EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food Chain
Chemicals, contaminants, pesticides

COMMISSION STAFF WORKING DOCUMENT[1]

Gibberellic acid
SANCO/2613/08 – rev. 3
07 July 2008
10 October 2014[2]

FINAL

Review report for the active substance **gibberellic acid**
Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 October 2008
in view of the inclusion of gibberellic acid in 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 gibberellic acid, 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([3]) 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([4]) have laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Gibberellic acid is one of the existing active substances covered by this Regulation.

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1 Does not necessarily represent the views of the Commission.

2 On 1 June 2012, the Standing Committee on Food Chain and Animal Health took note of the revision of the review report taking into account the EFSA conclusions referred to in points 1, 2, 3, 4 and 5 of this report (cfr. infra) and after the entry into force of Regulation (EC) No 1107/2009. As already stated in Chapter 1 of this review report, documents providing clarifications on the assessment finalised after a decision has been taken shall be considered as background document C and as such they are part of this review report.

On 10 October 2014, the Standing Committee on Plants, Animals, Food and Feed took note of the revision 3 of the review report which includes correct values of ADI and AOEL on the basis of EFSA conclusions referred to in points1, 2, 3, 4 and 5 of this report (cfr. infra) published with amendment on 26 March 2012 replacing earlier version of January 2012.

3 OJ No L 168, 27.06.2002, p.14.

4 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).

In accordance with the provisions of Article 4 in Regulation (EC) No 1112/2002, Aifar Agricola SRL, Fine Agrochemicals Ltd., Nufarm GmbH & Co KG, Sumitomo Chemical Agro Europe SA, Cequisa, Valagro S.p.A., and Gobbi SRL. notified to the Commission of their wish to secure the inclusion of the active substance gibberellic acid in Annex I to the Directive.

In Annex I to Regulation (EC) No 2229/2004 the Commission, designated Hungary as rapporteur Member State to carry out the assessment of gibberellic acid on the basis of the dossiers submitted by the notifiers. In Article 12 of Regulation (EC) No 2229/2004 the Commission specified furthermore that the deadline for the notifiers 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.

EU Gibberellic Acid Task Force submitted by the deadline a common dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore EU Gibberellic Acid Task Force was considered to be the sole data submitter. Members of EU Gibberellic Acid Task Force are: Aifar Agricola SRL, Fine Agrochemicals Ltd., Nufarm GmbH & Co KG, Sumitomo Chemical Agro Europe SA, Cequisa, Valagro S.p.A., and Gobbi SRL.

In accordance with the provisions of Article 21(1) of Regulation (EC) No 2229/2004, Hungary submitted in February 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 gibberellic acid 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 EU Gibberellic Acid Task Force being the sole data submitter, on 22 July 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 24b and Article 25 (1) a of Regulation (EC) No 2229/2004 as last amended by Regulation (EC) 1095/2007, the Commission referred on 28 October 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 28 October 2008.

Regulation (EC) No 1107/2009 repealed and replaced Directive 91/414/EEC and the active substance gibberellic acid is deemed to be approved under that Regulation and included in the Annex to Regulation (EC) No 540/2011.

Finally, in compliance with the provisions of Article 25a of Regulation (EC) No 2229/2004, EFSA delivered its conclusions on gibberellic acid (GA3) (approved as gibberellic acid on 16 December 2011[5]. The Commission referred on 9 March 2012 an updated review report to the Standing Committee on the Food Chain and Animal Health, for examination.

[5] European Food Safety Authority; European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance gibberellic acid. EFSA Journal 2012;10(1):2507. [45 pp.] doi:10.2903/j.efsa.2012.2507. Available online: www.efsa.europa.eu/efsajournal

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 document appendices thereto, has been developed in support of the Directive **2008/127/EC**[6] concerning the inclusion of gibberellic acid in Annex I to Directive 91/414/EEC. The Commission requested EFSA to deliver its view on the draft review report. When the Member States decide on individual plant protection products containing gibberellic acid they shall take into account this review report in accordance with the provisions of Regulation (EC) No 1107/2009, and in particular the provisions of Article 4(1), (2) and (3) of that Regulation and uniform principles laid down in Regulation (EC) No 546/2011.

