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

1993/0465(COD) - 08/10/2008 - Follow-up document

The aim of this report is to discuss the implementation of Directive 98/8/EC and the review programme referred to in Article 16(2), over the period from 14 May 2000 to 1 March 2008. It is noted, however, that the implementation of a significant part of the Directive's provisions has not started. Notably, there have been no authorisations of biocidal products yet. The report includes the situation in the 10 Member States who joined the EU on 1 January 2004, but does not cover the situation in Bulgaria or Romania.

Progress made under the review programme to date: at the end of the first phase of the review programme, the industry had identified 964 substances as active ingredients of biocidal products that were present on the market before 14 May 2000. Of these, 416 active substances were notified for evaluation in one or more product-types. 548 (about 60%) of the identified substances were not supported and were subsequently phased-out by 1 September 2006. It is estimated that these active substances were used in only 13%-33% of the biocidal products on the market. By 1 March 2008, half of the initially notified active substance/product-type combinations have been withdrawn from the review programme

Ongoing work under the review programme: the original timetable of the review programme (14/05 /2010) was based on the assumption that two years would suffice from submission of the dossier by the participant to adoption of a decision on the inclusion of an active substance. In practice this proved impossible to achieve. No active substance has been evaluated to-date in less than three years and the average period of evaluation seems to be closer to approximately four to five years so far. The Commission discusses the factors responsible for the slower than scheduled pace of the review programme. It is estimated that the last decisions on the remaining active substances will be taken only in **2014.**

The report goes on to discuss issues such as low-risk products, basic substances, frame formulations and data protection.

Conclusion: the Directive has set the foundations for improving environmental and public health in relation to biocidal products. During a five year effort before the effective start of the active substance review in 2004, the Commission has inventoried the European biocides market and put into place a structured procedure for the assessment and evaluation of the existing active substances. Although it has not been possible to meet the time lines originally envisaged, progress has been similar to if not faster than other comparable regulatory systems, such as for plant protection products (Directive 91/414/EEC) or existing chemical substances (Regulation (EC) n° 793/93).

The review programme will not be finalised by 14/05/2010, which is also the date by which the national rules for the placing on the market of biocidal products will cease to apply. Allowing the transitional period to elapse without completing the review programme for active substances would mean that the harmonised rules of the Directive about product authorisation could not apply for all the biocidal products already on the market. If neither set of rules – harmonised or national – could apply, there would be a legal void with regard to the placing on the market of biocidal products. This could have negative effects on public health and would have severe adverse economic effects on all companies operating in the biocides sector. Therefore, this paper is accompanied by a proposal for the revision of the Directive that would extend the review programme, the transitional period, and certain provisions on data protection that accompany this period for an additional three years (COD/2008/0188).

The substantive revision of the Directive: the Commission is also considering:

- the simplification and adaptation of the scope of the Directive;
- a tiered approach to data requirements that will take proportionality into consideration;
- a simplification of the data protection rules, including some mandatory data-sharing;
- greater harmonisation or co-ordination of fee structures;
- improvement of the simplified procedures;
- measures to facilitate complying with the Directive for SMEs, and measures to
- encourage innovation;
- measures to imptove the internal market in biocidal products.