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.8 (PPP) – Novagib

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

Version History

When	What
2019/April	Initial DRAR

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B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

This document reviews the environmental fate and behaviour studies and modelling for the plant protection product 'Novagib' a soluble concentrate formulation containing the active substance gibberellins GA4/7 (10 g/L) for application to apple and pear. The plant protection product 'Novagib' is considered representative of uses of the active substance gibberellins GA4/7 for the purposes of renewal of the approval of the active substance in the EU.

Introduction

Environmental exposure following the use of the representative product 'Novagib' has been assessed. The critical Good Agricultural Practice (GAP) for 'Novagib' is presented in Document D1. The critical GAP for the representative product 'Novagib' in the EU consists of i) a maximum of four applications to apple (GS 69-74), with a minimum interval of 7 days at a treatment rate of 5 g a.s./ha, ii) a single application to pear (GS 62-69), at a treatment rate of 12 g a.s./ha, or iii) a maximum of two applications to pear (GS 62-69), with a minimum interval of 3 days at a treatment rate of 6 g a.s./ha.

The initial predicted environmental concentration (PEC) of the formulated product 'Novagib', the active substance gibberellins GA4/7, the individual components gibberellins GA4 and gibberellins GA7 and any metabolites (where relevant) in soil, groundwater, surface water and sediment are provided where relevant, together with long term actual and time weighted average (TWA) concentrations, where appropriate.

Environmental fate studies on the formulation 'Novagib' have not been performed since it is possible to extrapolate from data obtained with the active substance and metabolites. Furthermore, the impact of formulants is limited to short-term effects and their influence on long-term processes, such as degradation and distribution is negligible. Therefore, for the purposes of this exposure and risk assessment it is assumed that formulants do not influence the fate and behaviour of the active substance in the environment and are not considered further.

Chemical names, synonyms and chemical structures of all components of interest for the active substance gibberellins GA4/7 are summarised in Appendix 1. The components of interest considered in the environmental exposure and risk assessment for each compartment are defined In Document M-CA, and summarised in Table 8-1:

Table 8-1: Definition of the residue for environmental risk assessment

Compartment	Component of interest
soil	gibberellins GA4 and gibberellins GA7
groundwater	gibberellins GA4 and gibberellins GA7
surface water (and sediment)	gibberellins GA4 and gibberellins GA7
Air	gibberellins GA4 and gibberellins GA7

A list of all references for the active substance gibberellins GA4/7 and the formulated product 'Novagib' is provided in Documents LCA Section 7 and LCP Section 9, respectively.

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.8.1. FATE AND BEHAVIOUR IN SOIL

The proposed use of the representative formulated product 'Novagib' can potentially lead to amounts reaching soil, therefore the fate and behaviour in soil of 'Novagib' is addressed.
The representative formulated product 'Novagib' contains the active substance gibberellins GA4/7 as a soluble concentrate formulation (10 g/L). Therefore, as it is possible to extrapolate the behaviour of the active substance resulting from use of the formulated product 'Novagib' from the studies on the active substance itself, no additional laboratory studies have been performed.

B.8.1.1. Route and rate of degradation in soil

B.8.1.1.1. Laboratory studies

a) Previous evaluation (2005-2011)
Before, no data were available on the aerobic route of degradation of GA4/7 in soil. However since gibberellins in higher plants may be degraded in soil as the plants decay, it is highly likely that any metabolites would already be present in soil from natural sources.

b) Evaluation of additional data for the purpose of renewal of Annex I inclusion
The rate of degradation in soil of the active substance gibberellins GA4/7 and any associated significant metabolites in laboratory studies is evaluated under Point CA 8.1.1 of the corresponding active substance dossier. As it is possible to extrapolate the behaviour of the active substance resulting from use of the formulated product 'Novagib' from the studies on the active substance itself, additional laboratory studies investigating the rate of degradation in soil have not been performed.

A summary of the fate and behaviour of the active substance and associated significant metabolites in laboratory soil degradation studies is presented Document M-CA, Section 8, under Point 8.1.1; and in general below:

The route and rate of aerobic degradation of the individual components gibberellins GA4 and gibberellins GA7 of the active substance gibberellins GA4/7 was investigated in four soil types (ranging from loamy sand to clay loam) of varying origin in the dark under laboratory conditions at a temperature of 20°C and moisture content of 100% pF 2. The individual components gibberellins GA4 and gibberellins GA7 degrade extensively in soil. Numerous degradation products were observed but not fully identified. Ultimate degradation led to the formation of un-extracted soil residues and mineralisation to carbon dioxide.

For both gibberellins GA4 and gibberellins GA7 the best-fit persistence half-lives were <2 days in all soil types (and a conservative protective value of 2 days is used for PEC generation). The DT_{50} and DT_{90} values are summarised in Table 8.1-1. The available data clearly indicate that the active substance gibberellins GA4/7 and its individual components gibberellins GA4 and gibberellins GA7 are not persistent in soil. Therefore, in accordance with Regulation (EC) No. 1272/2008, gibberellins GA4/7 fulfils the criteria for consideration as a low-risk active substance in this regard.

Table 8.1-1: DT50 of gibberellins GA4 and gibberellins GA7 (FOCUS persistence endpoints)

Soil	Kinetic Model	Degradation rate (days)		Chi2err (%)
		DT50	DT90	
gibberellins GA4				
(conducted at 20°C and pF 2 moisture content)				
Speyer 5M	SFO	0.171	0.568	3.188
Speyer 2.2	SFO	0.347	1.153	20.75
Brierlow	SFO	0.392	1.303	18.61
South Witham	SFO	0.104	0.346	28.78
(conducted at 20°C and 45% MWHC)				
Soil LUFA 2.1	SFO	1.542	5.083	7.2
Soil LUFA 2.2	DFOP	1.125	12.583	7.2
Soil LUFA 2.3	FOMC	1.000	5.333	14.7
Soil LUFA 6S	SFO	1.083	3.625	5.6
gibberellins GA7				
(conducted at 20°C and pF 2 moisture content)				
Speyer 5M	SFO	0.060	0.200	13.57
Speyer 2.2	SFO	0.064	0.212	13.20
Brierlow	SFO	0.132	0.440	16.67
South Witham	SFO	0.011	0.036	1.005
(conducted at 20°C and 45% MWHC)				
Soil LUFA 2.1	SFO	0.500	1.625	11.2
Soil LUFA 2.2	DFOP	0.292	0.917	12.2
Soil LUFA 2.3	FOMC	0.167	0.583	5.2
Soil LUFA 6S	SFO	0.583	1.917	11.3

The degradation of the active substance gibberellins GA4/7 in soil under anaerobic conditions has not been investigated as anaerobic conditions are not relevant for uses of the representative formulation.

B.8.1.1.2. Field studies

B.8.1.1.2.1. Soil dissipation studies

a) Previous evaluation (2005-2011)

Based on the information presented under laboratory route and laboratory rate studies and the summary of DT_{50} and DT_{90} values presented, the DT_{50} values for the degradation of the active substance gibberellins GA4/7 in soil (20°C, pF 2) do not exceed 60 days and the DT_{90} values do not exceed 200 days. The active substance gibberellins GA4/7 can potentially be used in colder climates and the DT_{50} value for degradation in soil (10°C, pF 2) does not exceed 90 days. Soil dissipation studies with the representative formulation Novagib have not been conducted as behaviour can be extrapolated from the active substance studies and soil dissipation studies with the active substance have not been triggered (see Document CA, Section 8, Point B.8.1.1.4).

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

Soil dissipation studies with the representative formulation 'Novagib' have not been conducted as behaviour can be extrapolated from the active substance studies and soil dissipation studies with the active substance have not been triggered (see Document M-CA, Section 8).

B.8.1.1.2.2. Soil accumulation studies

a) Previous evaluation (2005-2011)

Soil accumulation studies with the representative formulation Novagib have not been conducted as behaviour can be extrapolated from the active substance studies and soil accumulation studies with the active substance have not been triggered (see Document CA, Section 8, B.8.1.2).

