Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (repealed)

Article 10

Inclusion of an active substance in Annexes I, IA or IB

1 In the light of current scientific and technical knowledge, an active substance shall be included in Annex I, Annex IA or IB for an initial period not exceeding 10 years if it may be expected that

— biocidal products containing the active substance,

— low-risk biocidal products complying with the definition in Article 2(1)(b),

— commodity substances complying with the definition in Article 2(1)(c),

will fulfil the conditions laid down in Article 5(1)(b), (c) and (d), taking into account, where relevant, cumulation effects from the use of biocidal products containing the same active substances.

An active substance cannot be included in Annex IA if it is classified according to Directive 67/548/EEC as:

— carcinogenic,

— mutagenic,

— toxic for reproduction,

— sensitising, or

— is bioaccumulative and does not readily degrade.

Where appropriate, the entry of an active substance in Annex IA shall refer to the concentration ranges between which the substance can be used.

2 Inclusion of an active substance in Annexes I, IA or IB shall, where appropriate, be subject to the following:

(i) requirements on:

(a) the minimum degree of purity of the active substance,

(b) the nature and maximum content of certain impurities,

(c) product type in which it may be used,

(d) manner and area of use,

(e) designation of categories of users (e.g. industrial, professional or non-professional),

(f) other particular conditions from the evaluation of the information which has been made available in the context of this Directive;

(ii) the establishment of the following:

(a) acceptable operator exposure level (AOEL), if necessary,

(b) where relevant, an acceptable daily intake for man (ADI) and a maximum residue limit (MRL),

(c) fate and behaviour in the environment and impact on non-target organisms.

3 The inclusion in Annex I, IA or IB of an active substance shall be restricted to those product types in Annex V for which relevant data have been submitted in accordance with Article 8.

4 The inclusion of an active substance in Annex I, IA or IB may be renewed on one or more occasions for periods not exceeding 10 years. The initial inclusion, as well as any renewed inclusion, may be reviewed at any time if there are indications that any of the requirements referred to in paragraph 1 are not longer satisfied. Renewal may, where necessary, be granted only for the minimum period necessary to complete a review, where an application has been made for such renewal, and shall be granted for the period necessary to provide further information requested in accordance with Article 11(2).

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(i) An entry of an active substance in Annex I and, where relevant, IA or IB may be refused or removed,

— if the evaluation of the active substance in accordance with Article 11(2) shows that, under normal conditions under which it may be used in authorised biocidal products, risks to health or the environment still give rise to concern, and

— if there is another active substance on Annex I for the same product type which, in the light of scientific or technical knowledge, presents significantly less risk to health or to the environment.

When such a refusal or removal is considered, an assessment of an alternative active substance or substances shall take place to demonstrate that it can be used with similar effect on the target organism without significant economic and practical disadvantages for the user and without an increased risk for health or for the environment.

The assessment shall be circulated in accordance with the procedures in Article 11(2) for decision in accordance with the procedures laid down in Articles 27 and 28(3).

(ii) The refusal or removal of an Annex I and, where relevant, IA or IB entry shall be carried out under the following conditions:

1. the chemical diversity of the active substances should be adequate to minimise occurrence of resistance in the target organism;

2. it should be applied only to active substances which, when used under normal conditions in authorised biocidal products, present a significantly different level of risk;

3. it should be applied only to active substances used in products of the same product type;

4. it should be applied only after allowing the possibility, where necessary, of acquiring experience from use in practice, if it is not already available;

5. the complete data dossiers of the evaluation serving or having served for entry in Annex I, IA or IB shall be put at the disposal of the Committee referred to in Article 28(3).

(iii) A decision to remove an Annex I entry shall not have immediate effect but shall be delayed for a period of up to a maximum of four years from the date of that decision.