

# Retaining Pesticides for minor uses EU changes and Specific Off Label Approvals (SOLAS)

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## ABSTRACT

### Legislation revising the Plant Protection Products Directive 91/414/EEC

#### Background and update

The current pesticide authorisation is via Directive 91/414/EEC. Current pesticide approvals are highly regulated and are based on the **risks** posed by a particular material when used with the appropriate precautions designed to protect operators, consumers and the environment.

The timeline for the new regulation has been as follows: European Council decision June 08; EU Environment Committee decision Nov 08; Trialogue meeting Dec 08; European Parliament vote second reading 13 Jan 2009. The next stages are for the EU Council to adopt and publish the final text in Mar/Apr 2009 and for the regulation to be fully in place and functioning by the end of 2010.

The new criteria in the new regulation ignore the impact of the risk minimisation precautions taken by industry and are based purely on the intrinsic **hazard** from the use of the substance. So, if a pesticide has a particular property that triggers one of the hazard 'cut-off' criteria, it is likely to be banned, regardless of the actual risk. 'Cut-off' criteria means substances that are:

- Mutagens – M category 1 or 2
- Carcinogens or toxic to reproduction - C category 1 or 2 (unless exposure to humans is negligible)
- Endocrine disruptors – ED (unless exposure to humans is negligible)
- Persistent organic pollutants – POP
- Very persistent & very bio-accumulating - vPvB
- Persistent, bio-accumulating & toxic – PBT

An endocrine disruptor has been defined as an exogenous substance that alters the function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny or (sub)populations. However, for the purposes of this new legislation the definition has yet to be agreed. The endocrine system is the set of glands, and the hormones that they produce, that regulate the development, growth and behaviour of animals, including humans.

The timetable for implementation is reasonably benign. For existing substances, already included in Annex I of 91/414, these approvals will expire 10 years after the original inclusion when a renewal is required. Most products got onto Annex 1 during the last 2 years so will not be reviewed until 2016 onwards, although a few will start in 2011. The renewal of a product will be evaluated under the new regulation. From the end of 2010, submissions of new active substances will be fully under the new regulation.

Some products may be lost earlier however, as a comparative assessment will be undertaken aiming to substitute products containing active substances identified as 'candidates for substitution' with lower risk products. This will take into account toxicity, carcinogenicity, persistence, acceptable daily intake (for consumers), acceptable operator exposure level, risk to groundwater etc. This 'candidates for substitution' process will last up to 7 years.

On a more positive note, a limited derogation may be available for continued approval of substances that breach some of the 'cut-off' criteria where no alternatives are available, and until they are developed. Extended data protection for minor crops means products with a number of minor use approvals will get longer patent protection.

For pesticides approval, the EU will be split into 3 zones and a faster more equitable in-zone registration system is planned with 'mutual recognition' between countries in a zone being the norm. The UK will be in the Central Zone along with Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovak Republic and Slovenia.

The effects of the legislation will be reviewed every 5 years with the power to amend and reduce these effects where agreed.

The other legislation passed on 13 Jan 2009 was the Sustainable Use Directive. This essentially requires a 'National Action Plan' to minimise pesticides use, compulsory sprayer testing, training for agronomists and spray operatives and also options for each Member State to introduce pesticides taxes, prior notification and extended buffer zones. Much of this is already in place in the UK

[http://www.pesticides.gov.uk/uploadedfiles/Web\\_Assets/PSD/Outcomes\\_paper\\_-\\_summary\\_impact\\_assessment\\_\(Jan\\_09\).pdf](http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/Outcomes_paper_-_summary_impact_assessment_(Jan_09).pdf)

In addition, this paper will include HDC work on behalf of members with regard to Specific Off Label Approvals and other minor use issues.