



Scientific Advice Mechanism

Scoping paper: Authorisation processes of plant protection products in Europe from a scientific point of view

23 April 2017

This scoping paper was adopted at the 7th HLG meeting (23-24 March 2017). However, it was agreed by the Commission and High Level Group of Scientific Advisors that question (b) "Methods of arbitration" would be addressed only if time, and an appropriate form of evidence interrogation and consultation permits.

Authorisation processes of plant protection products in Europe from a scientific point of view

1. ISSUE AT STAKE

Plant protection products are indispensable in agriculture but their use may involve risks to human and animal health and to the environment. In order to ensure the safety and efficacy of plant protection products, the EU legal system concerning the placing on the market of such products provides for a double authorisation procedure before they can be placed on the market¹.

The Commission approves active substances (i.e. the agent used to achieve the protective effect) for the use in plant protection products (i.e. the end product) following a comprehensive assessment by experts of Member States and of the European Food Safety Authority (EFSA). The EU decisions define the content of the national measures authorising products containing those substances in terms of specification of the technical material, conditions of use, risk mitigation measures, and others. Only when a substance is approved, Member States can authorise plant protection products containing that substance. The national authorisation defines the source (production site) of active substance to be used in the products, the precise formulation of the products, its hazard classification and conditions of use. Issues that may arise from the co-existence of an active substances and for instance one or more co-formulants used in the plant protection product are currently considered at product authorisation stage at Member State level, but not at the stage of approval of an active substance. The applicable rules divide the EU in three zones with similar conditions as concerns e.g. climate, soils, or agricultural production. Authorisations by Member States belonging to a specific geographical zone are subject to mutual recognition unless a Member State considers that the risk associated to the use of the product is unacceptable.

2. EU POLICY BACKGROUND

Each of the steps of the EU procedure (approvals at EU level and authorisation at national level) is based on a scientific risk assessment. The two risk assessments follow harmonised data requirements and decision-making principles. The data requirements

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1. MRLs for pesticides to protect all consumer groups are set in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, OJ L 70, 16.3.2005, p. 1.

establish a catalogue of tests and studies that must be provided by any applicant for the approval of an active substance and the authorisation of a product as a basic minimum dossier as well as any necessary supplement in order to address possible requirements for a refined assessment. The Uniform Principles laid down in Commission Regulation (EU) No 546/2011² establish a harmonised methodology for the assessment and harmonised thresholds to decide whether an identified risk is acceptable or not. However, there is some flexibility within the risk assessment methodology. Risk assessments are carried out by different authorities, by EFSA for the active substance, by the different national competent Authorities for products) and not in all cases according to the same guidance documents. Consequently, different conclusions can be drawn from the same study even though the risk is supposed to be the same. Or one national guidance document might require additional studies which are not required by another country, increasing the burden on applicants in the absence of a clear scientific motivation for the difference between the two guidelines. In contrast to this EU system, not all third countries have dual authorisation systems despite the fact that many also have different agronomic zones.

Authorisation systems used in non-EU OECD countries might be a useful source of inspiration helping to formulate suggestions how current processes could be improved. When looking at possible improvements of such processes attention should be also given to the issue of scientific divergences, for instance divergences that may arise when different authorities assess the risk with a different result despite of the same science as a basis. The SAM HLG is asked to elaborate on possible methods of arbitration that could be used to solve such scientific divergences, taking into account not only technical and scientific considerations (e.g. full alignment of risk assessment procedures, scientific assessment of uncertainties, etc.) but also societal aspects such as for instance the underlying mechanisms of risk acceptance (incl. the way public opinions are formed, role of media and interest groups and the role of transparency in this process). The work on the scientific question addressed to the SAM HLG will therefore run in parallel with and complement the information that will be gathered in the context of the Refit Evaluation of Pesticides Legislation³, but should not overlap with it. The objective of the Refit evaluation is to perform an evidence-based assessment of the implementation of the current regulations on plant protection products and pesticides residues.

² Commission Regulation (EU) No [546/2011](#) implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles of evaluation

³ Roadmap is published at: http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_197_evaluation_plant_protection_products_en.pdf.

3. REQUEST TO THE SCIENTIFIC ADVICE MECHANISM

The SAM HLG is asked to provide a scientific opinion on the authorisation processes for plant protection products in Europe from a scientific point of view by 30 November 2017 in line with the request of Commissioners Moedas and Andriukaitis of July 2016⁴.

This date will allow the Commission to look at conclusions from the SAM High Level Group and those from the Refit evaluation in parallel before the Refit evaluation study is finalised. The opinion shall assess the current risk assessment and risk acceptance procedures underlying the decision making processes which determine the placing on the market of plant protection products and on how to make these processes more efficient, effective and transparent.

The questions to be answered by the Scientific Advice Mechanism are the following:

a) EU dual system for approval and authorisation of plant protection products

Could the current EU dual system for approval and authorisation of plant protection products rendered more effective, efficient and transparent, and if so, how could this be achieved? To this end, the SAM HLG may wish to consider comparing the situation in the EU with non-EU OECD countries and to discuss the advantages and disadvantages of different systems. The assessment should be in scientific terms and not examine legal and policy issues.

b) Methods of arbitration

While replying to the question under point (a), the SAM HLG is requested to focus particular attention on the following aspects:

Which methodology of arbitration could be used to solve issues arising from diverging assessments by different competent authorities based on the same science, or on a different assessment of uncertainties?

To which extent would full alignment of risk assessment procedures solve the problem of different risk acceptance by different authorities? Which other factors and mechanisms are influencing risk acceptance by authorities and by the public? Could they be used to develop arbitration methods, and if so, how?

Apart from arbitration methods based on purely natural science or procedural aspects, societal aspects should also be considered. Among other factors and mechanisms that influence risk acceptance, it may be helpful to consider for instance the role of media and interest groups, transparency aspects, etc.

⁴ Letter ARES (2016) 4126688 of 20 July 2016