



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Indolybutyric acid
SANCO/13559/2011 final
5 May 2011

Review report for the active substance **indolybutyric acid**
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
5 May 2011
in view of the inclusion of indolybutyric acid to Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of indolybutyric acid, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Indolybutyric acid 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. All notifiers withdrew their support and indolybutyric acid was not included through Commission Decision 2008/941/EC¹.

In accordance with Article 13 of Regulation (EC) No 33/2008, the Rhizopon BV as the sole data submitters presented, on 25 May 2009, a request to France, the rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

France finalised in January 2010 their 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 26 January 2010 and included a recommendation as to include indolybutyric acid in Annex I for the supported uses.

The EFSA organised the consultation on the draft assessment report and, in accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, on the additional report by all the Member States as well as by Rhizopon BV, being the sole data submitters, on 27 January 2010 by making it available.

¹ OJ No L 335, 13.12.2008, p. 91.

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008, the Commission asked EFSA to organise a focused consultation of scientific experts from a certain number of Member States, to review the additional report, draft assessment report and the comments received thereon (peer review) and to deliver its conclusion.

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 on the peer review of the pesticide risk assessment of the active substance indolylbutyric acid (issued on 3 September 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 5 May 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 **Directive 2011/28/EU**³ concerning the inclusion of indolylbutyric acid in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing indolylbutyric acid they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

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.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

² Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance indolylbutyric acid. *EFSA Journal* 2010;8(9):1720. [42 pp.] doi:10.2903/j.efsa.2010.1720. Available online: www.efsa.europa.eu/efsajournal.htm.

³ OJ L 60, 5.3.2011, p. 17–20

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

The overall conclusion from the evaluation is that it may be expected that plant protection products containing indolylbutyric acid will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each indolylbutyric acid containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

The following reference values have been finalised as part of this re-evaluation:

ADI	not necessary
ARfD	not necessary
AOEL	0.025 mg/Kg bw/d

The review has established that it is not relevant to establish ADI, ARfD and MRLs for the intended uses.

The above AOEL has been set on the basis of the Additional Report prepared by the RMS. On the basis of this AOEL, acceptable exposure scenarios for operators, workers and bystanders were identified, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC.

4. Identity

The main identity of indolylbutyric acid is given in Appendix I.

The active substance shall comply with the minimum purity of 994 g/kg (see appendix I). At the time of the evaluation no FAO specification was allocated.

The review has established that for the active substance notified by the main data submitter none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-

evaluation process. These endpoints are listed in the conclusion of the EFSA, and at section 3 of this report.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing indolylbutyric acid

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted.

Member States shall pay particular attention to:

- the fact that only uses as plant growth regulator in ornamentals may be authorised;
- the operators and workers safety. Authorised conditions of use shall include the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of indolylbutyric acid in Annex I under the current inclusion conditions.

The concerned Member States shall request the submission of:

- the absence of clastogenicity potential of indolylbutyric acid;
- the vapour pressure of indolylbutyric acid and, consequently, an inhalation toxicity study;
- the natural background concentration of indolylbutyric acid in the soil.

They shall ensure that the applicant provides such studies to the Commission within two years from the entry into force of the Directive of inclusion.

Some other endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. The list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusions.

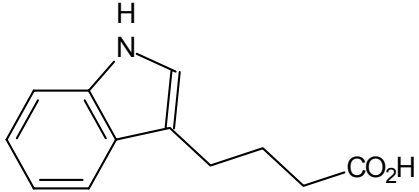
8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for indolylbutyric acid in Annex I of the Directive.

APPENDIX I**Identity
INDOLYLBUTYRIC ACID**

Common name (ISO)	-
Chemical name (IUPAC)	4-(1H-indol-3-yl)butyric acid
Chemical name (CA)	1H-indole-3-butanoic acid
CIPAC No	830
CAS No	133-32-4
EEC No	05-101-5
FAO SPECIFICATION	None
Minimum purity	994 g/kg (combined task force specification)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)	None
Molecular formula	C ₁₂ H ₁₃ NO ₂
Molecular mass	203.2 g/mol
Structural formula	 <p>The structural formula shows a benzene ring fused to an indole ring system. The indole ring has a hydrogen atom attached to the nitrogen atom. A butyric acid chain is attached to the 3-position of the indole ring, consisting of a three-carbon chain ending in a carboxylic acid group (-CO₂H).</p>

APPENDIX II
List of uses supported by available data
INDOLYL BUTYRIC ACID

Crop and/or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment**			PHI (days)	Remarks:
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/ha min max	water l/ha min max	kg as/ha min max		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)	(min)	min max	min max	min max	(l)	(m)
Herbaceous and wooden ornamental plants	-	RHIZOPON AA POWDER 2%	I*	Root growth stimulation of cuttings	AP	20 g/kg	Manually	N.A.	1	N.A.	N.A.	N.A.**	N.A.	N.A.	*restriction to indoor applications , uses treated plants can be grown outdoor in pots and containers. **RMS based his evaluation assessment on 25 mg PPP /cutting

Remarks:	*	For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).	(h)	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(a)	For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)	(i)	g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
	(b)	Outdoor or field use (F), greenhouse application (G) or indoor application (I)	(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants,
	(c)	e.g. biting and suckling insects, soil born insects, foliar fungi, weeds		1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on
	(d)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	season at time of application
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989	(l)	The minimum and maximum number of application possible under practical
	(f)	All abbreviations used must be explained		conditions of use must be provided
	(g)	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	(m)	The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)