



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Ethoxyquin
SANCO/12666/2010 final
28 January 2011

Review report for the active substance **ethoxyquin**

finalised in the Standing Committee on the Food Chain and Animal Health at its meeting
on 28 January 2011

in support of a decision concerning the non-inclusion of ethoxyquin 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 ethoxyquin, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Ethoxyquin is a substance that was covered by the fourth stage 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.

Article 24(e) of Commission Regulation (EC) No 2229/2004 laying down detailed rules for the implementation of the fourth stage offered the possibility for the notifier to withdraw, under specific conditions, its support for the active substance. The sole notifier withdrew their support and ethoxyquin was not included through Commission Decision 2008/941/EC¹.

In accordance with Article 13 of Regulation (EC) No 33/2008, XEDA International S.A., the sole data submitter presented, on 12 June 2009 a request to Germany, the rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

Germany finalised in October 2009 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was sent to the Commission and the European Food Safety Authority on 16 October 2009 and included a recommendation as to not include ethoxyquin in Annex I for the supported uses.

In accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by XEDA International S.A. being the sole data submitter, on 22 October 2009 by making it available.

¹ OJ L 335, 13.12.2008, p. 91–93.

The EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance ethoxyquin (issued on 20 August 2010)²]. This conclusion refers to background document A (draft assessment report and additional report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 21 of Regulation (EC) No 33/2008, the Commission referred 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 28/01/2011.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Decision **2011/143/EU**³ concerning the non-inclusion of ethoxyquin in Annex I to Directive 91/414/EEC.

In accordance with the provisions of Article 22 of Regulation (EC) No 33/2008, this review report will be made available for public consultation by any interested parties.

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

The overall conclusion of this evaluation, 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 toxicological risk assessment for ethoxyquin and its metabolites and for the potentially genotoxic impurity 7 in the technical specification*
 - *the consumer, the operator and the worker risk assessment which could not be conducted (reference values and residue definition could not be set due to the limited toxicological data package)*
 - *the exposure assessment of the environmental compartments via aerial deposition of potentially volatile photolytic transformation products and impurity 7*

² European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance ethoxyquin. *EFSA Journal* 2010;8(9):1710. [38 pp.]. doi:10.2903/j.efsa.2010.1710. Available online: www.efsa.europa.eu/efsajournal.htm

³ OJ L 59, 4.3.2011, p. 71–72.

- *the risk assessment for non-target organisms.*
- **concerns were identified with regard to**
- *consumers, operators and workers, since no residue definition and no reference values could be set for ethoxyquin and its metabolites.*

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

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