



REACH: The New European Union Chemicals Legislation

The European Parliament (EP) adopted the new regulation for chemicals, the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), based on the compromise text issued in June 2006, and interim discussions with various European agencies. The compromise package between the EP and the Council of Ministers was approved with 529 in favour, 98 against, and 24 abstentions.

The regulation will oblige producers and suppliers to register all those chemical substances produced or imported above a total quantity of 1 tonne per year. Registration will affect about 30,000 substances. For more hazardous substances, producers will have to submit a substitution plan to replace them with safer alternatives. When no alternative exists, producers will have to present a research plan aimed at finding one.

REACH will enter into force progressively from June 2007, and the registration process will take 11 years to be completed. The calendar for registration depends on the risk of the substance and the quantity produced, with priority placed on high supply volumes (at or above 1,000 tonnes per annum), and hazardous endpoints classified as Category 1 or 2 carcinogens, mutagens or toxins for reproduction (CMR), or are hazardous to the environment (persistent, bioaccumulative toxins (PBT), *i.e.*, classified N: R50-53).

REACH will replace the current system that differentiates between:

- “New” chemicals, *i.e.*, the roughly 3,000 substances placed on the market after 1981, the year since which formal authorisation has been required by community legislation; and
- “Existing” substances, placed on the market before 1981 and numbering around 100,000.

REACH replaces some 40 legislative texts by establishing a single regulation. Prior to registration, there will be a period for pre-registration for substances regarded as “phase-in” substances, which are:

- Listed on the EINECS inventory;
- Produced in the EU before 1 June 1992, but never placed on the market; and



REACH: The New European Union Chemicals Legislation
April 26, 2007

Page 2

- Fall under the EU's no-longer polymers criteria.

Pre-registration will occur over a six-month period starting in June 2008, closing at the end of November 2008.

European Chemicals Agency

As part of the regulation, Europe is establishing a new authority, which will be based in Helsinki, Finland. The European Chemicals Agency (ECHA) will be responsible for the registration and authorisation process, while some parts of the regulation will be overseen by national "rapporteur" Competent Authorities.

The authorisation process will cover about 3,000 substances considered more dangerous. The ECHA will be responsible to authorise them and the producers will have to present either replacement proposals or research plans to develop alternatives. The authorisation will be for a limited time period.

REACH transfers the burden of proof regarding testing and evaluation of the risks of chemicals from the authorities to industry. It also includes obligations of duty of care for the industry and of communication to the public about dangerous substances in products, as well as safeguards for confidential information and provisions to avoid duplication of animal testing.

The Issues at Second Reading

The EP Environment Committee, voting on 10 October 2006, adopted a very firm position by 42 votes to 12 with six abstentions, making no less than 172 amendments to the Council text, seeking to reinstate several points from first reading, which had not been accepted by the Member States. Apart from the substitution of the most hazardous substances, the amendments related to the operators' "duty of care," a compulsory chemical safety report for chemicals in amounts of more than 10 tonnes, and the promotion of alternatives to animal testing.

A series of trialogues -- EP, Council, and Commission -- was then held to narrow the gap between the different institutions and, if possible, clinch an agreement on REACH at a second reading so that it could be implemented swiftly. The talks concluded successfully on 30 November after the sixth triologue, less than a week before the deadline (6 December at 6:00 p.m.) for tabling amendments for the plenary vote.

REACH: The New European Union Chemicals Legislation

April 26, 2007

Page 3

The amendments adopted on 13 December reflect the compromise thrashed out with representatives of the Member States, and the REACH regulation, once rubber-stamped by the Council, will enter into force progressively from June 2007.

The main features of the compromise struck between Parliament and the Council and adopted by the European Parliament are:

- ***Authorisation of Hazardous Substances:*** For the most dangerous substances, there will be an obligation for producers to submit a substitution plan to replace them with safer alternatives. Where no alternative exists, producers will have to present a research and development plan aimed at finding one. Under a review clause, it will be decided after six years, on the basis of the latest scientific data, whether endocrine disruptors should be included in a list of substances that can only be authorised in the light of an analysis of their socio-economic costs and benefits. Under one clause it was agreed to review after six years, on the basis of the latest scientific data, the inclusion of these substances among those that can only be authorised in the light of an analysis of the socio-economic costs and benefits.
- ***Registration of Substances:*** The Commission must decide in 12 years' time whether or not to recommend extending the requirement for chemical safety reports for substances produced or imported in amounts of less than 10 tonnes per year. This deadline was shortened to seven years for cancerous or mutagenic substances or those toxic to reproduction. The intellectual property provisions were strengthened, with data protection extended from three to six years.
- ***Duty of Care:*** The “duty of care” principle will be enshrined in the regulation. It will be in a recital stipulating that the manufacturing, import, or placing on the market of substances must be done prudently and responsibly, to ensure that, under reasonably foreseeable circumstances, human health and the environment are not adversely affected. This will involve collection of all necessary information on the substances in question and relaying all recommendations about risk management along the distribution chain.

