

The EU REACH Regulation

(Registration, Evaluation, Authorisation and Restriction of Chemicals)

The Issue

The European Union's Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals was formally adopted on 18 December 2006 and enters into force on 1 June 2007. It will be implemented progressively over a period of 11 years.

REACH aims to enhance the protection of human health and the environment through the better and earlier identification of the hazardous properties of chemical substances and better management of risks throughout their use. It is a major landmark in chemicals policy, putting duties on manufacturers and importers to register and demonstrate safe use of any existing or new chemicals they produce.

The passing of the regulation brings to a conclusion some five years of debate about the balance between protecting health and the environment and promoting the competitiveness of European industry.

Guidelines on the implementation of various aspects of REACH are now being prepared by the Commission.

GlaxoSmithKline's Position

1. GSK strongly supports the aim of REACH to enhance the protection of human health and the environment against the hazardous properties of chemical substances. REACH is consistent with GSK's public policy position on [Hazardous Chemicals Management](#).
2. Chemicals are essential for research into human disease and the manufacture of medicines. GSK welcomes the efforts made by all parties in the negotiations to ensure that the REACH Regulation is workable and does not impose unnecessary costs on industry.
3. GSK welcomes the exemption from the principal requirements of REACH agreed for substances used in human medicinal products.. We believe that this exemption was necessary to ensure that the regulation did not adversely impact our ability to deliver essential therapeutic products to patients. We are confident that human health and the environmental risks of pharmaceuticals are adequately addressed by existing EU legislation on medicines.
4. Innovation is important for the discovery of new and enhanced treatments of disease and for the sustainability of our company. We are therefore supportive of the less burdensome requirements introduced by REACH for the registration of new chemicals. They provide a better incentive for research and development activities in the EU.
5. Acquiring the necessary knowledge on the hazardous properties of substances will entail some animal testing. However, GSK recognises and fully supports the efforts made in REACH to minimise testing on vertebrate animals and to promote use of alternative test methods where this does not compromise the assessment of human and environmental

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hazards. We will only use animals in research where there is no alternative and our scientists are guided by the principles and standards known as the '3Rs' (reduction, refinement, replacement). For further information see GSK's website: [Application of 3R's in medical research at GSK](#)

6. The REACH Regulation contains a number of technical requirements that will still need to be interpreted in practice. It is important that as guidance on implementation is developed, the need for workability is kept firmly in mind. The guidance must be clear and understandable for businesses, ensure compatibility with existing EU risk assessment legislation, and avoid duplication of effort and added bureaucracy.
7. We are particularly concerned about the proposed guidance from the Commission for registration of intermediates. In negotiating REACH, all parties agreed that intermediates did not justify the same level of testing as general chemicals because of their "strictly controlled" use within industry and the low risk of harm to the environment. However, the interpretation of "strictly controlled" now proposed would mean that manufacturers must either prepare a full dossier for their intermediates or demonstrate a level of control that is often unwarranted.
8. GSK will work with its suppliers to ensure that they comply with the Regulation and to safeguard the security of the supply chain, so that the research and manufacture of medicines is not disrupted by withdrawal of chemicals from the market.
9. One of the intended benefits of REACH is enhanced chemical hazard communication throughout the supply chain. GSK will expect to see improvements in the quality of hazard information received from our suppliers, and will work with them to make this happen.
10. It is important that the Commission monitors the cost and economic benefits of REACH to inform future decision making when REACH is reviewed.

BACKGROUND

REACH replaces 40 existing pieces of EU legislation, including the Notification of New Substances (NONS), with a unified, comprehensive strategy.

Registration requires that manufacturers or importers of new or existing ("phase-in") chemicals submit a basic data package to a European Chemicals Agency (ECHA) to be established in Helsinki. This technical dossier is required to contain information on the substance and information on how to manage effectively the risk entailed by using it .

Evaluation of the dossier allows the regulatory authorities to assess whether the information provided complies with requirements and to decide on proposals for animal testing. For selected substances, where a risk to health or the environment is suspected, substance evaluation provides a mechanism to require the submitter to obtain more information. Evaluation may also lead to the conclusion that action should be taken under the authorisations or restrictions procedures.



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Authorisation may be required for substances of very high concern (carcinogens, mutagens, substances toxic to the reproductive system, and substances which are persistent, bio-accumulative and toxic, very persistent and very bio-accumulative or of equivalent concern). It is estimated that 1,500-2,000 chemicals may fall into this category.

Restrictions are the safety net of the system. Any substance on its own, in a preparation or in an article may be subject to Community-wide restrictions if its use poses unacceptable risks to health or the environment. Restrictions can be decided for the use of a substance in certain products, for use by consumers or even for all uses (complete ban of a substance).

Exemptions

Chemicals used in finished pharmaceutical products (drug active, excipients etc) are exempt from the REACH Registration, Evaluation and Authorisation processes. GSK advocated in favour of this exemption because there are similar requirements already included in the EU medicines legislation. Finished pharmaceutical products could still be subject to Restriction under REACH, although this is unlikely in practice.

REACH and Animal Testing

Acquiring the necessary knowledge on the properties of substances will entail some animal testing. However, REACH has been designed to reduce animal testing to the absolute minimum. Unnecessary tests are avoided due to the obligation to share all data generated through testing on vertebrate animals, and by the provision that for large volume substances testing proposals must be approved by the Agency before a new test on animals can be performed. This will ensure that the testing programme does not duplicate other studies.

REACH also mandates a public consultation period of 45 days before certain tests can be carried out, to verify whether the data is already available and consequently the tests are unnecessary.

An increase of 3% of animal testing in comparison to the current level of animal tests in the EU is expected for the first eleven years after adoption of REACH. Thereafter the burden of the past concerning a lack of knowledge about the 30,000 qualifying substances in use today should be adequately addressed and the amount of testing should then go down steeply because only a few new substances per year will have to be tested.

GSK and REACH

Many chemicals purchased or manufactured by GSK will be affected by REACH. These will include chemicals used in the synthesis of drug actives (e.g. starting materials, reagents, solvents, catalysts, intermediates), ingredients in oral healthcare products and chemicals used in packaging materials. The size and complexity of GSK's supply chain makes it challenging to ensure that all these materials have been registered and will continue to be available under REACH.

REACH will primarily affect GSK operations in Europe but may also affect some GSK operations outside it. Failure to register a substance means that it cannot be manufactured, imported or used in the EU market. Sites outside the region will be affected if they source raw materials from Europe or export chemicals back into it.



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The impacts of REACH will be felt by GSK particularly in primary manufacture, but also in Consumer Health, secondary manufacture and R&D. GSK has set up an issue team consisting of representatives from EHS, Procurement, GMS, Pharmaceutical R&D and Consumer Healthcare R&D to ensure that we are ready to comply with REACH. The first compliance milestone will be a pre-registration for phase in substances in June 2008.

In 2006, the United Nations adopted a Strategic Approach to International Chemicals Management (SAICM) which is closely based on REACH. Implementation of SAICM is voluntary but it is already being adopted by other countries.

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Further Information

European Commission website on REACH:

http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

GSK Public Policy Position Paper on Hazardous Chemicals Management

<http://www.gsk.com/responsibility/Downloads/GSK-hazardous-chemicals-2006.pdf>