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

As described under previous points soil dissipation studies for the active substance gibberellic acid GA4/7 are not triggered, since the DT_{90} of GA_3 in soil is clearly < 1year.
Correspondingly, soil accumulation studies for the active substance gibberellins GA4/7 are not triggered.

B.8.1.2. Mobility in soil

a) Previous evaluation (2005-2011)

One existing study (CA 7.1.3.1.1/01) investigating the sorption properties of gibberellic acid GA4/7 in soil is available and was included in the original DAR for Annex I inclusion. The study is still considered adequate to address the requirements of Regulation EC 283/2013.

B.8.1.2.1. Laboratory studies

Adsorption/desorption studies with the active substance gibberellins GA4/7 and any associated significant metabolites are evaluated under Point CA 8.1.2 of the corresponding active substance dossier. As it is possible to extrapolate the behaviour of the active substance resulting from use of the formulated product Novagib from the study on the active substance itself, additional adsorption/desorption studies have not been performed.

The behaviour of the active substance and any associated significant metabolites in adsorption/desorption studies is addressed in Document M-CA, Section 8, under Points CA 8.1.2 and CA 8.1.2.1, respectively, and a summary is presented under Point CA 8.1.3.

The soil sorption properties of the individual components of the active substance gibberellins GA4/7, gibberellins GA4 and gibberellins GA7 were investigated in four soils (UK origin) with a range of characteristics (pH 3.8 to 7.4, %OC 0.8 to 5.2) at five concentrations (0.05 – 5 µg/mL) using the batch equilibrium technique with a soil to solution ratio of 1:1 w/v and a 3 hr equilibration time. The sorption parameters determined were Kf (0.19 - 1.32 mL/g), Koc 4 - 165 mL/g and 1/n (0.9611 - 0.9706) for gibberellins GA4 and Kf (0.22 - 1.33 mL/g), Koc (4 - 166 mL/g) and 1/n (0.9802 - 1.0464) for gibberellins GA7.

B.8.1.2.2. Lysimeter studies

Lysimeter studies with the representative formulation Novagib have not been conducted as behaviour can be extrapolated from the active substance studies and lysimeter studies with the active substance have not been triggered (see Document CA, Section 8, Point CA 8.1.3).

B.8.1.2.3. Field leaching studies

Field leaching studies with the representative formulation Novagib have not been conducted as behaviour can be extrapolated from the active substance studies and field leaching studies with the active substance have not been triggered (see Document CA, Section 8, Point CA 8.1.3).

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

Applicant presented no new data. RMS agree with applicant, that new adsorption/desorption studies are NOT necessary.

B.8.2. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC_s)

a) Previous evaluation (2005-2011)

Old calculations are not in line with current requirements and data.

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

Use of the formulated product 'Novagib' can potentially lead to amounts reaching soil, therefore the predicted environmental concentration in soil (PECsoil) of the formulated product 'Novagib', the individual components gibberellins GA4 and gibberellins GA7 in the active substance and any associated significant metabolites is considered. 'Novagib' is a soluble concentrate formulation containing the active substance gibberellins GA4/7 (10 g/L).

The critical Good Agricultural Practice (GAP) for 'Novagib' is presented in Document D1, with relevant agronomic parameters summarised in Table 8.2-1.

Table 8.2-1: GAP for 'Novagib'

Treatment details			Application timing	Crop Interception[1]	Effective treatment rate (g a.s./ha)
Crop	**No.**	**Rate**			
Apple	4 (7 d min interval)	5 g a.s./ha (0.5 L/ha)	GS 69-74	60	4 x 2.0
			1-Apr (earliest)	50	4 x 2.5
Pear	1	12 g a.s./ha (1.2 L/ha)	GS 62-69	60	1 x 4.8
			1-Apr (earliest)	50	1 x 6.0
Pear	2 (3 d min interval)	6 g a.s./ha (0.6 L/ha)	GS 62-69	60	2 x 2.4
			1-Apr (earliest)	50	2 x 3.0

(1) EFSA 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain $DegT_{50}$ values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662.

Based on the GAP parameters specified in Table 8.2-1, the predicted environmental concentration of the formulated product 'Novagib' and the two components of the active substance and any associated metabolite(s) in soil are determined as follows:

The predicted environmental concentration in soil (PECs) was calculated based upon the maximum proposed use

rate following the recommendations of the FOCUS Soils Group (FOCUS 1997[1]). Calculations assume any of the applied active substance reaching the soil surface is distributed uniformly to a depth of 5 cm (with no mechanical incorporation). The bulk density of soil is assumed to be 1.5 g/cm^3.

The initial predicted environmental concentration in soil of the formulated product 'Novagib' is presented in Table 8.2-2. Since the formulation components other than the active substance are assumed to dissipate rapidly in the environment, it is only necessary to consider the initial concentration for 'Novagib'. As a worst-case, it is assumed that the annual application rate is applied on a single occasion i.e. no dissipation of the formulation is considered between applications.

Table 8.2-2: Worst-case initial PECsoil for intact formulation 'Novagib' needed for risk assessment

Crop	Formulation application rate	Application timing	Crop interception	Soil concentration (mg 'Novagib'/kg dw soil)
Apple	4 x 0.5 L/ ha 'Novagib' (equivalent to 4 x 520 g 'Novagib'/ha[1])	GS 69-74	60	1.11
		1-Apr (earliest)	50	1.39
Pear	1 x 1.2 L/ ha 'Novagib' (equivalent to 1 x 1248 g 'Novagib'/ha[1])	GS 62-69	60	0.67
		1-Apr (earliest)	50	0.83
Pear	2 x 0.6 L/ ha 'Novagib' (equivalent to 2 x 624 g 'Novagib'/ha[1])	GS 62-69	60	0.67
		1-Apr (earliest)	50	0.83

(1) Based on a formulation relative density of 1.04 g/ml.

The maximum potential initial concentration of the intact formulated product 'Novagib' in soil following application is 1.39 mg/kg (dw soil).

The fate and behaviour of the active substance and any associated metabolites in soil is investigated in Document M-CA, Section 7, under Points CA 7.1.1 and CA 7.1.2 and summarised under Point CA 7.1.2.3. The definition of the residue for risk assessment (soil) is defined under Point CA 7.4.1. The active substance gibberellins GA4/7 contains two components (gibberellins GA4 and gibberellins GA7). Degradation of gibberellins GA4 and gibberellins GA7 in soil under aerobic conditions leads to the formation of numerous degradation products, however, due to the natural occurrence of the active substance these metabolites are considered to be of no environmental concern and have not been considered further.

The active substance gibberellins GA4/7 consists of two components gibberellins GA4 and gibberellins GA7. In the representative formulation 'Novagib' the two components are present in a certain ratio (see confidential section), however, in order to take into account other possible ratios of the two components and to provide a conservative assessment, PECsoil are calculated assuming 100% content of both gibberellins GA4 and gibberellins GA7.

[1] FOCUS (1997). Soil persistence models and EU registration. European Commission Document 7617/VI/96.

The actual initial predicted environmental concentrations in soil (PECsoil) for gibberellins GA4/7 are provided in Table 8.2-3 assuming, as a worst-case, a single application at the annual application rate i.e. no degradation of the active substance is considered between applications. Short and long term actual and time weighted average PEC values are not required for the risk assessment (see Document M-CP, Section 10, Point CP 10.4) and have therefore not been calculated.

