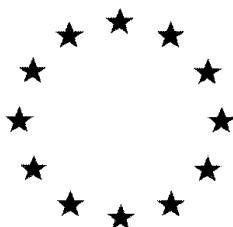


# **European Commission**



**Addendum  
VOLUME 2**

**Abamectin**

**Rapporteur Member State: The Netherlands**

**April 2015**

**Draft Assessment Report and Proposed decision of the Netherlands prepared  
in the context of the possible extension of the approval conditions of  
abamectin under Regulation (EC) 1107/2009**

## Version history page

Date	Version history
April 2015	Initial version

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**A. List of the tests, studies and information submitted****A.1 Identity**

Refer to Volume 4.

**A.2 Physical and chemical properties**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner</b>
KIIIA1 2.1 / 01 & KIIIA1 2.4.1 / 01 & KIIIA1 2.4.2 / 01 & KIIIA1 2.5.2 / 01 & KIIIA1 2.5.3 / 01 & KIIIA1 2.6.1 / 01 & KIIIA1 2.8.6.1 / 01	Kalt R.	2009	A12115I - Physical properties of batch SMU9EP004 Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 120109 GLP, not published Syngenta File No A12115I_10005	N	Y	SYN
KIIIA1 2.2.1 / 01 & KIIIA1 2.2.2 / 01 & KIIIA1 2.3.1 / 01 & KIIIA1 2.3.3 / 01	Jackson W.	2009	A12115I - Physical and chemical properties Syngenta Syngenta Technology & Projects, Huddersfield, United Kingdom, HT09/241 GLP, not published Syngenta File No A12115I_10013	N	Y	SYN
KIIIA1 2.7.1 / 01	Kalt R.	2009a	A12115I - Storage stability and shelf life statement (2 weeks 54°C) in packaging made of HDPE Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, Not GLP, not published Syngenta File No A12115I_10009	N	N	SYN
KIIIA1 2.7.1 / 02	Kalt R.	2009b	A12115I - Storage stability and shelf life statement (2 weeks 54°C) in packaging made of PET Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, Not GLP, not published Syngenta File No A12115I_10010	N	N	SYN
KIIIA1 2.7.4 / 01 &	Kalt R.	2009c	A12115I - Technical properties of batch SMU9EP004 Syngenta	N	N	SYN

KIIIA1 2.8.2 / 01 & KIIIA1 2.8.3.1 / 01 & KIIIA1 2.8.3.2 / 01 & KIIIA1 2.8.5.2 / 01 & KIIIA1 2.8.8.2 / 01			Syngenta Crop Protection, Münchwilen, Switzerland, 120251 Not GLP, not published Syngenta File No A12115I_10004			
KIIIA1 2.7.5 / 01 & KIIIA1 4.1.3 / 01	Kalt R.	2011	A12115I - Storage stability and shelf life statement (2 years 25°C) in packaging made of HDPE Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 10478696 Not GLP, not published Syngenta File No A12115I_10039	N	N	SYN
KIIIA1 2.7.5 / 02 & KIIIA1 4.1.3 / 02	Kalt R.	2011a	A12115I - Storage stability and shelf life statement (2 years 25°C) in packaging made of PET Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 10478743 Not GLP, not published Syngenta File No A12115I_10040	N	N	SYN
KIIIA1 3.3.1 / 01	Briswalter C.	2011	A12115I GAP Syngenta Crop Protection AG, Basel, Switzerland, Not GLP, not published Syngenta File No A12115I_10042	N	N	SYN

### A.3 Data on application and efficacy

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner SYN = Syngenta
KIIIA1 6/01	Ivacic D.	2012	A12115I (Tervigo) for nematodes on protected vegetables Syngenta - No Unpublished Regulatory document No. A12115I_10165	Y	SYN

**A.4 Further information**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner</b>
IIIA 4.2.2/01	Kalt, R	2009d	A12115I - The effectiveness of the spray tank cleaning procedure Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 120365 Not GLP, not published Syngenta File No A12115I_10012	N	N	SYN

