Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 27/06/2006 - Council position

The Council adopted a common position on the proposal for a regulation concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), and establishing a European Chemicals Agency. The text of the proposal was revised extensively during discussions carried out by the Council over the last two years. During this process, there has been a substantial convergence of views between the Council and the European Parliament. Accordingly, the Council has integrated into the common position about 200 of the European Parliament’s amendments, either in full, in part or in principle.

Recitals:

The Common Position is in line with around 20 amendments by the European Parliament, which correspond to the approach taken in the legal provisions (Articles and Annexes).

In addition, it takes on board the spirit of certain amendments which aim to: introduce a “duty of care” for manufacturers, importers and downstream users (the amended Article 1 states that chemical substances shall not adversely affect human health or the environment); ensure the free circulation of goods while enhancing competitiveness and innovation; emphasise the need to pay special attention to small and medium-sized enterprises. A new recital underlines the need to take special account of the potential impact of REACH on SMEs and the need to avoid any discrimination against them.

Scope and definitions:

The common position reflects either in full, in principle or in part about 15 of the Parliament’s amendments. The Council has consolidated and clarified the scope of the regulation as well as clarified certain exemptions (e.g. for waste, substances used in foods or feedingstuffs and in certain cases in the interests of defence). Furthermore, the exemptions from registration for individual substances listed in Annex IV have not been amended (with the sole exception of the addition of cellulose pulp) but will be reviewed by the Commission, together with Annexes I and V, 12 months after entry into force of REACH. The categories of exemption from registration listed in Annex V have been amended, particularly in relation to natural substances such as ores, ore concentrates, minerals and cement clinker.

With regard to the amendment 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.

Registration:

The common position has integrated about 20 of the Parliament's amendments. With a view to including the main elements of the "one substance - one registration" (OSOR) proposal, the provisions on multiple registrants of the same substance have been amended. 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.

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 notify substances meeting the criteria for authorisation if they are contained in those articles above a certain level and if 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 take decisions requiring producers or importers of articles to submit a registration.

In relation to information to be submitted at registration, registrants should be able to apply use and exposure categories voluntarily. Quality assurance of the registration dossier on a voluntary basis by an assessor chosen by the registrant as having appropriate experience would be a possibility.

The information submitted depending on tonnage, must be as follows:

-Low volume phase-in substances (those manufactured or imported in quantities of between 1 and 10 tonnes per manufacturer or importer per year): where a phase-in substance in this tonnage range meets simple criteria highlighting it as potentially of concern, the full Annex VII information is to be provided by the registrant. In other cases, only the physicochemical information listed in Section 5 of Annex VII, together with the information that is available to the registrant, would need to be provided. As Annex VII will only apply to a limited number of substances in this tonnage range, the common position includes additional information requirements in relation to acute toxicity, biodegradation and algal toxicity. Registrants of all non-phase-in substances would have to provide the full Annex VII information.

-Only one test for reproductive toxicity is proposed for Annex VIII (additional standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more per manufacturer or importer year).

-No significant changes have been introduced to Annexes IX and X (additional standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more 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 in Annexes VIII-X based on the exposure scenario(s) developed in the Chemical Safety Report.

In relation to phase-in substances, the common position provides for the inclusion in the first phase of registration of substances that are potentially persistent, bioaccumulative and toxic (PBT) based on current classification criteria and manufactured or imported in quantities of over 100 tonnes per manufacturer or importer per year.

With regard to those amendments which aim to reduce the number of animal tests, the Council fully shares the objective expressed in these amendments but considers that this objective is taken into consideration within the framework of Article 13(2) that lays down that test methods will be revised, as appropriate, to refine, reduce or replace animal tests. The idea is also acknowledged within the framework of the OSOR proposal and related amendments made in Title III regarding data sharing, which should lead to fewer tests on vertebrate animals.