Table 8.2-3: Worst-case initial PECsoil for the active substance gibberellins GA4/7 following treatment with 'Novagib'

Crop	Application details				Initial concentration in soil (mg a.s./kg soil dw) gibberellins GA4/7
	Actual rate (g a.s./ha)	Timing	Crop interception (%)	Effective rate (g a.s./ha)	
Apple	4 x 5 (7 d minimum interval)	GS 69-74	60	4 x 2	0.0107
		1-Apr (earliest)	50	4 x 2.5	0.0133
Pear	1 x 12 g a.s./ha	GS 62-69	60	1 x 4.8	0.0064
		1-Apr (earliest)	50	1 x 6.0	0.0080
Pear	2 x 6 g a.s./ha (3 d minimum interval)	GS 62-69	60	2 x 2.4	0.0064
		1-Apr (earliest)	50	2 x 3.0	0.0080

Following treatment with 'Novagib' according to the supported GAP, the maximum potential initial residue in soil of the active substance gibberellins GA4/7 is 0.0133 mg/kg dw (soil mixing depth 5 cm).

B.8.3. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER (PEC_{GW})

Use of the formulated product Novagib can potentially lead to the active substance and any associated metabolites reaching groundwater *via* soil, therefore the predicted environmental concentration in groundwater (PECgw) is considered.

B.8.3.1. Calculation of concentrations in groundwater

a) Previous evaluation (2005-2011)

Old calculations are not in line with current requirements and data.

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

Predicted environmental concentrations in groundwater (PECgw)

The predicted environmental concentration in groundwater (PECgw) of the active substance gibberellins GA4/7 and any associated metabolites following use of the formulated product 'Novagib' has been addressed in accordance with the recommendations of the FOCUS groundwater working group (FOCUS 2000[2], 2014a[3] and

[2] FOCUS (2000): FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS groundwater scenarios workgroup, EC Document Reference Sanco/321/2000 rev. 2.

2014b[4]) using the FOCUS PEARL (FOCUS version 4.4.4) and FOCUS PELMO (FOCUS version 5.5.3) models. Simulations were also conducted using the FOCUS MACRO model (FOCUS version 5.5.4), with the Châteaudun scenario. Since the formulation components other than the active substance are assumed to dissipate rapidly in the environment, the predicted environmental concentration in groundwater (PECgw) of the formulated product 'Novagib' is not calculated.

The supported GAP is presented with relevant agronomic parameters being summarised in Table 8.2-1. Based on the proposed application timings, the dates selected at each scenario location for the modelling simulations are presented in Table 8.3.1-1

Application dates were chosen using the AppDate utility (ver 2.03 SE, 2 Jun 2017) using the earliest specified growth stage within the recommended application window. In addition, to cover potential early applications i.e. as early as 1-April, additional application dates were also considered.

Table 8.3.1-1: Summary of modelled application dates and timings for groundwater simulations

Treatment pattern and actual application timings	Scenario	Default FOCUS dates for leaf emergence/harvest	Modelled application date (relative to emergence/harvest date)	
			Main	Earliest
Apple 4 x 5 g a.s./ha (7 day minimum interval)	Châteaudun (C)	1-Apr/1-Oct	7-Jul (97/-86 d), 14-Jul, 21-Jul, 28-Jul[1]	1-Apr, 8-Apr, 15-Apr, 22-Apr[4]
	Hamburg (H)	15-Apr/30-Oct	3-Jun (49/-149 d), 10-Jun, 17-Jun, 24-Jun	
	Jokioinen (J)	10-May/15-Oct	7-Jul (58/-100 d), 14-Jul, 21-Jul, 28-Jul	
	Kremsmünster (K)	15-Apr/30-Oct	3-Jun (49/-149 d), 10-Jun, 17-Jun, 24-Jun	
	Okehampton (N)	25-Mar/15-Sep	13-Jul (110/-64 d), 20-Jul, 27-Jul, 3-Aug	
	Piacenza (P)	1-Apr/1-Nov	16-Jul (106/-108 d), 23-Jul, 30-Jul, 6-Aug	
	Porto (O)	15-Mar/31-Oct	6-Aug (144/-86 d), 13-Aug, 20-Aug, 27-Aug	
	Sevilla (S)	15-Mar/15-Oct	11-Jul (118/-96 d), 18-Jul, 25-Jul, 1-Aug	

[3] FOCUS (2014a). Generic Guidance for Tier 1 FOCUS Ground Water Assessments. Version: 2.2, May 2014.
[4] FOCUS (2014b) "Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU" Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 3, 613 pp.

Treatment pattern and actual application timings	Scenario	Default FOCUS dates for leaf emergence/harvest	Modelled application date (relative to emergence/harvest date)	
			Main	**Earliest**
	Thiva (T)	15-Mar/20-Oct	2-Aug (140/-79 d), 9-Aug, 16-Aug, 23-Aug	
	Application timing and equivalent application rate		GS 69-74 (i.e. 60% crop interception). Effective application rate 4 x 2.0 g a.s./ha	1st Apr earliest (i.e. 50% crop interception). Effective application rate 4 x 2.5 g a.s./ha
Notes: Pome fruit (apples) was used as the crop type in the FOCUS modelling. Treatments were assumed to be conducted every year and made to the soil surface. Absolute application dates were used within the models.				
Pear 1 x 12 g a.s./ha	Châteaudun (C)	1-Apr/1-Oct	8-Jun (68/-115 d)[2]	1-Apr[5]
	Hamburg (H)	15-Apr/30-Oct	19-May (34/-164 d)	
	Jokioinen (J)	10-May/15-Oct	4-Jun (25/-133 d)	
	Kremsmünster (K)	15-Apr/30-Oct	19-May (34/-164 d)	
	Okehampton (N)	25-Mar/15-Sep	21-Jun (88/-86 d)	
	Piacenza (P)	1-Apr/1-Nov	10-Jun (70/-144 d)	
	Porto (O)	15-Mar/31-Oct	8-Jul (115/-115 d)	
	Sevilla (S)	15-Mar/15-Oct	9-Jun (86/-128 d)	
	Thiva (T)	15-Mar/20-Oct	7-Jul (114/-105 d)	
	Application timing and equivalent application rate		GS 62-69 (i.e. 60% crop interception). Effective application rate 1 x 4.8 g a.s./ha	1st Apr earliest (i.e. 50% crop interception). Effective application rate 1 x 6.0 g a.s./ha
Notes: Pome fruit (apples) was used as the crop type in the FOCUS modelling, as a surrogate for pear. Treatments were assumed to be conducted every year and made to the soil surface. Absolute application dates were used within the models.				
Pear 2 x 6 g a.s./ha, (3 day minimum interval)	Châteaudun (C)	1-Apr/1-Oct	8-Jun (68/-115 d), 11-Jun[3]	1-Apr, 4-Apr[6]
	Hamburg (H)	15-Apr/30-Oct	19-May (34/-164 d), 22-May	
	Jokioinen (J)	10-May/15-Oct	4-Jun (25/-133 d), 7-Jun	
	Kremsmünster (K)	15-Apr/30-Oct	19-May (34/-164 d), 22-May	
	Okehampton (N)	25-Mar/15-Sep	21-Jun (88/-86 d), 24-Jun	
	Piacenza (P)	1-Apr/1-Nov	10-Jun (70/-144 d), 13-Jun	

Treatment pattern and actual application timings	Scenario	Default FOCUS dates for leaf emergence/harvest	Modelled application date (relative to emergence/harvest date)	
			Main	**Earliest**
	Porto (O)	15-Mar/31-Oct	8-Jul (115/-115 d), 11-Jul	
	Sevilla (S)	15-Mar/15-Oct	9-Jun (86/-128 d), 12-Jun	
	Thiva (T)	15-Mar/20-Oct	7-Jul (114/-105 d), 10-Jul	
	Application timing and equivalent application rate		GS 62-69 (i.e. 60% crop interception). Effective application rate 2 x 2.4 g a.s./ha	1st Apr earliest (i.e. 50% crop interception). Effective application rate 2 x 3.0 g a.s./ha
Notes: Pome fruit (apples) was used as the crop type in the FOCUS modelling, as a surrogate for pear. Treatments were assumed to be conducted every year and made to the soil surface. Absolute application dates were used within the models.				

