

**REGISTRATION REPORT**

**Part B**

**Section 0**

**Product Background, Regulatory Context  
and GAP information**

Product code: 102000028562

Product name(s): Deltamethrin + flupyradifurone EC 85  
(10+75 g/L)

Central Zone

Zonal Rapporteur Member State: Poland

**CORE ASSESSMENT**

(Authorization)

Applicant: Bayer Crop Science Division

Submission date: 01/08/2019

MS Finalisation date: October 2021 (initial Core Assessment)

March 2022 (final Core Assessment)

May 2022 (update final Core Assessment)

### Version history

When	What
08/2019	Original Bayer Crop Science Division submission
October 2021	Initial zRMS assessment  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and <b>highlighted in grey</b> . Not agreed or not relevant information are <del>struck through and shaded for transparency</del> .
February 2022	Final report (Core Assessment updated following the commenting period)  Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are <b>highlighted in yellow</b> . Information no longer relevant <del>is struck through and shaded</del> .
May 2022	Update final Core Assessment  Correction by zRMS in the additional commenting box following the GAP table, p. 28-29, <b>highlighted in yellow</b> .

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## 0 Product background, regulatory context and GAP information

### 0.1 Introduction

#### 0.1.1 Reason for application

This application follows the data requirements for the active substances laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

It is submitted for the authorization of use of the product Deltamethrin + Flupyradifurone EC 85 (10+75 g/L), an EC formulation containing 10 g of the active substance deltamethrin and 75 g of the active substance flupyradifurone per liter. The main intended use is the foliar spray of oilseed rape against insects.

The reference list included in the dossier defines the list of studies and reports, submitted with the application, for which a claim for data protection is made. This claim for protection is made as the studies and reports were submitted and used as the basis for both the approval of the active substances deltamethrin and flupyradifurone and for the authorization for the first time in the different concerned countries of the product Deltamethrin + Flupyradifurone EC 85 (10+75 g/L) or any new use.

Based on Article 59 of Regulation 1107/2009 Bayer Crop Science Division claims 10 years protection for these studies and reports. In each country, the competent authority has to confirm that these studies and reports are protected for 10 years from the data of authorisation of the product and thus cannot be used for the benefit of another applicant.

#### 0.1.2 Details of zRMS(s) and concerned MS

**Table 0.1-1: Overview of zRMS and cMS**

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applica- ble)
<b>Northern zone</b>	not applicable	not applicable
<b>Central zone</b>	ZRMS : Poland Product name : Sivanto Energy No authorization yet	No authorization yet cMS : The Czech Republic, Hungary, <del>The Netherlands</del> , Romania, Slovakia, Slovenia
<b>Southern zone</b>	not applicable	not applicable
<b>Inter-zonal</b>	not applicable	not applicable

#### 0.1.3 Regulatory history of the active(s)

##### 0.1.3.1 Deltamethrin

**Table 0.1-2: Summary of regulatory history of deltamethrin (CAS No: 52918-63-5)**

<b>Status</b>	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2003/5EC or Commission Implementing Regulation (EU) No 540/2011
RMS	Sweden
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	1/11/2003

<b>Status</b>	
Date of first Commission (re-registration) deadline (Step 1)	30/04/2004
Date of final Commission (re-registration) deadline (Step 2)	31/10/2007
Current expiration of approval	<del>31/10/2019</del> <del>31/10/2021</del> <b>31/10/2022</b>
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the operator safety and must ensure that the conditions of authorisation include appropriate protective measures,
- the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels,
- the protection of aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate.

The SANCO report deltamethrin (SANCO 6504/VI/99-final, 17 October 2002) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report is not available.

**Table 0.1-3: Information on minimum purity of deltamethrin**

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report
980 g/kg (technical grade)	<p>min. 985 g/kg (This purity is in full compliance to the FAO specification 333/TC; may 2005);</p> <p>The lowest specified purity is 930 g/kg (The equivalence report from RMS UK from January 2012 for the Shenyang source stated a minimum purity of 940 g/kg. However, this was superseded by the AI renewal, where the same RMS stated a minimum purity of 930 g/kg in the RAR).</p>

