Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances (Text with EEA relevance) (repealed)

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[(1)], and in particular Article 6(1) thereof,

Whereas:

(1) Commission Regulations (EC) No 1112/2002[(2)] and (EC) No 2229/2004[(3)] lay down the detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes the active substances listed in the Annex to this Directive.

(2) By Commission Regulation (EC) No 1095/2007[(4)] a new Article 24b was inserted into Regulation (EC) No 2229/2004 to allow active substances for which there are clear indications that it may be expected that they do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, to be included in Annex I to Directive 91/414/EEC without detailed scientific advice from the European Food Safety Authority (EFSA) having been sought.

(3) For the active substances listed in the Annex to this Directive the Commission examined in accordance with Article 24a of Regulation (EC) No 2229/2004 the effects on human, animal health, groundwater and the environment for a range of uses proposed by the notifiers, with the conclusion that those active substances satisfy the requirements of Article 24b of Regulation (EC) No 2229/2004.

(4) In accordance with Article 25(1) of Regulation (EC) No 2229/2004 the Commission has submitted draft review reports for the active substances listed in the Annex to this Directive to the Standing Committee on the Food Chain and Animal Health, for examination. Those reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 11 July 2008 in the format of the Commission review reports. In accordance

with Article 25a of Regulation (EC) No 2229/2004 the Commission is to request the EFSA to deliver its view on the draft review reports by 31 December 2010 at the latest.

(5) It has appeared from the various examinations made that plant protection products containing the active substances listed in the Annex to this Directive may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which have been examined and detailed in the Commission review report. It is therefore appropriate to include in Annex I to that Directive the active substances listed in the Annex to this Directive, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

(6) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(7) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing authorisations of plant protection products containing the active substances listed in the Annex to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations, in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.

(8) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92[(5)] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the directives that have been adopted until now amending Annex I.

(9) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(10) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

(**1**) OJ L 230, 19.8.1991, p. 1.

(**2**) OJ L 168, 27.6.2002, p. 14.

(**3**) OJ L 379, 24.12.2004, p. 13.

(**4**) OJ L 246, 21.9.2007, p. 19.

(**5**) OJ L 366, 15.12.1992, p. 10.