(1) Julian dates for MACRO simulations: 188, 195, 202 and 209.
(2) Julian dates for MACRO simulations: 159
(3) Julian dates for MACRO simulations: 159 and 162
(4) Julian dates for MACRO simulations: 91, 98, 105 and 112.
(5) Julian dates for MACCO simulations: 91
(6) Julian dates for MACRO simulations: 91 and 94

The active substance gibberellins GA4/7 contains two components (gibberellins GA4 and gibberellins GA7). Degradation of gibberellins GA4 and gibberellins GA7 in soil under aerobic conditions leads to the formation of numerous degradation products, however, due to the natural occurrence of the active substance these metabolites are not considered to be of any environmental concern and have not been considered further.

As the ratio of gibberellins GA4 and gibberellins GA7 in the active substance can vary between sources, for the determination of PECs of the active substance the approach adopted as a precautionary worst-case has been to consider alternate situations where the active substance is 100% gibberellins GA4 and separately 100% gibberellins GA7.

FOCUS PEARL (ver 4.4.4)

The modelling parameters used for the simulations conducted using the FOCUS PEARL model are presented in Table 8.3.1-2.

Table 8.3.1-2: **Summary of input parameters for determination of worst-case PECgw for components gibberellins GA4 and gibberellins GA7 following treatment with 'Novagib' using PEARL 4.4.4**

Parameter	Input parameters		Remarks
	gibberellins GA4	**gibberellins GA7**	
General parameters			
Chemical name	(3*S*,3a*R*,4*S*,4a*R*,7*R*,9a*R*,9b*R*,12*S*)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-3,9b-propanoazuleno[1,2-*b*]furan-4-carboxylic acid (IUPAC)	(3*S*,3a*R*,4*S*,4a*R*,7*R*,9a*R*,9b*R*,12*S*)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-*b*]furan-4-carboxylic acid (IUPAC)	For structure see Appendix 1
Molecular weight (g/mol)	332.40	330.40	See appendix 1
Vapour pressure (Pa)	0	0	Worst-case
Molar enthalpy of vaporization (kJ/mol)	95	95	FOCUS recommendation
Water solubility (mg/L)	340 (20°C)	340 (20°C)	See Doc M-CA, Section 2, Point CA 2.5. (Note a value of 340 mg/L was used to be consistent with the agreed parameter specified in the existing EFSA LoEP (p37/50).
Molar enthalpy of dissolution (kJ/mol)	27	27	FOCUS recommendation
Freundlich Sorption parameters			
Sorption option	Kom, pH independent	Kom, pH independent	FOCUS recommendation
Soil adsorption coefficient, Kfoc (ml/g) at 20°C	4 (worst-case, pH dependant, n=4)	4 (worst-case, pH dependant, n=4)	See Doc M-CA, Section 7, Point CA 7.1.3.1.1 (Table CA 7.1.3.1.1-4)
Kfom (ml/g) at 20°C	2.3	2.3	Determined from Kfoc divided by 1.724
Molar enthalpy of sorption (kJ/mol)	0	0	FOCUS recommendation
Reference concentration in liquid phase (mg/L)	1	1	FOCUS recommendation
Freundlich exponent 1/n (-)	0.97 (average n=4)	1.01 (average n=4)	See Doc M-CA, Section 7, Point CA 7.1.3.1.1 (Table CA 7.1.3.1.1-4)
Desorption rate coefficient (d^{-1})	0	0	FOCUS recommendation
Factor relating CofFreNeq and CofFreEql (-)	0	0	FOCUS recommendation

Parameter	Input parameters		Remarks
	gibberellins GA4	gibberellins GA7	
Transformation parameters			
DT_{50} in soil (days)	2 (worst-case)[1]	2 (worst-case)[1]	See Doc M-CA, Section 7, Point CA 7.1.2.3 (Table CA 7.1.2.3-1)
Temperature correction function: - reference temperature (°C) - optimum moisture conditions (pF 2 or wetter) - Liquid content in incubation experiment (kg/kg) - exponent for the effect of liquid (-) - molar activation energy (kJ/mol)	 20 selected 1 0.7 65.4	 20 selected 1 0.7 65.4	FOCUS recommendations
Diffusion parameters			
Reference temperature for diffusion (C)	20	20	FOCUS recommendation
Diffusion coefficient in water (m^2/d)	4.3×10^{-5}	4.3×10^{-5}	FOCUS recommendation
Diffusion coefficient in air (m^2/d)	0.43 (20°C)	0.43 (20°C)	FOCUS recommendation
Crop parameters			
Wash off factor (m^{-1})	0.0001	0.0001	FOCUS recommendation
Canopy process option	Lumped	Lumped	FOCUS recommendation
Half life at crop surface (d)	1000000	1000000	FOCUS recommendation
Plant uptake factor	0	0	Worst-case
Transformation scheme			
Transformation pathway	Parent > sink	Parent > sink	PEARL option
Application data			
Kind of Application	To soil surface	To soil surface	PEARL option
Mode of application	Every year	Every year	FOCUS recommendation
Application rate (kg/ha)	see Table CP 9.2.4.1-1		-
Application depth (cm)	0	0	FOCUS recommendation

(1) The DT_{50} values reported in Document M-CA, Section 8, are based on FOCUS procedures for the determination of persistence endpoints i.e. best fit DT_{50} values. For modelling parameters DT_{50} values based on FOCUS procedures for the determination of modelling endpoints are required. In the absence of properly determined FOCUS modelling DT_{50} values, a protective worst-case value of 2 days was selected.

The parameters specified in Table 8.3.1-2 were used in conjunction with the application dates and agronomic parameters specified in Table 8.3.1-1. The resulting predicted 80th percentile annual average concentrations of each component of the active substance in groundwater are summarised in Table 8.3.1-3.

Table 8.3.1-3: Worst-case PECgw for components gibberellins GA4 and gibberellins GA7 following treatment with 'Novagib' using PEARL 4.4.4

Scenario	80th percentile annual average concentration (µg/L)			
	gibberellins GA4		gibberellins GA7	
	Main appln	Earliest appln	Main appln	Earliest appln
Apple 4 x 5 g a.s./ha (7 day minimum interval)				
Châteaudun (C)	<0.001	<0.001	<0.001	<0.001
Hamburg (H)	<0.001	<0.001	<0.001	<0.001
Jokioinen (J)	<0.001	<0.001	<0.001	<0.001
Kremsmünster (K)	<0.001	<0.001	<0.001	<0.001
Okehampton (N)	<0.001	<0.001	<0.001	<0.001
Piacenza (P)	<0.001	<0.001	<0.001	<0.001
Porto (O)	<0.001	<0.001	<0.001	<0.001
Sevilla (S)	<0.001	<0.001	<0.001	<0.001
Thiva (T)	<0.001	<0.001	<0.001	<0.001
Pear 1 x 12 g a.s./ha				
Châteaudun (C)	<0.001	<0.001	<0.001	<0.001
Hamburg (H)	<0.001	<0.001	<0.001	<0.001
Jokioinen (J)	<0.001	<0.001	<0.001	<0.001
Kremsmünster (K)	<0.001	<0.001	<0.001	<0.001
Okehampton (N)	<0.001	<0.001	<0.001	<0.001
Piacenza (P)	<0.001	<0.001	<0.001	<0.001
Porto (O)	<0.001	<0.001	<0.001	<0.001
Sevilla (S)	<0.001	<0.001	<0.001	<0.001
Thiva (T)	<0.001	<0.001	<0.001	<0.001
Pear 2 x 6 g a.s./ha (3 day minimum interval)				
Châteaudun (C)	<0.001	<0.001	<0.001	<0.001
Hamburg (H)	<0.001	<0.001	<0.001	<0.001
Jokioinen (J)	<0.001	<0.001	<0.001	<0.001
Kremsmünster (K)	<0.001	<0.001	<0.001	<0.001
Okehampton (N)	<0.001	<0.001	<0.001	<0.001
Piacenza (P)	<0.001	<0.001	<0.001	<0.001
Porto (O)	<0.001	<0.001	<0.001	<0.001
Sevilla (S)	<0.001	<0.001	<0.001	<0.001
Thiva (T)	<0.001	<0.001	<0.001	<0.001

Using the FOCUS methodology, the 80th percentile PECgw values for the two components gibberellins GA4 and gibberellins GA7 in the active substance gibberellins GA4/7 in groundwater were generated assuming repeated annual applications at the maximum seasonal treatment rate for the crops supported in the GAP. Annual average concentrations were calculated as the cumulative annual chemical flux divided by the cumulative annual water recharge volume at 1 m depth. The predicted concentration is a conservative estimate of what may actually be expected in groundwater used for drinking water, as soil pore water at one-meter depth is not a likely source of drinking water.