Lastly, since the risk due to exposure is generally considered to be relatively low and since it would put too much of a burden on Small and Medium-sized Enterprises (SMEs), the amendment introducing a requirement to make a Chemical Safety Assessment for all substances subject to registration has not been accepted.

Data-sharing and avoidance of unnecessary testing:

The common position takes on 30 of the Parliament's amendments. It provides that potential registrants are obliged to share information generated from vertebrate animal tests. Information from non-animal tests must be shared if requested by another potential registrant. As a general rule, the sharing of costs will be agreed amongst potential registrants themselves in a fair, proportionate and non-discriminatory way, particularly in relation to SMEs.

In cases where the sharing of costs cannot be resolved amongst potential registrants, a clear and unambiguous provision to assign costs equally is included. To facilitate data sharing, a single pre-registration phase starting 12 months after entry into force of the Regulation and finishing 18 months after the entry into force of the Regulation has been introduced.

The Common Position does not incorporate the amendment which would make any summaries or robust study summaries of studies freely available only 15 years after submission in the framework of a registration procedure, since this could add to the overall cost of REACH and has the potential to increase the burden for industry, particularly SMEs. It also does not take on board two amendments stipulating that sharing of costs should be proportionate to the production volume.

Information in the supply chain:

12 amendments made by Parliament are integrated into the common position. The Council has included in the text an additional requirement for safety data sheets to be provided for substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative and for certain preparations containing these substances. The role of distributors in ensuring that information flows through the supply chain has been clarified. Some changes to Annex I (General provisions for assessing substances and preparing chemical safety reports (CSR)) and Annex II (Guide to the compilation of safety data sheets (SDS)) have been introduced.

The common position does not include the amendment providing that workers would be granted access by producers to information given in the supply chain, since such a responsibility lies with the employer. The amendment concerning a supplier's obligation to grant access to information on the substances sold has not been taken on board, since such a provision should be subject to the general rules on communication of information up and down the supply chain.

Downstream users:

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. It also clarifies that downstream users can participate in a Substance Information Forum (SIEF). It clarifies the cases in which cases downstream users should conduct a Chemical Safety Assessment (CSA) and prepare a Chemical Safety Report (CSR), in particular by setting a minimum threshold of 1 tonne below which a CSR is not required. The Council has decided to delete Annex Ib (Chemical Safety Assessments for Preparations) given that the scientific methodology underpinning this Annex is still being developed.

Evaluation:

The common position includes 37 of the Parliament's amendments. the Council has decided on the approach described below:

-as regards dossier evaluation, the responsibility (both for checking testing proposals and for compliance checks) has been transferred to the Agency. The Agency will be able to decide how best to discharge these obligations, including the possibility of using external sources.

-a minimum number of compliance checks should be performed. This is set in the legislation as 5% of dossiers received. These checks should focus (although not exclusively) on dossiers where disagreements come to light between registrants of the same substance, where dossiers are for a substance that is listed in the EU-wide rolling plan for evaluation or, in the case of 1-10 tonne substances, where the full information specified in Annex VII has not been submitted.

-as regards substance evaluation, a single EU-wide rolling plan for substance evaluation will be established, prepared by the Agency with input from the Member States.

-the Agency is responsible for co-ordinating the substance evaluation process relying on the Member States' competent authorities to perform the evaluations. Member State competent authorities can, if appropriate, use expert institutes to perform the evaluation.

The common position does not reflect the amendments which would give full responsibility for substance evaluation to the Agency. The Council considers that the most workable solution is for the Agency to be responsible for coordinating the substance evaluation process, relying on the Member States' competent authorities to perform the evaluations. It has also not accepted the amendment concerning mandatory consultation of the European Centre for Validation of Alternative Methods (ECVAM) before deciding on animal testing.

Authorisation:

The common position takes on board 18 of the Parliament's amendments. Various amendments have been included which are designed to strengthen authorisation whilst ensuring that the provisions are workable. The scope of authorisation has not been amended, but it has been clarified. For reasons of increased transparency and to facilitate planning within industry, a candidate list of substances meeting the authorisation criteria will be published by the Agency. The published list will also state which substances are on the Agency's workplan for inclusion in Annex XIV. Substances will be identified and placed on the list following a period of public consultation. 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 the substance and where there are no suitable alternatives substances or technologies available.

In order to encourage the development of safer substitutes, all applications for authorisation will include an analysis of available alternatives considering their risks and the technical and economic feasibility of substitution. Furthermore, all authorisations will be subject to time-limited review periods and shall normally be subject to monitoring by the holder of the authorisation. The length of the time-limited review period will be set on a case-by-case basis. In order to close a potential loophole, the Agency will consider the need for EU-wide restrictions on the use of a substance in articles at the time of inclusion of that substance in Annex XIV.

The text does not include those amendments which would require mandatory substitution if suitable alternatives are available.

Restrictions:

7 amendments by Parliament are integrated in the common position. It provides for 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. Furthermore, clarifications to Annexes XV (Dossiers) and XVI (Socio-economic analysis) have been made.

Fees and charges:

The Council has introduced a new title making it clear that the fees and charges to be levied under the regulation shall be introduced in a Commission Regulation. The new title includes principles for these fees and charges, including the idea that some of the Agency's revenue will be forwarded to the Member State competent authorities responsible for undertaking work as in compliance with REACH. Lower fees will always be charged to SMEs.

Agency:

The common position includes 13 amendments made by Parliament. It clarifies several points, including the following : each Member States will have one representative on the Management Board; a clarification of the procedures for appeal has been included; it has been specified that the rules governing languages in the Agency should be in accordance with Regulation No 1/58; the reference to the seat of the Agency in the REACH Regulation has been deleted; the Agency will get its funding from contributions from the Community budget, fees paid by industry, and voluntary contributions from Member States.

All the amendments stipulating that the Agency should have overall responsibility for the management of REACH or putting emphasis on the Agency as the main authority in the field of REACH, have not been incorporated in the common position.

Classification and labelling:

The common position extends the possibility of harmonised classification and labelling across the EU for other endpoints than those proposed by the Commission on a case by case basis. Pending the Commission's proposal on a Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and in line with the Commission's proposal on REACH, it was not considered appropriate to incorporate the Parliament's amendments.

Information :

This title has been modified substantially with a view to bringing its provisions in line with Regulation 1049/2001/EC regarding public access to 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 1049/2001/EC. The common position reflects the amendment stipulating that Member States, the Agency and the Commission will submit a report every five years on experiences gained. It also reflects in principle the amendment stipulating that the Agency will publish non-confidential information on the website.

Competent authorities:

In line with the principle of Parliament's amendment, a clarification of the text concerning guidelines on how to inform the general public about risks arising from substances has been introduced in the common position. The Council has also introduced the principle of the amendment on special help and advice to SMEs. The Council considers that Member States helpdesks will be of great benefit to industry, in particular to SMEs.

Enforcement:

Some clarification of the sanctions regime to be established by Member States has been introduced. The common position does not reflect the amendments giving the Forum within the Agency the task to draw up guidelines on enforcement. However, the Forum shall identify enforcement strategies as well as best practice in enforcement. Certain other amendments have not been incorporated since Member States do not see the need for the Agency to be involved directly in enforcement of the Regulation and in drawing up of guidelines on sanctions to be taken as a result of infringement to it.

Transitional and final provisions:

The common position reflects in principle the amendment laying down that Member States have the right to maintain more stringent measures on the protection of workers, human health and the environment,

provided that the area is not harmonised by the REACH Regulation. Regarding the amendment on the preparation of the establishment of the Agency, the Commission and the Council have committed themselves in a joint statement to providing the necessary support towards setting up of the Agency.

Annexes:

The Council has introduced several modifications to the annexes and taken into account some 36 amendments made by Parliament.