The following tables provide the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Deltamethrin	
	EU agreed endpoint from EU Review Report on Deltamethrin (EU, 2002)	Endpoint used*
<del>DT<sub>50,soil field</sub> (d)</del>	<del>Overall realistic estimate: 3 weeks (field study)</del>	<p>28.3 days</p> <p>In the EU Review Report on Deltamethrin (EU, 2002), field DT<sub>50</sub> values of one to four weeks are given. A re-evaluation of the field data by Schäfer (2003, M 221665-01-1, dRR, Section 8) confirmed that visual assessment and gave first order DT<sub>50</sub> values between 7.5 and 28.3 days. The worst case DT<sub>50</sub> from kinetic evaluation of field data was chosen.</p>
K <sub>foc</sub> (mL/g)	10240000.0	<p>460000 (minimum, n = 4)</p> <p>(used for MACRO calculations, as the model cannot handle Koc values above approximately 1000000 mL/g. Using this reduced Koc value guarantees conservative predictions)</p>

Endpoint	Deltamethrin	
	EU agreed endpoint from EU Review Report on Deltamethrin (EU, 2002)	Endpoint used*
DT <sub>50,soil-lab</sub> (d)	26 (mean, n = 12)	17.1  Geometric mean of laboratory DT <sub>50</sub> normalised to field capacity and 25°C; see Schäfer & Mikolaseh (2004, M 236281 01 1, dRR, Section 8)
Water solubility (mg/L)	0.0002 at 25°C	Step 3+4: 0.001  Minimum limited to 0.001 mg/L in SWASH
K <sub>foc</sub> (mL/g)	10240000.0 (arithmetic mean, n = 4)	460000 (minimum, n = 4)  (used for FOCUS Step 3+4 calculations as SWASH cannot handle Koc values above approximately 1000000 mL/g. Using this reduced Koc value guarantees conservative predictions with regard to run-off exposure (as well as drainflow exposure).
Freundlich Exponent 1/n	0.74 - 1.2	0.93  Arithmetic mean
DT <sub>50,water</sub> (d)	Worst case DT <sub>50</sub> = 17 hours; obtained from higher tier studies (since no reliable DT <sub>50</sub> for the water phase alone was obtained from water/sed. study)	76  Highest DT <sub>50</sub> in total system (please refer to Schad & Zerbe (2016, M 553324 02 1), dRR, Section 8)
DT <sub>50,sed</sub> (d)	Not stated	Step 1+2: 76  Highest DT <sub>50</sub> in total system (please refer to Schad & Zerbe (2016, M 553324 02 1), dRR, Section 8)
DT <sub>50,whole-system</sub> (d)	40–90	76  Highest DT <sub>50</sub> in total system (please refer to Schad & Zerbe (2016, M 553324 02 1), dRR, Section 8)
wild-mammal long-term and reproductive risk assessment	NOEL 2.5 mg/kg bw/d Short term oral toxicity (13-week study dog)	NOAED of 80 ppm (4.2 mg/kg bw/d)  Since the mode of application of deltamethrin, and particularly the carrier, considerably influences the toxicity induced in the test animals, the endpoint for the wild-mammal long-term and reproductive risk assessment should only be taken from studies including relevant exposure of the test animals. In the context of this exposure evaluation for a spray application of deltamethrin, wild mammals may be mainly exposed through uptake of residues on their natural diet consisting of plant or animal material.  The endpoint for the long-term and reproductive risk assessment should therefore be selected only from studies with (i) dietary exposure and (ii) endpoints relevant to that risk assessment. Based on these criteria, the endpoint for the long-term and reproductive risk assessment can be best selected from the following two studies: <ul style="list-style-type: none"> <li>— The multigeneration study with deltamethrin (Hoberman, 1992) providing a NO(A)ED of 4.2 mg a.s./kg bw/d (NOEC = 80 ppm), this value was included in the List of end-points.</li> <li>— The developmental neurotox study with deltamethrin (Gilmore et al. 2006) providing a NO(A)ED of 6.78 mg a.s./kg bw/d (NOEC = 80 ppm)</li> </ul> In these studies, the toxicological effect potential of deltamethrin on survival chances or the reproductive capacity for wild mammal

