Biocidal products for non-agricultural uses: common rules for national authorisations

1993/0465(COD) - 10/02/2011 - Follow-up document

The Commission presents a proposal for a Council Directive amending Directive 98/8/EC of the European Parliament and of the Council so as to include creosote as an active substance in Annex I. In accordance with the requirements of Directive 98/8/EC on biocidal products, a work programme was carried out concerning the review of all active substances contained in biocidal products already on the market on 14 May 2000 (existing active substances). Creosote was identified as an existing active substance and evaluated in the context of that work programme.

In the Commission's view, the conclusions of the evaluation of creosote are that **the conditions for the inclusion of the substance in Annex I are met under certain conditions**. Accordingly, the Commission submitted a draft Directive for vote in the Committee established under Directive 98/8/EC. **The Committee did not deliver a favourable opinion** on the draft Directive in its meeting on 17 December 2010. Thus in accordance with the procedure set out in Article 5(a) of Decision 1999/468/EC this proposal for a Council Directive is submitted to Council and forwarded to the European Parliament.

It appears from the assessment report that wood preservatives containing creosote may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, when applied on wood in some of the scenarios evaluated. Furthermore, there were strong indications in the stakeholder consultation in 2008 that there are considerable socio-economic benefits of using creosote in certain applications. Life cycle analyses published in the context of the consultation have suggested that, in certain cases, no appropriate alternatives to creosote less damaging to the environment exist. However, for certain wood use scenarios presented in the assessment report, **unacceptable risks for the environment were identified in the risk assessment**.

Furthermore:

- creosote is considered to be a non-threshold carcinogen and is classified as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008;
- creosote, which is a mixture of hundreds of compounds, contains mainly polycyclic aromatic hydrocarbons ('PAHs'). Some of these have been considered by the Committee for Risk Assessment of the European Chemicals Agency as persistent, bioaccumulative and toxic ('PBT'; anthracene) or very persistent and very bioaccumulative ('vPvB'; fluoranthene, phenanthrene and pyrene) in accordance with the criteria set out in Regulation (EC) No 1907/2006 (REACH);
- PAHs are listed as substances subject to release reduction provisions in the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants ('POPs') and in Annex III to Regulation (EC) No 850/2004;
- **Directive 2000/60/EC** on water policy identifies PAHs as priority hazardous substances, from which pollution of surface waters through discharge, emission or loss must cease or be phased out.

The Commission considers that the conclusions of the evaluation of creosote are that the conditions for the inclusion of the substance in Annex I are met under certain conditions. These are as follows:

- biocidal products containing creosote may only be authorised for uses where the authorising Member State, based on an analysis regarding the technical and economic feasibility of substitution which it shall request from the applicant, as well as on any other information available to it, concludes that no appropriate alternatives are available. Those Member States authorising such

products in their territory shall no later than 31 July 2016 submit a report to the Commission justifying their conclusion that there are no appropriate alternatives and indicating how the development of alternatives is promoted. The Commission will make these reports publicly available;

- the active substance is to be subject to a comparative risk assessment in accordance with Article 10 (5)(i) before its inclusion in Annex I is renewed;
- when assessing the application for authorisation of a product, Member States shall assess those uses and those risks to environmental compartments and populations that have not been representatively addressed at the Union level risk assessment;

Member States shall ensure that authorisations are subject to the following conditions:

- creosote may only be used under the conditions mentioned in entry No 31 in Annex XVII to Regulation (EC) No 1907/2006 (REACH);
- creosote shall not be used for the treatment of wood intended for those uses referred to in point 3 of the second column of entry No 31 in Annex XVII to REACH;
- appropriate risk mitigation measures shall be taken to protect workers, including downstream users, from exposure during treatment and handling of treated wood in compliance with REACH and Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens mutagens at work (Sixth individual Directive);
- appropriate risk mitigation measures must be taken to protect soil and aquatic compartments. In particular, labels and safety data sheets of products authorised shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water and that any losses must be collected for re-use or disposal.