In reasonable worst-case scenarios using the FOCUS PEARL model, the annual average concentrations of the two components gibberellins GA4 and gibberellins GA7 in the active substance gibberellins GA4/7 in soil pore water at one-meter depth following use of 'Novagib' in pome fruit were all significantly less than 0.1 µg/L.

FOCUS PELMO (ver 5.5.3)

Simulations were also conducted using the FOCUS PELMO model as per current requirements. The modelling parameters used for the simulations conducted using the FOCUS PELMO model are presented in Table 8.3.1-4.

Table 8.3.1-4: Summary of input parameters for determination of worst-case PECgw for components gibberellins GA4 and gibberellins GA7 following treatment with 'Novagib' using PELMO 5.5.3

Parameter	Input parameters		Remarks
	gibberellins GA4	gibberellins GA7	
General parameters			
Chemical name	(3*S*,3a*R*,4*S*,4a*R*,7*R*,9a*R*,9b*R*,12*S*)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-3,9b-propanoazuleno[1,2-*b*]furan-4-carboxylic acid (IUPAC)	(3*S*,3a*R*,4*S*,4a*R*,7*R*,9a*R*,9b*R*,12*S*)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-*b*]furan-4-carboxylic acid (IUPAC)	For structure see Appendix 1
Molecular weight (g/mol)	332.40	330.40	See appendix 1
Application data			
Kind of Application	Soil Application	Soil Application	FOCUS option
Mode of application	Every year	Every year	FOCUS recommendation
Application rate (kg/ha)	see Table CP 9.2.4.1-1		-
Application depth (cm)	0	0	FOCUS recommendation
Plant uptake factor	0	0	Worst-case
Volatilisation and Soil Photolysis Data			
Henry's Law Constant	Calculated option	Calculated option	FOCUS recommendation
Vapour Pressure (Pa)	0 (20°C) 0 (30°C)	0 (20°C) 0 (30°C)	Worst-case
Aqueous Solubility (mg/L)	340 (20°C) (680, 30°C)	340 (20°C)	See Doc M-CA, Section, Point CA 2.5. (Note a value 340 mg/L was used to be consistent with the agreed parameter specified in the existing EFSA LoEP (p37/50).
Soil Photolysis Rate (1/d)	0 (worst-case)	0 (worst-case)	FOCUS recommendation
Reference Radiation (W/m^2)	500	500	FOCUS recommendation
Sorption Data			
Soil adsorption coefficient, Kfoc (ml/g), 20°C	4 (worst-case, pH dependant, n=4)	4 (worst-case, pH dependant, n=4)	See Doc M-CA, Section 7, Point CA 7.1.3.1.1 (Table CA 7.1.3.1.1-4)
Freundlich exponent 1/n (-)	0.97 (average n=4)	1.01 (average n=4)	See Doc M-CA, Section 7, Point CA 7.1.3.1.1 (Table CA 7.1.3.1.1-4)

Parameter	Input parameters		Remarks
	gibberellins GA4	gibberellins GA7	
Limit for Freundlich (µg/L)	1×10^{-20}	1×10^{-20}	FOCUS recommendation
Annual increase (%)	0	0	FOCUS recommendation
Equilibrium constant for DOC (L/kg)	0	0	FOCUS recommendation
Increase of sorption when soil is air dried (-)	1	1	FOCUS recommendation
pH-dependent sorption option	Not selected	Not selected	PELMO option
Kinetic sorption option	Not selected	Not selected	PELMO option
Depth Dependent Sorption and Transformation Data (Focus Tier 2)	Standard values (Tier 1) selected	Standard values (Tier 1) selected	PELMO option
Degradation in the liquid phase only	Not selected	Not selected	PELMO option
Transformation Scheme			
DT_{50} in soil (days)	2 (worst-case)[2]	2 (worst-case)[2]	See Doc M-CA, Section 7, Point CA 7.1.2.3 (Table CA 7.1.2.3-1)
Rate correction in soil	Individual, correction with $Q_{10} = 2.58$	Individual, correction with $Q_{10} = 2.58$	FOCUS recommendation
Transformation pathway	Parent > sink (ff=1)	Parent > sink (ff=1)	PELMO option

(1) The vapour pressure value for 30°C was determined using the value at 20°C and the PELMO default of x2.
(2) The DT_{50} values reported in Document M-CA, Section 8 are based on FOCUS procedures for the determination of persistence endpoints i.e. best fit DT_{50} values. For modelling parameters DT_{50} values based on FOCUS procedures for the determination of modelling endpoints are required. In the absence of properly determined FOCUS modelling DT_{50} values, a protective worst-case value of 2 days was selected.

The parameters specified in Table 8.3.1-4 were used in conjunction with the application dates and agronomic parameters specified. The resulting predicted 80th percentile annual average concentrations of each component of the active substance in groundwater are summarised in Table 8.3.1-5.

Table 8.3.1-5: Worst-case PECgw for components gibberellins GA4 and gibberellins GA7 following treatment with 'Novagib' using PELMO 5.5.3

Scenario	80th percentile annual average concentration (µg/L)			
	gibberellins GA4		gibberellins GA7	
	Main appln	Earliest appln	Main appln	Earliest appln
Apple 4 x 5 g a.s./ha (7 day minimum interval)				
Châteaudun (C)	<0.001	<0.001	<0.001	<0.001
Hamburg (H)	<0.001	<0.001	<0.001	<0.001
Jokioinen (J)	<0.001	<0.001	<0.001	<0.001
Kremsmünster (K)	<0.001	<0.001	<0.001	<0.001
Okehampton (N)	<0.001	<0.001	<0.001	<0.001
Piacenza (P)	<0.001	<0.001	<0.001	<0.001
Porto (O)	<0.001	<0.001	<0.001	<0.001
Sevilla (S)	<0.001	<0.001	<0.001	<0.001
Thiva (T)	<0.001	<0.001	<0.001	<0.001

Scenario	80th percentile annual average concentration (µg/L)			
	gibberellins GA4		gibberellins GA7	
	Main appln	Earliest appln	Main appln	Earliest appln
Pear 1 x 12 g a.s./ha				
Châteaudun (C)	<0.001	<0.001	<0.001	<0.001
Hamburg (H)	<0.001	<0.001	<0.001	<0.001
Jokioinen (J)	<0.001	<0.001	<0.001	<0.001
Kremsmünster (K)	<0.001	<0.001	<0.001	<0.001
Okehampton (N)	<0.001	<0.001	<0.001	<0.001
Piacenza (P)	<0.001	<0.001	<0.001	<0.001
Porto (O)	<0.001	<0.001	<0.001	<0.001
Sevilla (S)	<0.001	<0.001	<0.001	<0.001
Thiva (T)	<0.001	<0.001	<0.001	<0.001
Pear 2 x 6 g a.s./ha (3 day minimum interval)				
Châteaudun (C)	<0.001	<0.001	<0.001	<0.001
Hamburg (H)	<0.001	<0.001	<0.001	<0.001
Jokioinen (J)	<0.001	<0.001	<0.001	<0.001
Kremsmünster (K)	<0.001	<0.001	<0.001	<0.001
Okehampton (N)	<0.001	<0.001	<0.001	<0.001
Piacenza (P)	<0.001	<0.001	<0.001	<0.001
Porto (O)	<0.001	<0.001	<0.001	<0.001
Sevilla (S)	<0.001	<0.001	<0.001	<0.001
Thiva (T)	<0.001	<0.001	<0.001	<0.001

In reasonable worst-case scenarios using the PELMO model, the annual average concentrations of the two components gibberellins GA4 and gibberellins GA7 in the active substance gibberellins GA4/7 in soil pore water at one-meter depth following use of 'Novagib' in pome fruit were all significantly less than 0.1 µg/L.