Endpoint	Deltamethrin	
	EU agreed endpoint from EU Review Report on Deltamethrin (EU, 2002)	Endpoint used*
		<p>populations is considered to be best and fully reflected.</p> <p>In the <del>multigeneration study</del>, deltamethrin did not affect the reproduction in rats. The NOAEL in adult male and female rats was 80 ppm (the average consumed dosages ranged from 4.2 to 12.4 mg/kg bw/day in the periods evaluated in this study) based on mortality, clinical signs, reduced body weight, reduced food consumption and gastric erosion noted in animals of the 320 ppm level. The NOAEL in offsprings was 80 ppm based on increased pup mortality, a reduced lactation index and reduced body weight noted in animals of the 320 ppm dose level.</p> <p>In the <del>developmental neurotoxicity study (DNT)</del> by Gilmore et al. (2006), deltamethrin did not affect the development and behavioural fitness of the offspring at the NOEC of 80 ppm. In this study a test design was employed (exposure of pregnant dams, giving birth to the pups which are then raised on diet until completion of a range of behavioural fitness tests) which is basically very similar to a standard developmental toxicity study, except that the administration in the DNT study is more relevant (via diet rather than per gavage), and that the behavioural fitness of the offspring was tested. No environmentally relevant adverse effects on endpoints for wild mammals were observed at the NOEC of 80 ppm (6.78 mg a.s./kg bw/d).</p> <p>Thus, no adverse effects were observed in, neither reproduction, nor the developmental neurotoxicity study with dietary exposure at 80 ppm.</p> <p>For deltamethrin it is therefore proposed to apply a <b>NOAED of 80 ppm (4.2 mg/kg bw/d)</b> from the reproduction study in rat (with dietary administration over a full life cycle) in the reproductive wild mammal risk assessment.</p>
<i>G. fasciatus</i> / <i>A. aquaticus</i> 96 h	4 acute endpoint (96-h LC <sub>50</sub> ) values for the two most sensitive invertebrate species, namely <i>Gammarus fasciatus</i> (0.00031, 0.032 and > 0.043 µg/L) and <i>Asellus aquaticus</i> (0.0051 µg/L).	<p>LC<sub>50</sub> geomean = 0.00384 µg a.s./L.</p> <p>The EC Review Report for deltamethrin (6504/VI/99-final; 2002) provides four acute endpoint (96-h LC<sub>50</sub>) values for the two most sensitive invertebrate species, namely <i>Gammarus fasciatus</i> (0.00031, 0.032 and &gt; 0.043 µg/L) and <i>Asellus aquaticus</i> (0.0051 µg/L). These values were derived from additional laboratory toxicity tests (i.e., tier 2) with the same test item (EC formulation of deltamethrin). According to the EFSA Aquatic Guidance Document (2013), as the two species belong to the same taxonomic group (crustaceans), the four acute LC<sub>50</sub> can be used to calculate a geomean LC<sub>50</sub> to which an AF of 100 is applied to derive an acute tier-2 RAC. Using 0.043 µg/L as the most conservative LC<sub>50</sub> for <i>G. fasciatus</i>, the geomean 96-h LC<sub>50</sub> of deltamethrin for the most sensitive aquatic invertebrate species:</p> <p>LC<sub>50</sub> geomean = 0.00384 µg a.s./L.</p>
Mesocosm rainbow trout 3 applications onto water surface, spray interval 7 d	EAC values range from 1.7 to 2.2 ng a.s./L based on laboratory studies, to 100 ng a.s./L based on the microcosm enclosure study with rainbow trout	<p>EAC of 100 ng a.s./L for fish.</p> <p>Refined endpoint required for risk assessment.</p> <p>Regarding chronic laboratory data for fish, several studies are available for deltamethrin. However, the chronic risk assessment is based on a higher tier outdoor microcosm study, resulting in a NOEAEC of 0.1 µg a.s./L (Deneer, 2005, M 256605-01-1).</p> <p>For chronic exposure, the corresponding EAC values range from 1.7 to 2.2 ng a.s./L based on laboratory studies, to 100 ng a.s./L based on the microcosm enclosure study with rainbow trout (NOEAEC of ≥ 1000 ng a.s./L, Assessment Factor of 10). The 21d-LC<sub>50</sub> gained under flow-through conditions in the laboratory is &gt;&gt; 19 times lower than the 21d-LC<sub>50</sub> of &gt;&gt; 1000 ng a.s./L in the outdoor enclosure study, indicating the overestimation of risks.</p>



Endpoint	Deltamethrin	
	EU agreed endpoint from EU Review Report on Deltamethrin (EU, 2002)	Endpoint used*
		based on results from laboratory conditions. The NOEC of this outdoor study is based on short term behavioral symptoms (swimming behavior) as the most sensitive endpoint. A change in behavior is an expression of physiological effects, which is highly sensitive and may lead to a reduced growth over time, particularly because food intake will be hampered. Insofar, it is comparable to the integrative parameter of growth, which was determined as the most sensitive endpoint in the chronic ELS and FFLC studies on fathead minnow. In addition, the microcosm study was performed under realistic worst case exposure conditions with the maximum number of three applications of deltamethrin in minimum of 7 day intervals. Thus, the NOEAEC and the chronic assessment factor of 10 seems the most appropriate endpoint for the final chronic risk assessment resulting in an ecologically acceptable concentration of 100 ng a.s./L for fish.

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

Endpoint	Metabolite Br2CA	
	EU agreed endpoint from EU Review Report on Deltamethrin (EU, 2002)	Endpoint used*
<del>DT<sub>50,soil field</sub> (d)</del>	<del>DT<sub>50</sub> = 2.3 (mean, n = 7)</del>	<del>12.3 days Maximum of laboratory DT<sub>50</sub> values used as worst case, see Schäfer &amp; Mikolasch (2004, M 236281-01-1, dRR, Section 8)</del>
<del>DT<sub>50,soil lab</sub> (d)</del>	<del>2.3 (mean)</del>	<del>2.0 Geometric mean of laboratory DT<sub>50</sub> normalised to field capacity and 25°C; see Schäfer &amp; Mikolasch (2004, M 236281-01-1, dRR, Section 8)</del>
Water solubility (mg/L)	Not stated	60.5 at 25°C Calculated according to EPIWIN™, version 3.10 (EPA, 2001)
K <sub>foc</sub> (mL/g)	26 (mean, n = 3)	25.6 Rounded value in list of endpoints, an unrounded value was used for calculations.
Maximum occurrence observed (% molar basis with respect to the parent)	Not stated	Water/sediment: 13.3 Maximum formed in the outdoor microcosm study (please refer to Schad & Zerbe (2016, <a href="#">M-553324-02-1</a> ), dRR, Section 8)
Fish, acute Rainbow trout 96 h, s	Not stated	LC <sub>50</sub> > 100 000 µg p.m./L <sub>nom</sub>  New study endpoint to provide information on the toxicity of Br <sub>2</sub> CA to fish
Invertebrate, acute <i>Daphnia magna</i> 48 h, s	Not stated	EC <sub>50</sub> > 100 000 µg p.m./L <sub>nom</sub>  New study endpoint to provide information on the toxicity of Br <sub>2</sub> CA to daphnia

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

#### zRMS comments:

Information presented in ables above was amended accordingly by the zRMS with not agreed new active substance data being struck through. For justification, please refer to evaluation presented in area of Section 8 and 9.

### 0.1.3.2 Flupyradifurone

**Table 0.1-4: Summary of regulatory history of flupyradifurone (CAS No 951659-40-8)**

<b>Status</b>	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 2015/2084
RMS	The Netherlands
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	09/12/2015
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	not applicable
Date of final Commission (re-registration) deadline (Step 2)	not applicable
Current expiration of approval	09/12/2025
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the protection of workers and operators,
- the risk to non-target arthropods, aquatic invertebrates and small herbivorous mammals,
- the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions,
- residues in animal matrices and rotational crops.

The SANTE report for flupyradifurone (SANTE/11649/2015/ rev 1 – 09/10/2015) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 10/02/2015 and updated on 21/03/2016 (EFSA Journal 2015;13(2):4020).

**Table 0.1-5: Information on minimum purity of flupyradifurone**

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
960 g/kg	980 g/kg Equivalence report available : N RMS : The Netherlands

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\* If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU

endpoints.

Endpoint	Active Substance	
	EU agreed endpoint from EFSA Journal 2015;13(2):4020	Endpoint used*
PECgw		Tier 2 calculations consider TDS approach which was evaluated in the DAR but not included into the final list of endpoints as an EU agreed guidance document is not yet available. The endpoints used are in the first approach consistent with those concluded in the DAR and in a second approach, further elaborated taking into account the recent EFSA opinion on TDS (EFSA Journal 2018;16(8):5382)

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

#### 0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised

#### 0.2 zRMS conclusion

For the overview of accepted uses see the Complete GAP table in Appendix 1 of this document.  
For detailed information see the GAP tables in the individual relevant sections.

