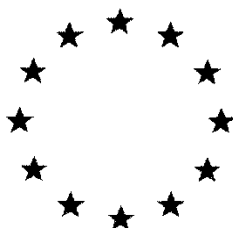


European Commission



**Combined Draft (Renewal) Assessment Report prepared according to
Regulation (EC) N° 1107/2009
and
Proposal for Harmonised Classification and Labelling (CLH Report)
according to Regulation (EC) N° 1272/2008**

GIBBERELLINS (GA4, GA7) Volume 3 – B.3 (AS)

Rapporteur Member State : Slovenia
Co-Rapporteur Member State : Slovakia

Version History

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B.3. DATA ON APPLICATION

Introduction

This document has been prepared to evaluate the European Gibberellins Task Force (Valent Biosciences Corporation (Sumitomo Chemical Agro Europe), Fine Agrochemicals Ltd, Globachem NV) application for EU renewal of the Annex I inclusion of active substance gibberellins (GA4, GA7). The document supplements and updates the corresponding Annex B section of the Draft Assessment Report produced during the first review of gibberellins (2005 - 2011).

Gibberelin has been identified as a presumed low-risk active substance in the Commission working document on the AIR-IV renewal programme (SANTE-2016-10616-rev 8). The EU Gibberellin Task Force (EGTF) proposes that Gibberelin is a low risk active substance according to Regulation (EC) 1107/2009 as amended by Commission Regulation 2017/1432.

In this report studies submitted for the first inclusion of gibberellins in Annex I to Directive 91/414/EEC and for the renewal of the approval of gibberellins have been evaluated.

Previous EU assessment

The dossier to support the first inclusion of gibberellins in Annex I to Directive 91/414/EEC was submitted to Hungary as the Rapporteur Member State in June 2005. The Draft Assessment Report is dated July 2006. Final Addendum to Draft Assessment Report, containing all individually submitted addenda on gibberellins, was compiled by EFSA in October 2011.

Structure of this document

Summaries of available data and overall assessments of each sub-section, as well as the exposure assessments, generally are not included in this document. Instead these parts of the assessment are included in Vol. 1, Level 2. The reason behind this structure is to avoid repetition and facilitate revisions of the assessment. As a result, this Annex B only contains the presentation and evaluation of individual study reports on the active substance.

In each section of this document, the following headings (a)-b)) occur:

a) Previous evaluation (2005-2011)

Under this heading study reports submitted for the first inclusion of gibberellins in Annex I to Directive 91/414/EEC are summarised. These studies have been re-evaluated for the purpose of the renewal in the light of current scientific and technical knowledge. The endpoints from the studies were also re-assessed and if considered relevant, re-calculated. However, full details from each study have not been repeated in this DRAR - therefore this DRAR is not a "stand-alone document" and for full reference sometimes the reader needs to consult the DAR (2005-2011).

b) Evaluation of additional data for the purpose of renewal of Annex I inclusion

Under this heading studies submitted prior to Annex I inclusion, but no evaluation of such material was presented in the form of Addenda to the DAR and studies that were submitted to support the application for renewal of Annex I inclusion are evaluated, i.e. new studies.

B.3.1. USE OF THE ACTIVE SUBSTANCE

Gibberellins (GA4/GA7) is used to aid growth of plants from germination to flower development and maturation. It is used to enhance cell elongation in plants and reduce natural fruit skin russet, and fruit cracking in apple varieties that experience these physiological problems. It also increases fruit set in some pear varieties that experience naturally low levels of fruit set.

B.3.2. FUNCTION

Plant growth regulator.

B.3.3. EFFECTS ON HARMFUL ORGANISMS

Gibberellins (GA4/GA7) is plant growth regulator and does not act against harmful organisms, against weeds, insects, fungi or other pests.

B.3.4. FIELD OF USE ENVISAGED

The active substance gibberellins (GA4/GA7) is present in plant protection product Novagib at a concentration of 10 g/L. Novagib is applied to apples at 2.5 - 5 g a.s./ha (0.25-0.5 L PPP/ha) and to pears at 6 -12 g a.s./ha (0.6-1.2 L PPP/ha).

B.3.5. HARMFUL ORGANISMS CONTROLLED AND CROPS OR PRODUCTS PROTECTED OR TREATED

Gibberellins (GA4/GA7), the active substance in plant protection product Novagib is a plant growth regulator intended to be used outdoors as plant growth regulator in agriculture, in orchards: apples and pears as representative uses for reduction of russet and fruit cracking, improvement of fruit and fruit set quality.

Gibberellins (GA4/GA7) is plant growth regulator and does not act against harmful organisms, against weeds, insects, fungi or other pests.

B.3.6. MODE OF ACTION

The mode of action of gibberellins is complex and the molecular basis of their effect of cell elongation is currently not fully understood. However, it is known that they induce the transcription of genes responsible for cell elongation in plants and upregulate expression of enzymes known to loosen cell wall structures. Increased plasticity of cellular wall structures then enhance cell expansion. The biological activity of different groups of gibberellins varies with plant species. For example, while golden delicious apple russet was significantly reduced by GA₄/GA₇, GA₃ showed no significant effect (Werthheim 1982).

B.3.7. INFORMATION ON THE OCCURRENCE OR POSSIBLE OF THE DEVELOPMENT OF RESISTANCE AND APPROPRIATE MANAGEMENT STRATEGIES

No data were provided for the renewal of the active substance. Detailed consideration of information on the development of resistance will be fully assessed in the context of subsequent product authorisation process when a full biological assessment dossier will be required. Gibberellins (GA4/GA7) is plant growth regulator and does

not act against weeds, insects, fungi or other pests and therefore occurrence of resistance is not relevant. However, based on the function of gibberellins (GA4/GA7) as plant growth regulator, there is no expectation of resistance in treated crops.

B.3.8. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
B.3.9.	anonym	2005	Result of the trial with plant strengtheners on fruit trees 2004. No. 04905W57001/02/03/04 GEF, unpublished	N	N	N	Globoc hem	IIA, 3.4/04 in original DAR