REACH: The New European Union Chemicals Legislation

April 26, 2007

Page 4

- ***Animal Welfare:*** The promotion of alternatives to the animal testing of chemicals is now included among the goals of REACH. To avoid duplication of animal testing, interested parties will have 45 days to state their views before each new plan for animal tests. Information on toxicity to human beings should, if possible, be discovered using means other than tests on vertebrate animals, including through use of alternative methods such as *in vitro* procedures. These alternative methods must be validated by the Commission, once recognised by the agency, or international institutions. The Commission will submit a report every three years on the use of alternative tests and, if necessary, bring forward fresh legislative proposals.

- ***Communication of Information:*** A clause was added on the duty to inform the public about dangerous substances contained in products. The distribution chain, including consumers who request it, must be informed of the presence of any chemical in an amount greater than 0.1% of the total product weight. The Commission must consider the possibility of establishing a European quality mark for chemical products.

Entry Into Force

Following the compromise, REACH is due to enter into force progressively from 1 June 2007. Any producers and/or suppliers that do not participate in the REACH process will be prohibited from supply in the EU, including the accession states.

Recommendations for Industry on How to Proceed

Producers and suppliers of chemicals to Europe need to take steps now to ensure that they have a strong position from which to defend their business when REACH takes effect. Recommendations of steps to take are:

- ***Review Internal Chemicals Inventory:*** Within each business unit or company as a whole, it is important to have an understanding of what chemicals are supplied to the EU, the volume at which they are supplied (in the whole EU, including accession states), and the properties of each substance. They should also assess the profitability of each chemical -- it is important to know whether supporting a chemical through REACH is likely to be cost effective for the sales return over time. If there is any doubt as to

REACH: The New European Union Chemicals Legislation

April 26, 2007

Page 5

whether your product (or chemicals in your product) will be affected under REACH, seek good advice from a reputable source early.

- ***Gather Information for Pre-registration of Phase-in Substances:*** The Council common position requires the following information for pre-registration:

- The name of the substance:
 - Name(s) in the IUPAC nomenclature or other international chemical name(s).
 - Other names (usual name, trade name, abbreviation).
 - EINECS or ELINCS number (if available and appropriate).
 - CAS name and CAS number (if available).
 - Other identity code (if available).
- Name and address of the potential registrant.
- Name of the contact person.
- Name and address of the representative where appropriate.
- The envisaged deadline for the registration/tonnage band.
- The substance(s) that you intend to use for read-across approach or (Q)SAR ((Quantitative) Structural Activity Relationship).

The Agency will publish the names of the pre-registered substances, including CAS and EINECS numbers, as well as the substances intended to be used for read-across approach, on its website.

REACH: The New European Union Chemicals Legislation

April 26, 2007

Page 6

For pre-registered substances, companies should have the information on substance identification available internally.

The final format for the submission of the pre-registration data is as yet unknown.

- ***Establish Relationships with Partners:*** REACH will require information to be available on chemicals throughout their complete life cycle. Therefore, not only the original producer needs to be involved, but also the suppliers, formulators, and users (but not the public) of the chemical. Downstream users need to confirm whether their supplier will cover their use category while suppliers need to know how their chemicals are used to adequately report use patterns in the EU.

There are also provisions for representation, either to provide anonymity to EU entities (Third Party Representative) or to allow non-EU entities to identify an independent partner in the EU to represent their business interests and administrative duties under the regulation (Only Representative).

- ***Check for Any Available Data:*** An essential method of reducing the cost burden of REACH on the business will be to share data or use replacement data (using a weight of evidence approach) to avoid conducting testing. Data which will be useful under REACH will include (but not limited to):
 - Any animal data conducted on the chemical to which the company has access -- essentially any animal data should be considered regardless of age or quality.
 - Any human exposure data.
 - Any environmental impact studies or other environmental studies.

Companies should consider trends in their chemical inventory that could be exploited for read across and/or grouping of chemicals and be aware of any classification for each chemical.



REACH: The New European Union Chemicals Legislation

April 26, 2007

Page 7

- ***Consider Your Resources:*** Many companies are already preparing for REACH, but an important consideration is what resources are available in terms of staffing and technical know-how for working with REACH. Outsourcing may be an option worth considering, but companies should take time before the regulation comes into force to locate reputable consultants who understand the details of the regulation, can effectively and constructively assist with reducing the burden of REACH, and, importantly, will work in their best interests.

If there is any doubt, pre-register every phase-in substance supplied or used by your company. Pre-registration places no obligation on companies to support a chemical through the registration process, but could make a wealth of difference to the future of your products.

Mr. Steve Green
Business and Regulatory Manager
Acta Group EU, Ltd
sgreen@actagroupeu.com