Uses to be considered safe on the basis of EU methodology:

See column 15 of the Complete GAP table presented in Appendix 1 of this document.

Uses to be considered non-safe on the basis of EU methodology:

See column 15 of the Complete GAP table presented in Appendix 1 of this document.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

See column 15 of the Complete GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs for uses in Central Zone.

No use / GAPs is covered by established MRLs. An application for amending the MRLs for flupyradifurone and DFA has been submitted to The Netherlands on 18/02/2019 (application No 20190446 MRL).

#### **Additional information regarding residue section:**

In the meantime new MRLs (0.3 mg/kg) for oilseed rape and mustard seed were set for flupyradifurone and DFA in Commission Regulation 2021/1842 of 20 October 2021, applying from 10 November 2021 on. Available results of residue trials show that the in force MRLs of flupyradifurone and DFA on oilseed rape seed and mustard of 0.3 mg/kg (Reg. (EU) 2021/1842) will not be exceeded. The current EU MRLs for flupyradifurone and DFA are sufficient to support the proposed uses. Additionally, there is no sufficient data to support application of DLT+FPF EC 85 at flowering oilseed rape (BBCH 60-69). Following the review done by zRMS, the applicant would like to request to restrict the use of the product to applications outside of flowering.

The intended use patterns supported for Sivanto Energy in oilseed rape and mustard seeds will not be covered

by the currently approved MRLs for flupyradifurone and its metabolite DFA. Until the new MRLs for flupyradifurone and its metabolite DFA come into force, authorisation of the GAP (oilseed rape and mustard) will not be possible.

## Appendix 1 ALL intended uses

PPP (product name/code):	deltamethrin + flupyradifurone EC 85 (10+75 g/L)	Formulation type:	GAP rev. , date: 2022-03 EC <sup>(a, b)</sup>
Active substance 1:	deltamethrin	Conc. of as 1:	10 g/L <sup>(c)</sup>
Active substance 2:	flupyradifurone	Conc. of as 2:	75 g/L <sup>(c)</sup>
Safener:	none	Conc. of safener:	not applicable <sup>(c)</sup>
Synergist:	none	Conc. of synergist:	not applicable <sup>(c)</sup>
Applicant:	Bayer Crop Science Division	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	central <sup>(d)</sup>	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes		
Field of use:	insecticide applied as a foliar spray		

For the sake of clarity, the uses are presented

1. In a Master Summary GAP table where all uses are grouped across countries
2. In a Complete GAP table Given the residue extrapolation rules described in document ~~SANCO-7525/VI/95~~ SANTE/2019/12752, a great number of crops may be concerned. In order not to unnecessarily increase the size of the Complete GAP table, only the intended uses in the main crops or the crop groups are listed (see details in footnotes). The crops are sorted according to Commission Regulation (EU) No ~~752/2014~~ 2018/62.

## Master Summary GAP table

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Mem- ber state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/syner- gist per ha <sup>(i)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1, 2, 5, 6, 7, 8, 11, 12, 17, 18, 23, 24, 27, 28	CZE HUN NLD POL ROU SVK SVN	Rape, winter (BRSNW) Rape, spring (Can- ola) (BRSNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600  250- 400 (Rape winter) 200- 600 (Rape, spring)	as per growth stage	For authorization in <b>spring oilseed rape</b> see the complete GAP starting next page, which is identical to the one in Part B Sec- tion 3 (Efficacy)
13, 14, 19, 20	POL ROU	Rape, winter (BRSNW) Rape, spring (Can- ola) (BRSNS)	F	MELIAE	spraying (foliar)	50-57 50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600  250- 300 (POL) 200- 600 (ROU)	as per growth stage	For authorization in <b>spring oilseed rape</b> see the complete GAP starting next page, which is identical to the one in Part B Sec- tion 3 (Efficacy)
3, 4, 9, 10, 15, 16, 21, 22, 25, 26, 29, 30	CZE HUN POL ROU SVK SVN	Rape, winter (BRSNW) Rape, spring (Can- ola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	250- 400 (Rape winter) 200- 600 (Rape, spring) 200- 600	45	For authorization in <b>spring oilseed rape</b> see the complete GAP starting next page, which is identical to the one in Part B Sec- tion 3 (Efficacy)  Restricting the use of the product to applica- tions outside of flow- ering (Residue and ecotox).

