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No. Cion prop.:	11063/09 ENV 440 MI 246 AGRI 267 CHIMIE 50 CODEC 849 - COM(2009) 267 final
Subject:	Proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products - Progress report

1. The Commission adopted the above-mentioned proposal in June 2009.

The **aim** of the proposal is to revise and replace Directive 98/8/EC concerning the placing of biocidal products on the market, to tackle the identified operational weaknesses of the existing regulatory framework, to improve and update certain elements of the authorisation and mutual recognition system and to prevent future problems.

Concretely, the proposed Regulation should result in greater harmonisation, in particular since its rules would be directly applicable and in simplification concerning the procedures. It would also make it possible to authorise some types of biocidal products directly at the EU level rather than going through a system of national authorisation followed by mutual recognition. The scope of the proposed Regulation would be significantly extended, compared to the existing Directive, to cover the placing on the market of treated materials and articles as well as the use of biocidal products. The proposal would clarify the rules on data protection and reduce animal testing by requiring the sharing of data involving animal tests.

The Council held a policy debate on certain key issues at its meeting on 22 December 2009.

Adoption of the European Parliament's first-reading opinion is not expected before the second half of 2010.

2. The Working Party on the Environment began examining the proposal in July 2009 and has continued examining it on a regular basis since (on a total of 12 separate days during the first semester of 2010). By the end of the semester it will have discussed all of the Articles of, and some of the Annexes to, the proposed Regulation. The Presidency has made a number of suggestions to clarify or modify the text in the light of delegations' comments. The revised text is annexed to document 6564/1/10 REV 1 *.

3. The Committee of Permanent Representatives took note of the progress report at its meeting on 28 May 2010.

4. In addition to the improvements made to the **drafting** of the Regulation, discussions also indicate broad agreement on the following **principles**:

   – that the new instrument should be a **Regulation** and, therefore, be directly applicable in all Member States;

* A REV 2 should be issued shortly.

- on the need to extend the **exclusion criteria** for biocidal substances to some key environmental criteria;
- on the desirability of establishing a **centralised Union authorisation** procedure for some biocidal products;
- on the need for clear and efficient procedures for the **mutual recognition** of national authorisations, avoiding undue differences between national authorisations;
- that articles or materials with a primary biocidal function should be authorised as biocidal products, while articles or materials **treated** with or incorporating biocidal products but without a primary biocidal function should be regulated in a lighter manner;
- on the need to avoid unnecessary **animal testing** through **data waiving and data sharing;** and
- that, while Member States should be free to set the amount of fees, there is a need for a harmonised structure of fees.

5. While there is support for the system of **Union authorisations**, there are differences in views on the scope of the system and the relevant decision-making procedures. With respect to scope, there seems to be a preference to include specific product types (e.g., in-can preservatives, metal-working fluids).

6. Several **areas of disagreement** remain at this stage, in particular regarding the role of the European Chemicals Agency (**ECHA**), specific procedures to encourage the placing on the market of **low-risk products** and on what measures, if any, should be taken to deal with "**free-riders**" (companies that place substances and products on the market without having contributed to the costs of their evaluation).