**A.5 Methods of analysis**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Owner</b>
KIIIA1 5.2.1 / 01	Dos Santos Alves A.	2009	Determination of MK936 in A12115I Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, SF-328/1 Not GLP, not published Syngenta File No A12115I_10017	N	N	SYN
KIIIA1 5.2.1 / 02	Heintz K.	2009	A12115I - Validation of analytical method SF-328/1 Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 120106 GLP, not published Syngenta File No A12115I_10018	N	Y	SYN

## A.6 Toxicology and metabolism data

Data point	Author(s)	Year	Title Company 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
KIIIA1 7.1.1 / 01	[REDACTED]	2009a	Abamectin SC (A12115I) - Acute Oral Toxicity Study in the Rat (Up and Down Procedure)  Syngenta - Jealott's Hill, Bracknell, United Kingdom [REDACTED]  GLP, not published Syngenta File No A12115I_10020	Y	Y	Y	SYN
KIIIA1 7.1.2 / 01	[REDACTED]	2010	Abamectin SC(A12115I) - Acute Toxicity Study in Rats Syngenta - Jealott's Hill, Bracknell, United Kingdom [REDACTED]  GLP, not published Syngenta File No A12115I_10021	Y	Y	Y	SYN
KIIIA1 7.1.3 / 01	[REDACTED]	2009	Abamectin SC (A12115I) - Acute 4 Hour (Nose Only) Inhalation Study In The Rat Syngenta - Jealott's Hill, Bracknell, United Kingdom [REDACTED]  GLP, not published Syngenta File No A12115I_10011	Y	Y	Y	SYN
KIIIA1 7.1.4 / 01	[REDACTED]	2009b	Abamectin SC (A12115I) - Primary Skin Irritation Study in Rabbits (4 Hour Semi-Occlusive Application) Syngenta [REDACTED]  GLP, not published Syngenta File No A12115I_10015	Y	Y	Y	SYN
KIIIA1 7.1.5 / 01	[REDACTED]	2009c	Abamectin SC (A12115I) - Primary Eye Irritation Study in Rabbits Syngenta [REDACTED]  GLP, not published	Y	Y	Y	SYN

			Syngenta File No A12115I_10016				
KIIIA1 7.1.6 / 01		2009d	Abamectin SC (A12115I) - Contact Hypersensitivity in Albino Guinea Pigs, Buehler Test (9-induction) Syngenta - Jealott's Hill, Bracknell, United Kingdom  GLP, not published Syngenta File No A12115I_10019	Y	Y	Y	SYN



**A.7 Residue data**

OECD data point number / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed  Y/N	Owner
KIIIA1 8.1.1 / 01	Kwiatkowski A., Hill S.	2007	Abamectin - Storage Stability in Crops Stored Deep Frozen for up to Two Years - Final Report  Syngenta Crop Protection AG, Basel, Switzerland  Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, T022438-04-REG 05-S504  GLP, not published  Syngenta File No MK936/1798	Y	SYN
KIIIA1 8.3.1 / 01	Schulz H.	2010a	Abamectin - Residue Study on Protected Tomatoes in Germany and the United Kingdom in 2009  Syngenta  SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T001014-09-REG  GLP, not published  Syngenta File No A12115I_10028	Y	SYN
KIIIA1 8.3.2 / 01	Schulz H.	2010b	Abamectin - Residue Study on Protected Pepper in Germany and the United Kingdom in 2009  Syngenta - Jealott's Hill, Bracknell, United Kingdom  SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T001977-09-REG  GLP, not published  Syngenta File No A12115I_10027	Y	SYN
KIIIA1 8.3.4 / 01	Schulz H	2010c	Abamectin - Residue Study on Protected Cucumber in Germany and the United Kingdom in 2009  Syngenta - Jealott's Hill, Bracknell, United Kingdom  SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T001016-09-REG  GLP, not published  Syngenta File No A12115I_10026	Y	SYN