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Mem- ber state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/syner- gist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
31 to 34	POL ROU	Mustard, winter (SINSS) Mustard, spring (SINSS)	F	MELIAE	spraying (foliar)	50-57 <del>50-59</del>	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600	as per growth stage	For authorization in <b>Mustard, winter and spring</b> see the com- plete GAP starting next page, which is identical to the one in Part B Section 3 (Effi- cacy)

## Complete GAP table

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. *	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between appli- cations (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology ***	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	CZE	Rape, win- ter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600  200- 600 250- 300	as per growth stage		A	A	A	A	A	R Aquatic org. bees NTAs	A	A
																			A Re- main- ing species		
2	CZE	Rape, spring (Canola) (BRSNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600	as per growth stage		A	A	A	A	A	R Aquatic org. bees NTAs	A	C
																			A Re- main- ing species		
3	CZE	Rape, win- ter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200- 600  200- 600 250- 400	45	Restricting the use of the product to ap- plications out- side of flower- ing (Residue and ecotox).	A	A	A	A	A	R Aquatic org. bees NTAs	A	A
																			A Re- main- ing species		



1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. *	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between appli- cations (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology ***	Relevance of metabolites in groundwater	Efficacy
4	CZE	Rape, spring (Canola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 <del>65-79</del>	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200- 600	45	Restricting the use of the product to ap- plications out- side of flower- ing (Residue and ecotox).	A	A	A	A	A	R Aquatic org. bees NTAs	A	C
																			A Re- main- ing species		
5	HUN	Rape, win- ter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600 <del>200- 600 250- 300</del>	as per growth stage		A	A	A	A	A	R Aquatic org. bees NTAs	A	A
																			A Re- main- ing species		
6	HUN	Rape, spring (Canola) (BRSNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600	as per growth stage		A	A	A	A	A	R Aquatic org. bees NTAs	A	C
																			A Re- main- ing species		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. *	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between appli- cations (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology ***	Relevance of metabolites in groundwater	Efficacy
7	NLD	Rape, win- ter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600 <del>200- 600 250- 300</del>	as per growth stage		A	A	A	A	A	R Aquatic org. bees NTAs	A	A
																			A Re- main- ing species		
8	NLD	Rape, spring (Canola) (BRSNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600	as per growth stage		A	A	A	A	A	R Aquatic org. bees NTAs	A	C
																			A Re- main- ing species		
9	NLD	Rape, win- ter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 <del>65-79</del>	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200- 600 <del>200- 600 250- 400</del>	45	Restricting the use of the product to ap- plications out- side of flower- ing (Residue and ecotox).	A	A	A	A	A	R Aquatic org. bees NTAs	A	A
																			A Re- main- ing species		
10	NLD	Rape, spring (Canola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 <del>65-79</del>	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200- 600	45	Restricting the use of the product to ap- plications out-	A	A	A	A	A	R Aquatic org. bees NTAs	A	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. *	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between appli- cations (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology ***	Relevance of metabolites in groundwater	Efficacy
													side of flower- ing (Residue and ecotox).						A Re- main- ing species		
11	POL	Rape, win- ter (BRNSW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600 <del>200- 600 250- 300</del>	as per growth stage		A	A	A	A	A	R Aquatic org. bees NTAs	A	A
																			A Re- main- ing species		
12	POL	Rape, spring (Canola) (BRNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600	as per growth stage	possible regis- tration as mi- nor uses ac- cording to Ar- ticle 51 (Part B3)	A	A	A	A	A	R Aquatic org. bees NTAs	A	N
																			A Re- main- ing species		
13	POL	Rape, win- ter (BRNSW)	F	MELIAE	spraying (foliar)	50-57 <del>50-59</del>	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600 <del>200- 600 250- 300</del>	as per growth stage	Application not later than 10 days before flowering	A	A	A	A	A	R Aquatic org. bees NTAs	A	A
																			A Re- main- ing species		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. *	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between appli- cations (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology ***	Relevance of metabolites in groundwater	Efficacy
14	POL	Rape, spring (Canola) (BRSNS)	F	MELIAE	spraying (foliar)	50-57 <del>50-59</del>	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600 <del>200- 600 250- 300</del>	as per growth stage	Application not later than 10 days before flowering	A	A	A	A	A	R Aquatic org. bees NTAs	A	A
15	POL	Rape, win- ter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 <del>65-79</del>	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200- 600 <del>200- 600 250- 400</del>	45	Restricting the use of the product to ap- plications out- side of flower- ing (Residue and ecotox).	A	A	A	A	A	R Aquatic org. bees NTAs	A	A
16	POL	Rape, spring (Canola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 <del>65-79</del>	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200- 600	45	possible regis- tration as mi- nor uses ac- cording to Ar- ticle 51 ( Part B3) Restricting the use of the product to ap- plications out- side of flower- ing (Residue and ecotox).	A	A	A	A	A	R Aquatic org. bees NTAs	A	N
17	ROU	Rape, win- ter	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25	200- 600	as per growth		A	A	A	A	A	R Aquatic org.	A	A