FOCUS MACRO (ver 5.5.4)

Simulations were also conducted using the FOCUS MACRO model as per current requirements. The modelling parameters used for the simulations conducted using the FOCUS MACRO model are presented in Table 8.3.1-6.

Table 8.3.1-6: **Summary of input parameters for determination of worst-case PECgw for components gibberellins GA4 and gibberellins GA7 following treatment with 'Novagib' using MACRO 5.5.4**

Parameter	Input parameters		Remarks
	gibberellins GA4	gibberellins GA7	
General parameters			
Molecular weight (g/mol)	332.40	330.40	See appendix 1
Vapour Pressure (Pa)	0	0	Worst-case
Sorption parameters			
Soil adsorption coefficient, Kfoc (ml/g), 20°C	4 (worst-case, pH dependant, n=4)	4 (worst-case, pH dependant, n=4)	See Doc M-CA, Section 7, Point CA 7.1.3.1.1 (Table CA 7.1.3.1.1-4)
Kfom (ml/g) at 20°C	2.3	2.3	Determined from Kfoc divided by 1.724
Freundlich exponent 1/n (-)	0.97 (average n=4)	1.01 (average n=4)	See Doc M-CA, Section 7, Point CA 7.1.3.1.1 (Table CA 7.1.3.1.1-4)
Transformation parameters			
DT_{50} in soil (days)	2 (worst-case)[1]	2 (worst-case)[1]	See Doc M-CA, Section 7 Point CA 7.1.2.3 (Table CA 7.1.2.3-1)
Exponent for temperature response Exponent for moisture response	0.0948 0.49		FOCUS recommendations
Crop parameters			
Plant uptake factor	0		Worst-case
Transformation scheme			
Transformation pathway	Parent > sink (ff=1)	Parent > sink (ff=1)	Model option
Application data			
Kind of Application	To soil surface		Model option
Mode of application	Every year		Model option
Application rate (kg/ha)	see Table CP 9.2.4.1-1		-
Application depth (cm)	0		FOCUS recommendation

(1) The DT_{50} values reported in Document M-CA, Section 8, are based on FOCUS procedures for the determination of persistence endpoints i.e. best fit DT_{50} values. For modelling parameters DT_{50} values based on FOCUS procedures for the determination of modelling endpoints are required. In the absence of properly determined FOCUS modelling DT_{50} values, a protective worst-case value of 2 days was selected.

The parameters specified in Table 8.3.1-6 were used in conjunction with the application dates and agronomic parameters specified in Table 8.3.1-1. The resulting predicted 80th percentile annual average concentrations of each component of the active substance in groundwater are summarised in Table 8.3.1-7.

Table CP 9.2.4.1-7: Worst-case PECgw for components gibberellins GA4 and gibberellins GA7 following treatment with 'Novagib' using MACRO 5.5.4

Scenario	80th percentile annual average concentration (µg/L)			
	gibberellins GA4		gibberellins GA7	
	Main appln	Earliest appln	Main appln	Earliest appln
4 x 5 g a.s./ha (7 day minimum interval)				
Châteaudun (C)	<0.001	<0.001	<0.001	<0.001
1 x 12 g a.s./ha				
Châteaudun (C)	<0.001	<0.001	<0.001	<0.001
2 x 6 g a.s./ha (3 day minimum interval)				
Châteaudun (C)	<0.001	<0.001	<0.001	<0.001

In reasonable worst-case scenarios using the MACRO model, the annual average concentrations of the two components gibberellins GA4 and gibberellins GA7 in the active substance gibberellins GA4/7 in soil pore water at one-meter depth following use of 'Novagib' in pome fruit were all significantly less than 0.1 µg/L.

In all cases, the predicted concentrations of gibberellins GA4 and gibberellins GA7 in groundwater are <0.1 µg/L. In accordance with Regulation (EC) No. 1272/2008, the active substance gibberellins GA4/7 therefore fulfils the criteria for consideration as a low-risk active substance in this regard.

Additional field tests

Based on the predicted environmental concentrations in groundwater of gibberellic acid GA4/7 determined under Point CP B.8.3, additional field tests are not considered necessary.

B.8.4. FATE AND BEHAVIOUR IN WATER AND SEDIMENT

Use of the formulated product 'Novagib' can potentially lead to amounts reaching surface water during treatments by spray drift or *via* soil drainage and run-off, therefore the fate and behaviour in water and sediment of 'Novagib' is addressed. The representative formulated product 'Novagib' contains the active substance gibberellins GA4/7 as a soluble concentrate formulation (10 g/L). Therefore, as it is possible to extrapolate the behaviour of the active substance resulting from use of the formulated product 'Novagib' from the studies on the active substance itself, no additional laboratory studies have been performed.

Gibberellins GA4 was stable to hydrolysis at pH 4, 7 and 9 (i.e. half-life values of > 1 year at 20°C). Gibberellins GA7 was stable to hydrolysis at pH 7 but was hydrolysed at pH 4 and pH 9 at 50°C. However, the rate of hydrolysis at 20°C is expected to be slow. Degradation products were not identified, but may include the diol derivative of gibberellins GA7 following hydroxylation at the double bond position in the gibberellins GA7 unsaturated ring. Potential degradation products are not considered to be of any environmental concern and are not considered further.

The molar absorption coefficients of gibberellins GA4 and gibberellins GA7 are <10 L/mol/cm and therefore a measurement of the photolytic half-life and quantum yield is not required. Nevertheless, the rate of photolysis of gibberellins GA4 and gibberellins GA7 in aqueous buffer solutions at pH 5, 7 and 9 was investigated using

artificial sunlight. The photochemical degradation of combined gibberellins GA4 and gibberellins GA7 was slow with a half-life in the range of 104 to 267 days. The photo-degradation of gibberellins GA4 and gibberellins GA7 measured separately was 101 to 163 days and 57 to 145 days, respectively. Photolysis of gibberellins GA4 and gibberellins GA7 can therefore be regarded as a slow process and not a significant route of degradation in the environment.

The active substance gibberellins GA4/7 was determined to be readily biodegradable in a modified Sturm test (OECD 301B). However, a second study, which was also conducted using the carbon dioxide evolution (Modified Sturm) test, provided a conflicting result (i.e. not readily biodegradable). It is therefore concluded that the active substance gibberellins GA4/7 cannot be reliably classified as being readily biodegradable. However, on the basis of the degree of biodegradation observed in the non-positive test (in conjunction with the rapid and extensive microbial degradation and ultimate complete mineralisation via other natural components observed in the soil and aquatic metabolism studies), it is concluded that the active substance gibberellins GA4/7 can be considered inherently biodegradable.

B.8.4.1. Aerobic mineralisation in surface water

a) Previous evaluation (2005-2011)

No data were available during the Annex I inclusion.

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

The aerobic mineralisation in surface water of the active substance gibberellins GA4/7 is evaluated under Point CA 7.2.2.2 of the corresponding active substance dossier. As it is possible to extrapolate the behaviour of the active substance resulting from use of the formulated product 'Novagib' from the data on the active substance, additional studies with the formulation have not been performed.

B.8.4.2. Water/sediment study

a) Previous evaluation (2005-2011)

No data on the degradation of GA4/7 in natural water/sediment systems were available during the Annex I inclusion. However as the compound degrades rapidly by chemical hydrolysis and has a very low soil sorption constant, it can be inferred that it will rapidly degrade in natural waters (at least at the same rate as by hydrolysis) and will not partition to sediment.

