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The Biocidal Products Regulation

Note: this is an updated version of the original briefing which reflects the current position. The changed text is in italics.

What are biocides?

Biocides are defined as active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

Biocides uses and products are very diverse, being widely used to protect

- disinfectants - for home and industrial use;
- preservatives - for manufactured and natural products;
- pest control products;
- other biocidal products, e.g. vertebrate control and other specialized products

Those products regulated under certain other European legislation are not included as biocides e.g. pesticides, veterinary medicines. The main agricultural uses of biocides would be rodenticides, some disinfectants and teat dips.

What is being proposed?

The European Commission are proposing that a new Biocides Regulation to replace the existing Directive 98/8/EC and published its proposals in June 2009. The current Directive has seen only 40 actives reach the EU list after 10 years causing the review project to be extended to 2018. Very few products are currently authorised, there have been high compliance costs and many actives and products to have been withdrawn for commercial reasons. Hence a review of the Directive is required. In addition changes are also required to bring the biocides legislation in line with the new pesticides legislation and REACH. This will involve the introduction of cut-off criteria and a substitution process similar to pesticides.

Where are we in the process?

This comes under the co-decision process requiring a proposal to be agreed between the Parliament (the elected MEPs) and the Council (representing the Member states). After publication of the initial Commission proposals work is delegated to specific Parliamentary Committees then forwarded to the full parliament. This then passes on to the Council. If agreement is reached then the legislation is published. If not it enters a second round aimed at finding compromise. Currently the proposal is at the committee stage. The lead committee is the Environment Committee and they debated the issue in April and *voted on it on 3rd June. Plenary (the full Parliament) is currently scheduled for September* with a co-decision agreement targeted for 2011 and application from 2013

So what is the concern?

The original concern was over the potential impact on rodenticides. The introduction of the same cut-off criteria as have been introduced in the new pesticides legislation would have seen 95% of rodenticides fail the cut-off criteria leaving very few options left on the market. A derogation to allow key biocides to stay on the market in the absence of alternative control options specifically did not apply to rodenticides.

A large lobbying campaign by the industry raised our concerns and potential impacts of this. The rapporteur recognised the concerns and eventually a compromise amendment was agreed and accepted by the Environment Committee. This amendment allows use in the following conditions:

- *Exposure is negligible e.g. used in closed systems or in other conditions excluding contact with humans;*
- *the active substance is necessary to prevent or control a serious danger to public or animal health or to the environment to food and feed safety, or to the public interest and that there are no effective alternative substances or technologies available;*
- *The use of any biocidal product shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment is minimised.*

This was accepted at the recent vote. This amendment represents the best outcome possible from the situation.

What action is required now and what happens next?

Now the compromise has been accepted no further action is required on rodenticides. It is expected that plenary will accept the Environment Committee report.

Additional facts about rats

- They are responsible for 50% of farm fires in the UK at a cost of £28 million/year due to gnawing electric cables
- 130 million people could be fed each year on the food destroyed by rats
- Rats carry about 40 diseases with Schistosomiasis alone estimated to infect as many as 200 million people worldwide