

WORLD TRADE ORGANIZATION

G/SPS/N/EEC/213

4 September 2003

(03-4630)

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Member to Agreement notifying: <u>EUROPEAN COMMUNITIES</u> If applicable, name of local government involved:
2. Agency responsible: Commission of the European Communities. Directorate-General Environment, Directorate C – Air quality, Climate change, Chemicals & Biotechnology
3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): All active substances used in biocidal products as defined in Directive 98/8/EC
4. Regions or countries likely to be affected, to the extent relevant or practicable: Member States of the European Communities (EC) and third countries exporting the products concerned to the EC.
5. Title, language and number of pages of the notified document: Draft Commission Regulation (EC) No .../... of [...] on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, and amending Regulation (EC) No 1896/2000. (113 pages, available in English (text and annexes), Danish, German, Greek, Spanish, French, Italian, Dutch, Portuguese, Finnish, Swedish (text only).
6. Description of content: Directive 98/8/EC lays down in Article 16 that the Commission and the Member States have to review all existing active substances in biocidal products within a 10-year programme of work with regard to the safety of their use for human health and the environment with a view of their possible inclusion into Annex I or IA to the Directive. Once the review of an active substance is completed, biocidal products containing it will have to be authorised in the Member States. According to Article 5 of the Directive, Member States can only authorise biocidal products, if the active substance (or substances) is listed in Annex I or IA and if the product, among others, is: (i) sufficiently effective (ii) has no unacceptable effects on the target organisms, such as unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates (iii) has no unacceptable effects itself or as a result of its residues, on human or animal health, directly or indirectly (through drinking water, food or feed, indoor air or consequences in the place of work) or on surface water or groundwater, (iv) has no unacceptable effect itself, or as a result of its residues, on the environment having particular regard to the following considerations:

<ul style="list-style-type: none"> - its fate and distribution in the environment, particularly contamination of surface waters (including estuarine and seawater), groundwater and drinking water; - its impact on non-target organisms <p>(v) the nature and quantity of its active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants, and its residues of toxicological or environmental significance, which result from authorised uses, can be determined according to the relevant requirements in Annex IIA, IIB, IIIA, IIIB, IVA or IVB to the Directive</p> <p>(vi) its physical and chemical properties have been determined and deemed acceptable for purposes of the appropriate use, storage, and transport of the products</p> <p>Regulation 1896/2000 established the first phase of this review programme. The new draft Regulation establishes all necessary provisions for the second phase. For substances not notified, no dossiers will be provided to allow their evaluation. It is therefore not possible to demonstrate that their continued use meets the requirements established by Directive 98/8/EC and their marketing and use will have to be phased out after a period of grace of 3 years, unless a complete dossier will be prepared during that period of grace. The draft Commission Regulation provides for the detailed rules for the implementation of the second phase of the programme of work for the systematic examination of all active substances already on the market in biocidal products when Directive 98/8/EC entered into force (on 14 May 2000).</p> <p>Annex I contains the exhaustive list of existing active substances (i.e. those used in biocidal products on 14 May 2000 in the EC).</p> <p>Annex II contains the list of notified existing active substances (i.e. those for which operators will prepare comprehensive dossiers allowing for the evaluation of the safety of their use regarding human health and the environment with a view of their inclusion into one of the Annexes of the Directive. The Regulation further lays down all necessary details regarding the submission of dossiers, including the schedule for their submission and evaluation (Annex V).</p> <p>Annex III contains the list of 'only-identified' substances (i.e. those for which, at the current time no operator expressed an interest to prepare a dossier or have them included in the Annexes of the Directive). Marketing and use of these substances for biocidal purposes will have to cease as of 1 September 2006. However if operators deem this necessary in the future, they can prepare dossiers for these substances and request inclusion into one of the Annexes of the Directive at a later stage.</p>	<p>7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input checked="" type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input checked="" type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.</p> <p>8. International standard, guideline or recommendation: <input type="checkbox"/> Codex Alimentarius Commission, <input type="checkbox"/> Office International des Epizooties, <input type="checkbox"/> International Plant Protection Convention, <input checked="" type="checkbox"/> None</p> <p>If an international standard, guideline or recommendation exists, give the appropriate reference and briefly identify deviations:</p>
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<p>9. Relevant documents and language(s) in which these are available: Directive 98/8/EC of the European Parliament and the Council on the placing of biocidal products on the market (OJ L 123, 24.4.1998, page 1)</p> <p>Commission Regulation 1896/2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC on biocidal products (OJ L 228, 8.9.2000, page 6)</p> <p>Further information can be found on the Commission's websites at: http://europa.eu.int/comm/environment/biocides/index.htm and http://ecb.jrc.it/biocides</p>
<p>10. Proposed date of adoption: End October 2003</p>
<p>11. Proposed date of entry into force: Mid November 2003</p>
<p>12. Final date for comments: 24 October 2003</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> EC notification authority, <input type="checkbox"/> National enquiry point, or address, fax number and E-mail address (if available) of other body:</p>
<p>13. Texts available from: <input type="checkbox"/> National notification authority, <input checked="" type="checkbox"/> EC enquiry point, or address, fax number and E-mail address (if available) of other body:</p>