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

The degradation of the active substance gibberellins GA4/7 in water/sediment systems is evaluated under Point CA 7.2.2.3 of the corresponding active substance dossier. As it is possible to extrapolate the behaviour of the active substance resulting from use of the formulated product 'Novagib' from the data on the active substance, additional studies with the formulation have not been performed.
Degradation of the active substance gibberellins GA4/7 in aquatic systems (pelagic water and water/sediments systems) was assessed by read across to studies conducted using the structurally related active substance gibberellins GA3.
On this basis degradation of the active substance gibberellins GA4/7 in these systems is assumed to proceed via isomerisation and/or opening of the lactone ring to form metabolites which are not likely to be environmentally

important and would also be formed by degradation of naturally occurring gibberellins GA4 and gibberellins GA7.
The available data indicate that gibberellins GA4/7 and its individual components gibberellins GA4 and gibberellins GA7 are not persistent in pelagic water or water-sediment systems. Therefore, in accordance with Regulation (EC) No. 1272/2008, gibberellins GA4/7 fulfils the criteria for consideration as a low-risk active substance in this regard.

B.8.4.3. Irradiated water/sediment study

Irradiated water/sediment studies with the representative formulation 'Novagib' have not been conducted as behaviour can be extrapolated from the active substance studies and an irradiated water/sediment study with the active substance is not considered necessary (see Document CA, Section 8, Point CA 8.2.4).

B.8.5. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (PEC_{sw}, PEC_{sd})

a) Previous evaluation (2005-2011)

Old calculations are not in line with current requirements and data.

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

Use of the formulated product 'Novagib' can potentially lead to the active substance reaching surface water during treatments by spray drift or *via* soil drainage and run-off, therefore predicted environmental concentrations in surface water (PECsw) are considered.

Predicted environmental concentrations in surface water (PECsw) and sediment (PECsed)

The predicted environmental concentration of the formulated product 'Novagib' and the two components gibberellins GA4 and gibberellins GA7 in the active substance gibberellins GA4/7 and any significant components in surface water (PECsw) is determined using the standardised recommendations of the FOCUS working group on surface water scenarios (FOCUS 2001[5] and 2015[6]). The FOCUS Surface Water Modelling Working Group described a step by step modelling procedure for the calculation of PECsw in which the estimation of pesticide surface water and sediment concentrations is conducted using a tiered approach that introduces increasing levels of realism into the modelling assessment.

The initial predicted environmental concentration in surface water of the formulated product 'Novagib' is presented in Table 8.5-1. Since the formulation components other than the active substance are assumed to dissipate rapidly in the environment, it is only necessary to consider the initial concentration for the formulated product.

The FOCUS spray drift calculator (model v.1 12-Apr-2001) was used to determine the maximum potential concentration of the intact formulation in surface water via spray drift. As a worst-case situation for the intact formulation, it is assumed that the total annual application rate is applied on a single occasion i.e. number of applications = 1.

[5] FOCUS (2001): "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.
[6] FOCUS (2015). Generic guidance for FOCUS surface water scenarios, ver 1.4, May 2015.

Table 8.5-1: Worst-case initial PECsw for intact formulation 'Novagib' needed for risk assessment

Crop	Formulation application rate	Application timing	PECsw (µg 'Novagib' /L)[1] at default distance		
			Water body type Ditch	Water body type Pond	Water body type Stream
Apple	4 x 0.5 L/ ha 'Novagib' (equivalent to 4 x 520 g 'Novagib'/ha[1])	GS 69-74	163.6	9.838	149.6
Pear	1 x 1.2 L/ ha 'Novagib' (equivalent to 1 x 1248 g 'Novagib'/ha[1])	GS 62-69	98.17	5.903	89.78
Pear	2 x 0.6 L/ ha 'Novagib' (equivalent to 2 x 624 g 'Novagib'/ha[1])	GS 62-69	98.17	5.903	89.78

(1) Using FOCUS drift calculator (v.1) and the crop scenario pome/stone fruit early applications (as a worst-case).
(2) Based on a formulation relative density of 1.04 g/ml.

The maximum initial concentration of the formulated product 'Novagib' in surface water following application is 163.6 µg 'Novagib'/L (worst-case assumptions, no mitigation).

Exposure of surface water can occur directly *via* spray drift or *via* soil drainage and run-off, therefore the fate and behaviour of the active substance in soil and aquatic systems is considered.

The fate and behaviour of the active substance and any associated metabolites in soil is investigated in Document CA, Section 8. The definition of the residue for risk assessment (soil) is defined too. The active substance gibberellins GA4/7 contains two components (gibberellins GA4 and gibberellins GA7). Degradation of gibberellins GA4 and gibberellins GA7 in soil leads to the formation of numerous degradation products. However, due to the natural occurrence of the active substance these metabolites are not considered to be of environmental concern and have not been considered further.

The fate and behaviour of the active substance and associated metabolites in aquatic systems is investigated in Document CA, Section 8 too. The degradation of gibberellins GA4 and gibberellins GA7 in aquatic systems is expected to be rapid and complete with the formation of numerous degradation products. However, due to the natural occurrence of the active substance these metabolites are not considered to be of environmental concern and are not considered further.

As the ratio of gibberellins GA4 and gibberellins GA7 in the active substance can vary between sources, for the determination of PECs of the active substance the approach adopted as a precautionary worst-case has been to consider alternate situations where the active substance is 100% gibberellins GA4 and separately 100% gibberellins GA7.

The supported GAP is presented in Document D1, with relevant agronomic parameters being summarised in Table 8.5-1.

FOCUS Steps 1 and 2

Worst-case precautionary predicted environmental concentrations in surface water of the two components (gibberellins GA4 and gibberellins GA7) in the active substance following treatment with 'Novagib' have been calculated using the procedures recommended by the FOCUS Working group on surface water scenarios according to Step 1 and Step 2, using the FOCUS Steps 1 & 2 calculator (ver 3.2).

Table 8.5-2: Summary of key agronomic input parameters used for FOCUS Step 1 and 2 calculations

Run no.	FOCUS Step	Location[2]	Application details			Crop inter-ception[1]	Crop type
			Timing[2,3]	No. of applns (interval)	Appln rate (g a.s./ha)		
38c1t1	1-2	S EU	Mar-May	4 x (7 d)	5	average (i.e. 40%)	Pome fruit, early
38c1t2	1-2	S EU	Mar-May	1 x (n.a.)	12	average (i.e. 40%)	Pome fruit, early
38c1t3	1-2	S EU	Mar-May	2 x (3 d)	6	average (i.e. 40%)	Pome fruit, early

(1) The crop interception values chosen within the constraints of the FOCUS drift calculator were selected to be as consistent as possible (without being preferential) with the worst-case application timings specified in Table 8.5-1.
(2) Only the worst-case location/application timing combination was considered.
(3) The worst-case timing range takes into account all the application timings specified in Document D1 and Table 8.5-1.

Chemical parameters used for the two components (gibberellins GA4 and gibberellins GA7) of the active substance are presented in Table 8.5-3.

Table 8.5-3: Summary of key chemical input parameters used for FOCUS Step 1 and 2 calculations

Endpoint	Parameter value used		Comments
	gibberellins GA4 (component code[1] 38c1)	**gibberellins GA7 (component code[1] 38c2)**	
Physico-chemical parameters			
Water solubility (mg/L)	340	340	See Doc M-CA, Section 3, Point CA 2.5. (Note a value of 340 mg/L was used to be consistent with the agreed parameter specified in the existing EFSA LoEP (p35/50).
Environmental behaviour			
DT_{50} in soil (days)	2 (worst-case)	2 (worst-case)	See Doc M-CA, Section 7, Point CA 7.1.2.3 (Table CA 7.1.2.3-1) (Note based on the persistence DT_{50} values, a worst-case modelling DT_{50} of 2 days was assumed)
Soil adsorption coefficient, Kfoc (ml/g)	4 (worst-case, pH dependant, n=4)	4 (worst-case, pH dependant, n=4)	See Doc M-CA, Section 7, Point CA 7.1.3.1.1 (Table CA 7.1.3.1.1-4)
Half-life water (days, 20ºC)	1000	1000	worst-case default (precautionary)
Half-life sediment (days, 20ºC)	1000	1000	worst-case default (precautionary)
Half-life sediment/water system (days, 20ºC)	1000	1000	worst-case default (precautionary)

(1) Used in modelling files

Using the agronomic information supplied in Table 8.5-2 and the endpoints and chemical parameters specified in Table 8.5-3, the maximum predicted environmental concentrations of the two components in the active substance (gibberellins GA4 and gibberellins GA7) according to FOCUS Steps 1-2 calculations are presented in Table 8.5-4. Short and long term actual and time weighted average PEC values are not required for the risk assessment (see Ecotox part) and have therefore not been calculated.

