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Council adopts its common position on new chemicals EU legislation - the REACH system

The Council, following its political agreement on 13 December 2005, adopted two common positions *(7524/06, 7525/06)* on:

– the draft regulation for the registration, evaluation, authorisation and restriction of chemicals (REACH), and establishing a European Chemicals Agency[1]

– the draft directive amending Council Directive 67/548/EEC[2] relating to the classification, packaging and labelling of dangerous substances, in order to adapt it to the draft regulation on REACH.

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1 On the basis of this proposal, a European Chemicals Agency is established for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of REACH and to ensure consistency at Community level in relation to these aspects.

2 OJ 196, 16.8.1967, p. 1–98

The common positions will be now forwarded to the European Parliament for a second reading under the codecision procedure.

The Community chemicals policy aims at avoiding chemical contamination of air, water, soil and the human environment in order to preserve biodiversity and to safeguard workers' and citizens' health and safety. This policy seeks to balance health and environmental benefits with the need to sustain a competitive, innovative and job-creating European industry and the proper functioning of the internal market.

In this context, the main objectives of the new REACH system are:

- To establish a coherent registration system designed to provide basic hazard and risk information on new and existing chemical substances manufactured in or imported into the EU;

- To reverse the burden of proof, moving it away from Member States' authorities to producing and importing companies, who will be responsible for demonstrating that substances can be used safely;

- To introduce responsibility for downstream users to provide information on uses and associated risk management measures relating to substances;

- To maintain the existing restriction system and to introduce an authorisation procedure for the most hazardous substances as a new instrument;

- To ensure greater transparency and openness for the public by providing easier access to relevant information on chemicals;

- To establish a European central entity (the Agency) to facilitate the administration of REACH and ensure that the system is applied in a harmonised way across the EU.

The text of the Commission's proposal has been extensively discussed by the Council before reaching agreement. The main key features of the Council's common position are:

1. Scope of application and substances concerned

REACH will apply to all substances manufactured or imported in quantities over 1 tonne per year. As the definition of a substance has a wide ranging scope, the Council has consolidated and clarified the scope of the Regulation as well as the scope of certain exemptions (e.g. for waste, substances used in foods or feeding stuffs and in certain cases for defence purposes).

The Council also made changes to the definition of existing substances ("phase-in substances") in order to cover all substances listed in the European inventory of existing commercial chemical substances (EINECS).

Furthermore, the Council did not amend the exemptions from registration for individual substances on which sufficient information is known and, because of their intrinsic properties, are not expected to be hazardous (with the sole exception of the addition of cellulose pulp). This list will however be reviewed by the Commission within 12 months after the entry into force of the Regulation.

The Council decided to exclude from registration a number of "natural substances" such as ores, ore concentrates, minerals and cement clinker. Concerning alloys and their definition as special preparations, the Council welcomes the Commission's intention to develop guidance, in close cooperation with Member States and stakeholders, on the assessment of special preparations.

2. Registration

Overall, the Council's common position is aimed at designing a workable system for registration while 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, the original provisions on multiple registrants for the same substance have been modified by the Council in order to include the main elements of the "one substance-one registration" proposal. Thus, the common position provides for all manufacturers or importers of the same substance to submit certain parts of the registration dossier jointly.

However, specific possibilities for opting out of this obligation have been introduced where there are differences of opinion between registrants on the selection of data, where joint submission would entail disproportionate costs and where it would lead to commercially sensitive information being exchanged.

To reduce the impact on SMEs, which has been one of the Council's main concerns, key elements of a proposal for targeted information requirements for low volume substances have been included in the Council's common position. Manufacturers or importers of low volume substances (1-10 tonnes) would only have to submit already available data with regard to these substances unless the substances were identified as meeting simple criteria highlighting them as of potential concern.

Regarding substances manufactured or imported in quantities of 10 tonnes or more per manufacturer or importer and year, it is proposed that only one test for reproductive toxicity would normally be required in addition to the information requested for low-volume substances of potential concern.

The Council decided not to introduce significant changes to additional standard information requirements for substances falling into the two categories manufactured or imported in quantities of 100 tonnes to 1000 tonnes and 1000 tonnes or more per manufacturer or importer per year, respectively. Within 18 months of entry into force, the Commission will adopt criteria defining what constitutes adequate justification for omitting certain tests based on the exposure scenario(s) developed in the Chemical Safety Report.

3. Substances in articles

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, producers and importers of articles will be obliged to notify to the Agency if substances meeting the criteria for authorisation are contained in their articles above a certain level and exposure to humans or the environment cannot be excluded throughout the life-cycle.

Where the Agency considers that there are grounds for suspecting that a substance is released from articles and that this release presents a risk to human health or the environment, it may require producers or importers of articles to submit a registration.

4. Information in the supply chain

The common position clarifies the role of distributors and downstream users in the supply chain, especially as regards how manufacturers, importers or downstream users should react to information on identified uses provided by distributors and/or downstream users. The common position also clarifies that downstream users can participate in a Substance Information Forum and the cases in which downstream users should conduct a Chemical Safety Assessment and prepare a Chemical Safety Report.

5. Evaluation

The Council decided to give the Agency a more central role than foreseen in the proposal in the evaluation phase of REACH under which registration dossiers will be examined and substances of potential concern identified for further examination. The aim is to ensure that evaluation is carried out more efficiently and consistently across the EU. At the same time, the Council considered that the core scientific work on evaluation of substances would still need to be done in Member States, which have the requisite expertise. Therefore under the terms of the common position, responsibility for dossier evaluation 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.

6. Authorisation

The agreement by the Council on authorisation rules aims to achieve a balance between the need of providing for strong incentives or even requirements to substitute dangerous substances and the impact on industry if excessive requirements for authorisation were to be adopted.

The Council decided that authorisations will be granted where the risks from the use of a substance are adequately controlled or where it is shown that the socio-economic benefits outweigh the risks to human health or the environment arising from the use of substances for which there are no suitable alternative substances or technologies available. At the same time, the common position provides that adequate control is not a sufficient ground for granting authorisations in the case of substances that are persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB).

For substances where it is not possible to determine safe thresholds with current methods, the proposal provides for a review within 12 months after entry into force of the regulation based on work in the REACH implementation projects (RIPs). In addition, it was agreed that applications for authorisations should always include an analysis of possible alternatives by the registrant.

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. Substances will be identified and placed on the list following a period of public consultation.

7. Restrictions

The Council has included in its common position a transition 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.

8. Information

The Council modified substantially rules on access to information with a view to bringing its provisions in line with Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents.

The common position 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 stipulates that the Agency will publish non-confidential information on the website, in order to facilitate registration, inter alia for SMEs.