EU Regulation concerning the Placing of Plant Protection Products on the Market

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European Glyphosate Environmental Information Source

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This document is part of a toolbox which provides independent information on the sustainable use of glyphosate. It cannot however be definitive and users must ensure that they assess local factors and particularly take account of any national or regional legislative requirements. At the end of the document reference sources used in its preparation and links to other relevant documents are provided.

Summary
This new Regulation (1107/2009), which was agreed in late 2009, updates the EC's regulatory framework for placing plant protection products on the market and replaces the previous Directive 91/414/EEC after a transitional period. The main changes include: disallowing marketing approval of products based on some intrinsic properties of active substances (hazard criteria) rather than purely on the risk posed (which includes taking degree of exposure into account); the provision of criteria for identifying some active substances as candidates for substitution where they can be removed from the market if safer alternatives are available (comparative risk assessment); safeners and synergists are to be approved in a similar way to active substances, and unacceptable co-formulants identified which cannot be included in products; approval of products to be made on a zonal basis where approval by one Member State in the zone leads to approval by all other Member States in that zone.

Detailed information

The previous EU Directive 91/414/EEC concerning the placing of plant protection products on the market provided for rules governing the approval to market of plant protection products and the active substances contained in those products. Following a progress report on the directive presented by the Commission the European Parliament and the Council asked the Commission to review Directive 91/414/EEC and identified a number of issues for the Commission to address.

Plant production has a very important place in the Community. One of the most important ways of protecting plants and plant products against harmful organisms, including weeds, and of improving agricultural production is the use of plant protection products. However, such products can only be placed on the market after a rigorous testing regime which checks that they do not have any non-beneficial effects on plant production or cause harm to humans, animals and the environment.

The purpose of this new Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention was paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The Regulation was designed to ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment. A high regulatory hurdle has been imposed. Substances should only be included in plant protection products where it has been demonstrated that they present a clear benefit for plant production and they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment.

Under the new Regulation, active substances are approved at EC level, following evaluation by a rapporteur Member State and peer review by the European Food Safety Agency (EFSA), in much the same way as operated under Directive 91/414/EEC. Approvals of active substances may be renewed for up to 15 years in the case of 'standard' and low-risk substances, or up to five years in the case of those approved under an 'exemption', or up to seven years in the case of candidates for substitution. Much like existing arrangements, plant protection products are authorised by Member States where they meet

the criteria for approval. Active substances must first be approved, unless the approval process is delayed, in which case provisional authorisations may be granted for up to three years. Authorisations are granted for up to one year after the expiry of the first approval of the active substance, safeners and synergists, and thereafter for as long as they are approved. The Commission may develop a programme for reviewing approved substances, and may review them *ad hoc* if there are concerns that they no longer meet their conditions of approval or, following a review of national product authorisations, they may compromise compliance with the Water Framework Directive 2000/60/EC. Authorisation holders must notify all potential adverse data which suggest that approval or authorisation conditions may no longer be met.

Some of the most important new provisions include the following:

Non-approval of active substances based on substance intrinsic properties

- no category 1 or 2 mutagens
- no category 1 or 2 carcinogens, unless exposure is negligible
- no category 1 or 2 reproductive toxins, unless exposure is negligible
- no endocrine disrupters which may cause adverse effects in humans, unless exposure is negligible. Interim provisions will apply until the Commission develops definitive measures
- no persistent organic pollutants
- no persistent, bioaccumulative and toxic substances
- no very persistent and very bioaccumulative substances
- no endocrine disrupters which may cause adverse effects on non-target organisms, unless exposure is negligible

Unless there are no other means of control available, in which case the active may be approved for up to five years under a temporary approval.

Candidates for substitution (comparative risk assessment)

Candidate substances are those which meet any of the following conditions:

- they have toxicological endpoints which are significantly lower than those of most similar approved substances
- they meet two of the criteria to be considered persistent, bioaccumulative and toxic substances
- there are concerns about critical effects (such as developmental neurotoxic or immunotoxic effects) in use, even with very restrictive risk mitigation measures
- they contain a significant proportion of non-active isomers
- they are classified category 1 or 2 carcinogens or reproductive toxins, or endocrine disrupters, which are not excluded by the hazard criteria

Zonal authorisations

New to the scheme, the EC is now divided into three zones, within which applications for product authorisation may be made to one or more Member States; and if to more than one, a lead member State evaluates the dossier on behalf of the others. All Member States grant or refuse authorisations with the same conditions as the lead member State, unless their specific national conditions justify alternative conditions of use or refusal of authorisation.

Subsequent applications may be made to other member States in the zone for mutual recognition of authorisations. Those member States evaluate the dossier as appropriate to their national circumstances and grant authorisations on the same conditions of use, unless alternative conditions or refusal of authorisation is justified. Applications for authorisation and mutual recognition may be made regardless of zone for uses in greenhouses or storage facilities, or as post-harvest or seed treatments.

The Commission is required to propose subsidiary legislation, including:

- data requirements and a review programme for safeners and synergists
- detailed rules for authorisations of adjuvants
- determining definitive provisions for endocrine disrupters in humans

Plant protection product approval procedures are continually evolving, and the uncertainties still evident in the new Regulation are an indicator of this, especially in the area of environmental risk assessment. It is also clear that different EU environmental legislative instruments are increasingly beginning to impact on each other; in this case the requirements of the Water Framework Directive are particularly relevant to the Plant Protection approval legislation.

Current authorisation status of glyphosate

Glyphosate has been on Annex I (positive list of authorised substances) of Directive 91/414/EC since 1 July 2002 (Commission Directive 01/99/EC). This authorisation will expire on 30 June 2012. Notifiers are already preparing the registration renewal and updating the dossier in line with the requirements of the new Regulation.

Reference for further detailed information:

- 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 (Click here)

See also:

- EU Directive on Sustainable Use of Pesticides
- EU drinking water quality legislation
- EU Water framework directive

Document status:

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