



EUROPEAN COMMISSION
HEALTH AND CONSUMER DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants, pesticides

Nicotine
SANCO/2686/08 – rev. 0
8 August 2008

FINAL

Review report for the active substance Nicotine
Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting
on 26 September 2008
in support of a decision concerning the non-inclusion of Nicotine
in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant
protection products containing this active substance

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of Nicotine, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EC) No 1112/2002⁽¹⁾ laying down the detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, and Regulation (EC) No 2229/2004⁽²⁾ have laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Nicotine is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 in Regulation (EC) No 1112/2002, J. A. Humphrey Agriculture notified to the Commission of their wish to secure the inclusion of the active substance Nicotine in Annex I to the Directive.

In Annex I to Regulation (EC) No 2229/2004 the Commission, designated United Kingdom as rapporteur Member State to carry out the assessment of Nicotine on the basis of the dossiers submitted by the notifier. In Article 12 of Regulation (EC) No 2229/2004 the Commission specified furthermore that the deadline for the notifier with regard to the submission to the rapporteur Member States of the dossiers required, as well as for other parties with regard to further technical and scientific information was 30 June 2005.

¹ OJ No L 168, 27.06.2002, p.14.

² OJ No L 379, 24.12.2004, p.13. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.09.2007, p. 19).

J.A. Humphrey Agriculture submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore, J.A. Humphrey Agriculture was considered to be the sole data submitter.

In accordance with the provisions of Article 21(1) of Regulation (EC) No 2229/2004, United Kingdom submitted on January 2008 to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of Nicotine in Annex I to the Directive.

In accordance with the provisions of Article 24 of Regulation (EC) No 2229/2004 as last amended by Regulation (EC) 1095/2007, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by J.A. Humphrey Agriculture being the sole data submitter, on 7 April 2008 by making it available.

In accordance with the provisions of Article 24a of Regulation 2229/2004 as last amended by Regulation (EC) 1095/2007 the Commission examined the draft assessment report, the recommendations by the rapporteur Member State and the comments received from other Member States in consultation with experts from Member States.

In accordance with the provisions of Article 24f and Article 25 (1) a of Regulation (EC) No 2229/2004 as last amended by Regulation (EC) 1095/2007, the Commission referred on 26 September 2008 a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 26 September 2008.

The present review report contains the conclusions of the final examination by the Standing Committee.

2. Purposes of this review report

This review report including the background documents has been developed and finalised in support of the Decision **2009/9/EC**³ concerning the non-inclusion of Nicotine in Annex I to Directive 91/414/EEC.

In accordance with the provisions of Article 26 of Regulation (EC) No 2229/2004, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion of this examination, based on the information available and the proposed conditions of use, is that:

- **the information available is insufficient** to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC in particular with regard to

³ Commission Decision 2009/9/EC (OJ L 5, 9.1.2009, p. 7)

- the substantial lack of data to establish an Acceptable Operator Exposure Level and assess the risk to operators, workers and bystanders
- the substantial lack of data to assess the risk to consumers
- the substantial lack of data to assess the risk to non target organisms.

- **concerns were identified with regard to**

- toxicity for human health
- toxicity for aquatic organisms.

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general the requirements laid down in Article 5 (1) (a) and (b) of Council Directive 91/414/EEC.

Nicotine should therefore not be included in Annex I to Directive 91/414/EEC.