Table 8.5-4: **FOCUS Step 1 and Step 2 PECsw (µg/L) and PECsed (µg/kg) of components gibberellins GA4 and gibberellins GA7 following treatment with 'Novagib'**

Step	Crop	Application details (g a.s./ha)	EU Region and season of application	Predicted environmental concentration	
				Initial PECsw (µg/L)	Max. PECsed (µg/kg dw)
gibberellins GA4 and gibberellins GA7					
1	Pome fruit	4 x 5	n.a.	8.58	0.343
2			S EU Mar-May	1.66 (0.583)[1]	0.066 (0.023)[1]
1	Pome fruit	1 x 12	n.a.	5.15	0.206
2			S EU Mar-May	1.40 (-)	0.056 (-)
1	Pome fruit	2 x 6	n.a.	5.15	0.206
2			S EU Mar-May	1.18 (0.700)[1]	0.047 (0.028)[1]

(1) Values in brackets are the corresponding PEC resulting from a single application.
Following use of 'Novagib' according to the representative GAP, the maximum potential concentrations in surface water and sediment of the two components gibberellins GA4 and gibberellins GA7 according to FOCUS Step 2 calculations are 1.66 µg/L and 0.066 dw µg/kg.

On the basis of the aquatic risk assessment, no further refinements are necessary.

B.8.6. FATE AND BEHAVIOUR IN AIR

B.8.6.1. Route and rate of degradation in air and transport via air

Based on vapour pressure values of 0.160 and 0.067 Pa (22°C) for the components gibberellins GA4 and gibberellins GA7, respectively, the components are potentially volatile from plant and soil surfaces. However, no volatility of the individual components gibberellins GA4 or gibberellins GA7 was observed in any of the environmental fate studies and therefore volatility under the conditions of use is not expected. Furthermore, the estimated photochemical oxidative degradation half-lives in air of the components gibberellins GA4 and gibberellins GA7 (calculated using the Atkinson equation), are 1.67 and 0.99 hours, respectively (EFSA LoEP, page 39/50). Therefore, these components will not persist in the atmosphere, if present.

The available data clearly indicate that gibberellins GA4/7 and its individual components gibberellins GA4 and gibberellins GA7 are not persistent in air. Therefore, in accordance with Regulation (EC) No. 1272/2008, gibberellins GA4/7 fulfils the criteria for consideration as a low-risk active substance in this regard.

B.8.6.2. Predicted environmental concentrations from airborne transport

Not applicable. Based on a vapour pressure value, the active substance GA4/7 is potentially volatile from plant (but not soil) surfaces.

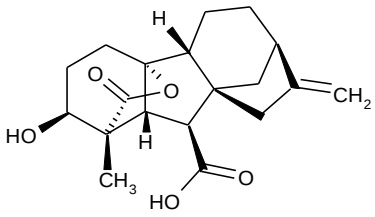
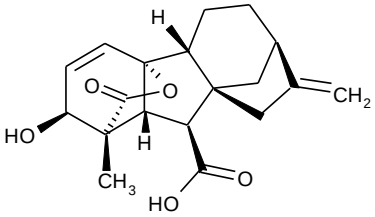
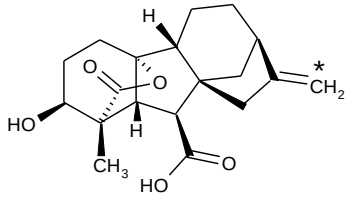
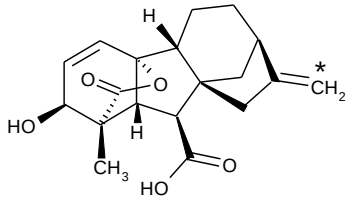
B.8.7. PREDICTED ENVIRONMENTAL CONCENTRATIONS FROM OTHER ROUTES OF EXPOSURE

Exposure to the active substance via other routes of exposure is not envisaged. Further data are therefore not required.

B.8.8. REFERENCES RELIED ON

No studies are submitted, only summary of the calculations presented in this document.

Appendix 1: Chemical names and structures of components

Code Number (Synonyms)	Description	Compound	Structure
GA4	(3S,3aR,4S,4aR,7R,9aR,9bR,12S)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-3,9b-propanoazuleno[1,2-b]furan-4-carboxylic acid (IUPAC) Synonym(s): (1α,2β,4aα,4bβ,10β)-2,4a-dihydroxy-1-methyl-8-methylenegibbane,-1,10-dicarboxylic acid 1,4a-lactone (CAS), Gibberellins GA4 CAS no. 468-44-0	active substance	 Mol wt – 332.40 g/mol
GA7	(3S,3aR,4S,4aR,7R,9aR,9bR,12S)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-b]furan-4-carboxylic acid (IUPAC) Synonym(s): (1α,2β,4aα,4bβ,10β)-2,4a-dihydroxy-1-methyl-8-methylenegibb-3-ene,-1,10-dicarboxylic acid 1,4a-lactone (CAS), Gibberellins GA7 CAS no. 510-75-8	active substance	 Mol wt – 330.40 g/mol
Radiolabelled GA4 (* position of 14C)	As above	active substance	
Radiolabelled GA7 (* position of 14C)	As above	active substance	

Appendix 2: Modelling files

The simulation files generated are provided in the associated electronic documents. For the individual files, the following coding has been used:

Timing	**Scenario**	**File names**			
		PEARL (.sum files)		**PELMO (psm file)**	
		gibberellins GA4	**gibberellins GA7**	**gibberellins GA4**	**gibberellins GA7**
Apple (FOCUS pome fruit), **4 x 5 g a.s./ha (7 day minimum interval)**					
Main GS69-74 i.e. early (worst-case)	C H J K N P O S T	2-10 (macro003)	11-19 (macro009)	38c1t1	38c2t1
Earliest 1-Apr		65-73 (macro006)	74-82 (macro012)	38c1t1	38c2t2
Pear (FOCUS pome fruit), **1 x 12 g a.s./ha**					
Main GS62-69 i.e. early (worst-case)	C H J K N P O S T	20-28 (macro004)	29-37 (macro010)	38c1t3	38c2t3
Earliest 1-Apr		83-91 (macro007)	92-100 (macro013)	38c1t4	38c2t4
Pear (FOCUS pome fruit), **2 x 6 g a.s./ha (3 day minimum interval)**					
Main GS62-69 i.e. early (worst-case)	C H J K N P O S T	38-46 (macro005)	56-64 (macro011)	38c1t5	38c2t5
Earliest 1-Apr		101-109 (macro008)	110-118 (macro014)	38c1t6	38c2t6

The following codes were used in the modelling files:

- Substances/components: Gibberellins GA4 (38c1) and gibberellins GA7 (38c2).
- Treatment patterns:
  i) apple 4 x 5 g as/ha (7d interval) main applications (treatment pattern t1), earliest applications (treatment pattern t2)
  ii) pear 1 x 12 g as/ha main applications (treatment pattern t3), earliest applications (treatment pattern t4)
  iii) pear 2 x 6 g as/ha (3d interval) main applications (treatment pattern t5), earliest applications (treatment pattern t6)