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 26 of Regulation (EC) No 2229/2004, 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 Regulation (EC) No 1107/2009. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Regulation (EC) No 1107/2009, 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.

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

The overall conclusion from the draft assessment report, the recommendations by the rapporteur Member State and the result of the examination in accordance with the provisions of Article 24a of Regulation No 2229/2004 is that there are clear indications that it may be expected that gibberellic acid does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, as set out in Annex VI of regulation (EC) No 2229/2004 as last amended by Regulation (EC) 1095/2007.

These indications are however subject to compliance with the particular requirements in sections 4 and 5 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EC) No 546/2011, for each gibberellic acid containing plant protection product for which Member States will grant or review the authorisation.

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

6 Commission Directive 2008/127/EC (OJ L 344, 20.12.2008, p. 89)

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 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EC) No 546/2011.

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

ADI: 0.68 mg/kg bw/day,
ARfD: not necessary,
AOEL: 0.68 mg/kg bw/day.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is < 0.1 % of the Acceptable Daily Intake (ADI) (when LOQ value of 0.05 mg/kg considered for grapes) only informative since no MRLs are proposed, based on the EFSA PRIMo Model.

Additional intake from water and products of animal origin are not expected to give rise to intake problems.

Exceedance of the Acute Reference Dose (ARfD) for estimates of acute dietary exposure of adults and toddlers was not calculated as no ARfD was allocated. The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

It has also been 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, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and biological properties

The main properties of gibberellic acid are given in Appendix I.

It has been 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 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EC) No 546/2011, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in EFSA conclusions.

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 gibberellic acid

On the basis of the proposed and supported uses (as listed in Appendix II), no 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, varied or withdrawn.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary on the basis of the EFSA Conclusions of 16 December 2011.

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 main 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 and Articles 59 to 62 of Regulation (EC) No 1107/2009 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 Articles 59 to 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

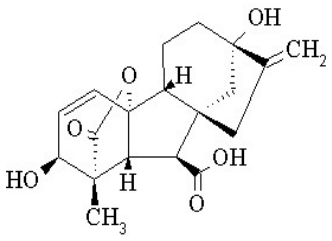
9. Updating of this review report

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 21 or 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the inclusion conditions for gibberellic acid in Annex of the Regulation (EC) No 540/2011.

APPENDIX I

Identity; physical and chemical properties

GIBBERELLIC ACID

Common name (ISO)	Gibberellic acid – GA_3
Chemical name (IUPAC)	(3S,3aS,4S,4aS,7S,9aR,9bR,12S)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenol(1,2-b)furan-4-carboxylic acid *Alt:* (3S,3aR,4S,4aS,6S,8aR,8bR,11S)- 6,11-dihydroxy-3-methyl-12-methylene-2-oxo-4a,6-methano-3,8b-prop-lenoperhydroindenol (1,2-b) furan-4-carboxylic acid
Chemical name (CA)	(1α,2β,4aα ,4bβ,10β)-2,4a, 7-trihydroxy-1-methyl-8-methylenegibb- 3ene-1,10-dicarboxylic acid 1,4a-lactone
CIPAC No	307
CAS No	77-06-5
EEC No	EINECS: 201-001-0
FAO SPECIFICATION	-
Minimum purity	850 g/kg (Gibberellic acid Task Force)
Molecular formula	$C_{19}H_{22}O_6$
Molecular mass	346.37 g
Structural formula	

APPENDIX II
List of uses supported by available data
GIBBERELLIC ACID

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/hl min max	water l/ha min max	g as/ha min max		
Grapes	North and South EU	Berelex	F	PGR	TB	10 % w/w gibberellic acid	spraying	berry sizing 9 mm (BBCH growth stage 75-76) earlier applications at BBCH growth stages 57-65 and 68	1-6	7-12 days	0.125 -6	1000	1.25-60 maximum 280 g/ha	Not relevant	specific rates vary with cultivar and growing conditions

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions