Position Paper

UEAPME[1] comments on the Proposal for a Regulation concerning the placing on the market and use of biocidal products (Doc. 2009/0776- COD)

UEAPME finds in the Proposal several positive elements in comparison with Directive 98/8/EC. The choice of the juridical form (Regulation instead of Directive) both as a general framework as well as specific issues, which will have a relevant impact on European SMEs. Nevertheless, UEAPME regrets with major concern that no real steps forward have been taken with respect to the crucial point of data sharing. In this document, we present an overview of the main points of concern of our members.

DATA SHARING

It is since many years that UEAPME has presented to the European authorities, the strong negative impact on SMEs of the actual rules on the data sharing and data compensation for existing active ingredients. It seems that nothing has substantially changed in the Proposal for Regulation issued from the Commission.
If compared with Directive 98/8/EC, it is quite clear that the Articles of Chapter XI made just a very poor improvement on this crucial item. The obligation not to repeat studies on vertebrate animals and the subsequent obligation of data sharing and costs has its grounds on Directive 86/609/EEC regarding the care and use of animals for experimental procedures. The improvement is therefore due to fully agreed ethic principles but which cannot be showed as a "courtesy" to support SMEs. Furthermore it has to be underlined that the Proposal for a Regulation, like Directive 98/8/EC, foresees the longest data protection period from first authorization – 15 years for new substances and 10 years for existing ones – in comparison with any other legislation which regulates similar fields (REACH, Plant Protection Products, Human Pharmaceuticals, Veterinary Medicines).

Data protection periods (years):

Data Protection	Biocides	REACH	PPP	Human medicines	Veterinary medicines
First authorization new active ingredients	15 (Compulsory data sharing for vertebrate studies)		10	10	10
First authorization existing active ingredients	10 (Compulsory data sharing for vertebrate	Compulsory data sharing for all studies	5 (Compulsory data sharing for vertebrate	---	---

[1] UEAPME subscribes to the European Commission's Register of Interest Representatives and to the related code of conduct as requested by the European Transparency Initiative. Our ID number is 55820581197-35.

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	studies)		studies)		
Renewal/Review	5 (Compulsory data sharing for vertebrate studies)	-	5 (Compulsory data sharing for vertebrate studies)	---	---

In spite of this very long period of time, the current Proposal grants a further protection for renewal and review of authorizations; if considered for new active ingredients this data protection period even overlaps with the existing protection, being authorizations for biocidal products granted for a 10 year period. As already expressed in several occasions, this ruling of data protection and data sharing, grants to data owners a power substantially unlimited creating a clear dominant position. UEAPME therefore asks that following amendments are introduced in the Proposal:

a) compulsory data sharing for all data, and not only those related to vertebrate studies, for existing active ingredients;
b) withdrawal of data protection for studies supplied for renewal or review of an authorization;
c) reduction of data protection period to 10 and 5 years respectively for new and existing active substances;
d) definition at EU level of fair criteria for data compensation;
e) definition at EU level of clear cut-off criteria to establish which data effectively deserve a protection.

FEES

UEAPME welcomes the adoption in the Proposal for Regulation of a harmonized structure and reduced fees for SMEs, criterion introduced in the EU by REACH and to be adopted shortly by other sectors. In fact, high fee costs have already blocked some SMEs to approach the notification of existing substances, thus sometimes being kept out from the market because of their low profitability for big research-based industry but of real interest for both SMEs and consumers.

High concern is nevertheless felt by producers in the introduction of an annual fee, for which no justification is found. UEAPME therefore asks to remove from the text Paragraph 2, point d) of Art. 70.

CENTRALIZED PROCEDURES

The introduction of a centralized procedure for authorization of new active ingredients or low risk products gives rise to different opinions. Basically, to simplify: on one side it is seen as an additional opportunity granted to multinational companies to enter the whole EU market. On the other side, it could be seen as the possibility to approach the same procedure for low risk products and maybe to obtain from big industry some more space left for existing substances because of their main interest in the new products. UEAPME however prefers to analyse this point further and therefore postpones a final deliberation on this topic.

MUTUAL RECOGNITION PROCEDURE

Better definition of mutual recognition procedures has been very much appreciated by SMEs. A smooth functioning of this mechanism allows also SMEs to envisage opportunities even outside of their national markets without duplicate efforts and costs, which are already so high. UEAPME therefore supports the current definitions of Chapter VI.

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SIMPLIFICATION

Without going now in details SMEs welcome a simplification of the system and of authorization procedures, as well as more clear criteria for waiving of data requirements. In fact, in small and medium- sized companies, personnel to be exclusively dedicated to regulatory matters is in most cases reduced to few units, sometimes even just a person. Besides, very often SMEs outsource this service to professionals and consultants. The simplification of dossiers and procedures allow to this kind of companies to reduce regulatory costs and instead invest, for instance, in improving formulations or plants.

SUBSTITUTION PRINCIPLE AND COMPARATIVE ASSESSMENT

All industry, both large research-based companies and SMEs generic companies, is very much concerned about the above principle/criteria. In addition, SMEs consider that these items will produce a further reduction of the generic substances availability, already substantially reduced by the Review Program, with a heavy impact on their own activity. It is clear that these elements will not be removed by the Proposal for a Regulation but UEAPME wants to stress the need to manage them with high care and caution.

CONCLUSIONS

UEAPME confirms the need to improve the text of the Proposal in order to amend the parts which strongly affect SMEs, in particular those concerning data protection and data sharing. Without the necessary amendments, the current Proposal may cause the disappearance of companies now working in the area of Biocides.

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