



EUROPEAN COMMISSION
HEALTH & CONSUMER DIRECTORATE-GENERAL

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

Butralin

SANCO/1054/08 – rev. 0

25 April 2008

FINAL

Review report for the active substance **butralin**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting
on 20 May 2008

in support of a decision concerning the non-inclusion of butralin 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 butralin, 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 451/2000⁽¹⁾ laying down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1490/2002⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. butralin is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 10 of Regulation (EC) No 451/2000, Nufarm notified to the Commission of their wish to secure the inclusion of the active substance butralin in Annex I to the Directive.

Under Annex I to Regulation (EC) No 1490/2002, France has been designated by the Commission as rapporteur Member State to carry out the assessment of butralin on the basis of the dossiers submitted by the notifier. In Regulation (EC) No 1490/2002 the Commission specified furthermore that the deadline for the notifier with regard to the submission to the rapporteur Member States of the dossiers required under Article 7(1) of Regulation (EC) No

¹ OJ No L 55, 29.02.2000, p.25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p.32).

² OJ No L 224, 21.8.2002, p.23. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.09.2007, p. 19).

1490/2002, as well as for other parties with regard to further technical and scientific information was 30 November 2003.

Nufarm 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 Nufarm was considered to be the sole data submitter.

In accordance with the provisions of Article 10(1) of Regulation 1490/2002, France submitted on 20 February 2006 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 butralin in Annex I to the Directive. Moreover, in accordance with the provisions of Article 10(2) of Regulation (EC) 1490/2002, the Commission and the Member States received also the summary dossier on butralin from the notifier.

In accordance with the provisions of Article 11 of Regulation (EC) No 1490/2002 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 Nufarm being the sole data submitter, on 21 July 2006 by making it available.

In accordance with the provisions of Article 11a of Regulation 1490/2002 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 a certain number of Member States.

In accordance with the provisions of Article 11f and Article 12(1) a of Regulation (EC) No 1490/2002 as last amended by Regulation (EC) 1095/2007, the Commission referred on 20 May 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 20 May 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 **2008/819/EC**³ concerning the non-inclusion of butralin in Annex I to Directive 91/414/EEC.

In accordance with the provisions of Article 13 of Regulation (EC) No 1490/2002, 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 Commission Decision 2008/819/EC (OJ L 285, 29.10.2008, p. 15)

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
 - the substantial lack of data to assess the risk to aquatic organisms, in particular with regard to the metabolite DNTBA
 - the substantial lack of data in the field of fate and behaviour
 - the substantial lack of data to assess the risk to small herbivorous mammals

- **concerns were identified with regard to**
 - the operator exposure
 - the toxicity to aquatic organisms
 - the toxicity to some species of non target arthropods

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.

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