

**The Royal Society of Chemistry Response to the Potential Impact of
Proposals to Revise Directive 91/414/EEC
5 October 2008**

Changing regulation

Recently there have been disturbing trends towards the use of hazard-based non-approval criteria in regulatory decision-making. The proposal to use intrinsic properties of a chemical to deny approval based on hazard criteria or classification categories is scientifically questionable as neither reflects potency such that safety/risk can be assessed.

The use of hazard-based cut-off criteria is scientifically incomplete and does not necessarily increase safety especially when, in the case of crop protection chemicals, this is weighed against the impact it may have on productivity, food security and by extension, consumer health protection.

Royal Society of Chemistry supports an evaluation system that continues to be based on a proper scientific risk assessment and calls for:

- Hazard-based criteria to be used to identify areas of concern, which can then be subject to a rigorous risk assessment to establish if the product can be used safely. In addition, there is a need to specify in more detail the endocrine disruption criterion to be used in decision making.
- A holistic approach to regulation which is based on a clear understanding of the consequences for agricultural productivity, resistance management, food prices, food security and trade, as well as potential consequences for the wider environment before these criteria are adopted.
- Opposition to any reduction in chemical diversity resulting from hazard-based assessments that could impact negatively on the research and development of new insecticides and alternative modes of action.
- Any regulatory non-approval hazard criteria to be limited to internationally agreed guidelines such as the Stockholm Convention regarding persistent organic pollutants and areas of genuine concern such as genotoxic carcinogens.

Crop protection chemicals

Regulatory testing and assessment schemes have been developed across the world, which assess safety based on risk and the scheme for crop protection chemicals is one of the most rigorous.

Crop protection chemicals are by nature designed to be biologically active and the desirable activity for which the compound has been developed must be differentiated from any adverse

effects. This is usually achieved through differences in potency and exposure. Consequently regulatory decisions concerning the authorisation and use of crop protection chemicals must be based on risk assessment, considering both hazard **and** exposure.

Safety assessments

When assessing the safety of a chemical, the optimum scientific approach is to consider its intrinsic toxicological properties and their potency (**hazard**) and to understand their occurrence or in-use scenarios relative to humans or the environment (**exposure**). These two elements can then be used to determine the level of risk and its acceptability in relation to either humans or the environment.

risk = hazard x exposure

This approach is predicated on the concept that there is a threshold for a biological/toxicological effect, i.e. the “dose makes the poison”. Generally speaking chemicals have a threshold level below which they have no biological effect (with notable exceptions such as genotoxic carcinogens and mutagens, although it should be noted that this is an unproven precautionary assumption).

It is this principle that forms the basis of any sound safety assessments. Exposure must not exceed the threshold value and in general an extra margin of safety (usually 100 fold) is added. It maybe that a given compound has a particular level of potency which means there is no practically acceptable level of exposure. In other cases a chemical may demonstrate a genuine and significant biological effect in appropriate assays/animal studies but the mechanism of action may not be relevant to man and so safety to humans is not a concern. These aspects need to be understood to perform a meaningful safety/risk assessment¹.

Impact of the cut-off criteria

Several impact assessments performed in the Member States underline the potential severe impact of the hazard-based non-approval criteria. The UK Pesticides Safety Directorate² estimated that the Commission criteria could lead to the loss of up to 15% of active substances, while Parliament's criteria could ban up to 85% of substances currently used. With an estimated 60 to 80% yield loss without pesticides, the lack of active substances resulting from the proposed criteria would not only cause more plant losses due to pests and diseases, but would also limit the needed increase in productivity as a result of the growing

¹ Publication: <http://www.cefic.be/Files/Publications/Risk%20&%20Hazard2.pdf>

² Report:

[http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/Impact_report_final_\(May%202008\)\(1\).pdf](http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/Impact_report_final_(May%202008)(1).pdf)

demand for food and biofuel. The ADAS study³ performed for the UK shows that a yield loss of 25% can be expected with the Commission criteria, and up to 45% with the Parliament criteria. A study by Nomisma⁴ assessed that 27% of wheat yields could be lost by 2020 due to the new Regulation, as well as 50% of potato yields.

With the ongoing authorisation review in Europe under the current legislation, half of the 900 substances which were available in 1993 have already been taken out of the market. Further reducing their number, with no scientific basis, would force farmers to increase the dosage of the few products left, thus increasing the risk of pest resistance to these products and the potential for increased residues on crops. Leading European Agricultural Institutes⁵ underlined that sufficient modes of action are needed for resistance management, and that the risk assessment principle should be used instead of hazard criteria. Farmers and growers have also warned that the loss of crop protection chemicals could severely reduce EU agricultural production and competitiveness⁶. The proposed cut-off criteria would deprive EU agriculture of the necessary tools to produce good quality and affordable food, especially fruits and vegetables which are, from an agricultural point of view, considered as minor uses while forming an essential part of a healthy diet.

Furthermore, the use of a hazard based approach could have a direct impact on innovation by disproportionately reducing the availability of some chemical groups. This could severely restrict the rate of new active substance discovery and development of alternative solutions

Notes:

Since 1841, the **Royal Society of Chemistry** has been the leading society and professional body for chemical scientists and we are committed to ensuring that an enthusiastic, innovative and thriving scientific community is in place to face the future. The RSC has a global membership of over 44,000 and is actively involved in the spheres of education, qualifications and professional conduct. It runs conferences and meetings for chemical scientists, industrialists and policy makers at both national and local level. It is a major publisher of scientific books and journals, the majority of which are held in the RSC Library and Information Centre. In all its work, the RSC is objective and impartial, and is recognised throughout the world as an authoritative voice of the chemical sciences.

³ ADAS (2008), *Evaluation of the impact on UK agriculture of the proposal for a regulation of the European Parliament and of the council concerning the placing of plant protection products on the market*.

⁴ Nomisma (2008), *European agriculture of the future, the role of plant protection products – economic impacts*.

⁵ http://www.mkqp.gov.si/fileadmin/mkqp.gov.si/pageuploads/Novinarsko_sredisce/Sporocila_za_javnost_novice/FURS/Final_declarationA.pdf, "Declaration of Ljubljana", April 2008,

⁶ Press release on Brussels workshop www.copa-cogeca.be/Download.ashx?ID=381138&fmt=pdf