OECD data point number / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
KIIIA1 8.3.5 / 01	Schulz H.	2012a	Abamectin - Residue Study on Protected Melon in Southern France and Spain in 2011 Syngenta SGS Institut Fresenius GmbH, Taunusstein, Germany, TK0055923-REG GLP, not published Syngenta File No A12115I_10064	Y	SYN
KIIIA1 8.3.6 / 01	Schulz H.	2012b	Abamectin - Residue Study on Protected Beans with Pods (Fresh) in Spain in 2011 Syngenta SGS Institut Fresenius GmbH, Taunusstein, Germany, TK0055927-REG GLP, not published Syngenta File No A12115I_10063	Y	SYN

## A.8 Environmental fate and behaviour

Annex point(s)	Author(s)	Year	Title Source Report ID GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
KIIIA1 9.6.1 / 01	Mason D, Li Z	2010	Abamectin - A Leaching Assessment for Parent and Soil Metabolites NOA448111, NOA448112, NOA457464 and NOA457465 Using the FOCUS Groundwater Scenarios Following Application to Grass Syngenta - Jealott's Hill, Bracknell, United Kingdom Syngenta - Jealott's Hill, Bracknell, United Kingdom, RAJ0775B Not GLP, not published Syngenta File No NOA422601_10007 This is CONFIDENTIAL INFORMATION*	N	SYN
KIIIA1 9.6.1 / 02	Mason D	2010	Abamectin - Predicted Environmental Concentrations in Groundwater for Abamectin using the FOCUS Groundwater Scenarios Following Application to Grass Syngenta - Jealott's Hill, Bracknell, United Kingdom Syngenta - Jealott's Hill, Bracknell, United Kingdom, TK0006924_1 Not GLP, not published Syngenta File No NOA422601_10016 This is CONFIDENTIAL INFORMATION*	N	SYN
KIIIA1 9.6.1 / 03	Wallace D.	2012	Abamectin - Predicted Environmental Concentration of metabolite U8 in ground water Syngenta European Product Registration, Basel, Switzerland, Not GLP, not published Syngenta File No NOA422601_10021 This is CONFIDENTIAL INFORMATION*	N	SYN
KIIIA1 9.6.1 / 04	Carnall J.	2014	Abamectin - A Leaching Assessment for Parent and Soil Metabolites NOA448111, NOA448112, NOA457464 and NOA457465 Using the FOCUS Groundwater Scenarios Following Drip Irrigation Application to Beans and Tomatoes in the EU  DRAFT Report	Y	SYN
KIIIA 9.6.2/1	Patterson D.	2014	Abamectin A Fate assessment for Parent using the FOCUS Surface Water Scenarios at Step 3 Following Application to Walk-in Tunnel Cultivated Fruiting Vegetables.	Y	SYN

\* Syngenta requests data confidentiality for these data. Disclosure of the information might undermine Syngenta commercial interests by providing access to Syngenta specific know-how used to develop unique positions and approaches to risk assessments

**A.9 Ecotoxicology data**

<b>Annex point</b>	<b>Author</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished</b>	<b>Data protection claimed Y/N</b>	<b>Owner (SYN = Syngenta)</b>
KIIIA1 10.1.6 / 01	[REDACTED]	2011	Abamectin SC (A12115I) - An acute oral toxicity study with the northern bobwhite using a sequential testing procedure Syngenta [REDACTED] GLP, not published Syngenta File No A12115I_10034	Y	SYN
KIIIA1 10.2.2.1 / 01	[REDACTED]	2011	Abamectin SC (A12115I) - Acute toxicity to rainbow trout ( <i>Oncorhynchus mykiss</i> ) in a 96-hour test Syngenta [REDACTED] GLP, not published Syngenta File No A12115I_10041	Y	SYN
KIIIA1 10.2.2.2 / 01	Hoger S	2010	Abamectin SC (A12115I) - Acute toxicity to <i>Daphnia magna</i> in a 48-hour immobilization test Syngenta - Jealott's Hill, Bracknell, United Kingdom Harlan Laboratories Ltd., Zelgliweg 1, 4452 Itingen, Switzerland, C86663 GLP, not published Syngenta File No A12115I_10025	Y	SYN

