], i.e. those classified as N:R50-53, manufactured or imported above 100 tonnes within three years of entry into force.

In addition to this the Common Position also now allows the use of 'use and exposure categories', in terms of generic exposure scenarios, and limits the application of Good Laboratory Practice (GLP) to toxicological and eco-toxicological tests and analyses.

To reduce costs for industry and the Authorities, the Common Position requires registrants 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. The information is submitted by one company on behalf of the others (the lead registrant); the other registrants have 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.

Substances in articles

In its Common Position the Council made a number of significant changes to the Commission's proposal.

Substances that are intentionally released from articles will in principle be treated like all other substances and registered according to the phase-in periods of 3, 6 and 11 years. 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 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.

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 in the Common Position. 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 or a member of a Substance Information Exchange Forum.

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 has been reduced and the workings of the SIEF have been clarified.

INFORMATION IN THE SUPPLY CHAIN

The Common Position has clarified the communication requirements of REACH in that Safety Data Sheets are now required for substances that are PBT and vPvB and preparations containing them and has clarified the duties of distributors.

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

DOWNSTREAM USERS

The Common Position has clarified that downstream users can participate in SIEFs, apply a system of brief general descriptions of uses (to be developed in guidance) to identify their uses to the supplier, and has added a threshold for this obligation of 1 tonne per substance per year.

EVALUATION

In the Common Position, the Council has given the Agency 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.

AUTHORIZATION

The agreement by the Council on authorisation strengthens the incentive to substitute dangerous substances. The Council decided that adequate control is not a sufficient ground for granting authorisations in the case of substances that are PBT, vPvB, or where it is not possible to determine a safe threshold. The Commission will review whether to include some other substances where it is possible to determine a threshold within 12 months of entry into force.

To make the system more transparent and facilitate planning within industry, a candidate list of substances meeting the authorisation criteria will be published by the Agency. The Agency will publish a list of substances meeting the criteria above and reflecting its multi-annual work plan, taking into consideration comments from interested parties. In addition, applications for authorisations should always include an analysis of possible alternatives by the registrant.

Furthermore, the criteria to identify substances of equivalent concern, on a case-by-case basis, were also changed so scientific evidence of a probable effect would be required. The European Commission will develop guidance to clarify the criteria in close co-operation with industry, member States and other relevant stakeholders.

RESTRICTIONS

The Council has included in its Common Position a transitional period after REACH comes into force to allow member States to update existing national legislation relating to current restrictions on the marketing and use of chemicals. In addition, the Common Position excludes persistent organic pollutants (POPs) from REACH, thus maintaining such POPs within the scope of Regulation (EC) n° 850/2004.

EUROPEAN CHEMICALS AGENCY

As already mentioned above, the European Chemicals Agency will have a greater role to play in evaluation of substances. In addition, the Common Position introduces a number of structural changes, such as increasing member State representation on the Management Board.

CLASSIFICATION AND LABELLING INVENTORY

The Common Position extends the EU harmonised classifications to also 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, respiratory sensitisers.

ACCESS TO INFORMATION

The Common Position modifies the rules on access to information 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 Common Position also requires the Agency 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.