<b>Annex point</b>	<b>Author</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished</b>	<b>Data protection claimed Y/N</b>	<b>Owner (SYN = Syngenta)</b>
KIIIA1 10.2.2.3 / 01	Liedtke A.	2011a	Abamectin SC (A12115I) - Toxicity to <i>Pseudokirchneriella subcapitata</i> in a 96-hour algal growth inhibition test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D36398 GLP, not published Syngenta File No A12115I_10038	Y	SYN
KIIIA1 10.2.3 / 01	Rufli H.	1999	Assessment of the potential biological effects of Abamectin (MK936, 018 EC) (A-8612 A) exposures on aquatic ecosystems as measured in an outdoor microcosm tank system Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 982570 GLP, not published Syngenta File No MK936/0638	Y	SYN
KIIIA1 10.2.3 / 02	Knauer K.	2002	Assessment of the Effects of Abamectin 018 EC (A8612A) in Outdoor Microcosms Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 2002590 GLP, not published Syngenta File No MK936/0817	Y	SYN

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner (SYN = Syngenta)
KIIIA1 10.3.2.1 / 01	[REDACTED]	2009	Abamectin SC (A12115I) - Acute Oral Toxicity Study in the Rat (Up and Down Procedure)  Syngenta - Jealott's Hill, Bracknell, United Kingdom [REDACTED] [REDACTED]  GLP, not published Syngenta File No A12115I_10020	Y	SYN
KIIIA1 10.4.2.1 / 01	Kling A.	2011	Abamectin SC (A12115I) - Acute oral and contact toxicity to the honeybee Apis mellifera L. in the laboratory  Syngenta Eurofins Agroscience Services GmbH, Niefern-Öschel., Germany, S11-02876  GLP, not published Syngenta File No A12115I_10035	Y	SYN
KIIIA1 10.5.2 / 01	Fussell S.	2004	MK936 (abamectin): a rate-response extended laboratory test to determine the effects of an 18 g/L EC formulation (A8612AB) on the parasitic wasp Aphidius rhopalosiphi  Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox. Ltd., Southampton, United Kingdom, SYN-04-1 2032631  GLP, not published Syngenta File No MK936/1105	Y	SYN

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner (SYN = Syngenta)
KIIIA1 10.5.2 / 02	Waterman L.	2004	MK936 (abamectin): A rate-response extended laboratory test to determine the effects of an 18 g/L EC formulation (A8612AB) on the predatory mite Typhlodromus pyri  Syngenta Crop Protection AG, Basel, Switzerland  Mambo-Tox. Ltd., Southampton, United Kingdom, SYN-04-2  GLP, not published  Syngenta File No MK936/1106	Y	SYN
KIIIA1 10.5.2 / 03	Reber B.	1999	Acute toxicity of MK 936 EC 018 (A-8612 A) to the predatory ground beetle Poecilus cupreus L. (Coleoptera: carabidae)  Novartis Crop Protection AG, Basel, Switzerland  Novartis Crop Protection AG, Basel, Switzerland, 982611  GLP, not published  Syngenta File No MK936/0626	Y	SYN
KIIIA1 10.5.2 / 04	Kuhner C.	1998	Vertimec EC 0.18 (A-8612 A): combination of a semi-field and an extended laboratory study (field aged residue) to evaluate the effects on the ground beetle, poecilus cupreus L. (Coleoptera, Carabidae)  Novartis Crop Protection AG, Basel, Switzerland  GAB Biotechnologie GmbH, Niefern, Germany, 98247/01-NEPc  GLP, not published  Syngenta File No MK936/0540	Y	SYN

<b>Annex point</b>	<b>Author</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished</b>	<b>Data protection claimed Y/N</b>	<b>Owner (SYN = Syngenta)</b>
KIIIA1 10.6.2 / 01	Friedrich S.	2011	Abamectin SC (A12115I) - Acute toxicity to the earthworm <i>Eisenia fetida</i> Syngenta BioChem Agrar, Gerichshain, Germany, 11 10 48 099 S GLP, not published Syngenta File No A12115I_10037	Y	SYN