[illegible]

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. *	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between appli- cations (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology ***	Relevance of metabolites in groundwater	Efficacy
																			Re- main- ing species		
21	ROU	Rape, win- ter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 <del>65-79</del>	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200- 600 <del>200- 600 250- 400</del>	45	Restricting the use of the product to ap- plications out- side of flower- ing (Residue and ecotox).	A	A	A	A	A	R Aquatic org. bees NTAs  A Re- main- ing species	A	A
22	ROU	Rape, spring (Canola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 <del>65-79</del>	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200- 600	45	Restricting the use of the product to ap- plications out- side of flower- ing (Residue and ecotox).	A	A	A	A	A	R Aquatic org. bees NTAs  A Re- main- ing species	A	C
23	SVK	Rape, win- ter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600 <del>200- 600 250- 300</del>	as per growth stage		A	A	A	A	A	R Aquatic org. bees NTAs  A Re- main- ing species	A	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. *	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between appli- cations (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology ***	Relevance of metabolites in groundwater	Efficacy
24	SVK	Rape, spring (Canola) (BRSNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600	as per growth stage		A	A	A	A	A	R Aquatic org. bees NTAs	A	C
																		A Re- main- ing species			
25	SVK	Rape, win- ter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 <del>65-79</del>	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200- 600 <del>200- 600 250- 400</del>	45	Restricting the use of the product to ap- plications out- side of flower- ing (Residue and ecotox).	A	A	A	A	A	R Aquatic org. bees NTAs	A	A
																		A Re- main- ing species			
26	SVK	Rape, spring (Canola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 <del>65-79</del>	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200- 600	45	Restricting the use of the product to ap- plications out- side of flower- ing (Residue and ecotox).	A	A	A	A	A	R Aquatic org. bees NTAs	A	C
																		A Re- main- ing species			
27	SVN	Rape, win- ter (BRSNW)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600 <del>200- 600</del>	as per growth stage		A	A	A	A	A	R Aquatic org. bees NTAs	A	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. *	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between appli- cations (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology ***	Relevance of metabolites in groundwater	Efficacy
											250- 300								A Re- main- ing species		
28	SVN	Rape, spring (Canola) (BRSNS)	F	CEUTNA, CEUTQU	spraying (foliar)	30-49	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600	as per growth stage		A	A	A	A	A	R Aquatic org. bees NTAs	A	N
																			A Re- main- ing species		
29	SVN	Rape, winter (BRSNW)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200- 600 200- 600 250- 400	45	Restricting the use of the product to ap- plications out- side of flower- ing (Residue and ecotox).	A	A	A	A	A	R Aquatic org. bees NTAs	A	A
																			A Re- main- ing species		
30	SVN	Rape, spring (Canola) (BRSNS)	F	CEUTAS, DASYBR	spraying (foliar)	71-79 65-79	a) 2 b) 2	14	a) 0.5 b) 1	a) DLT 5 + FPF 37.5 b) DLT 10 + FPF 75	200- 600	45	Restricting the use of the product to ap- plications out- side of flower- ing (Residue and ecotox).	A	A	A	A	A	R Aquatic org. bees NTAs	A	N
																			A Re- main- ing species		



1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. *	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between appli- cations (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology ***	Relevance of metabolites in groundwater	Efficacy
31	POL	Mustard, winter (SINSS)	F	MELIAE	spraying (foliar)	50-57 50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600	as per growth stage	possible regis- tration as mi- nor uses ac- cording to Ar- ticle 51 (Part B3)  In area of efate and ecotox, exposure and risk covered by evaluation performed for oilseed rape.  Application not later than 10 days before flowering  NDE exposure covered by evaluation performed for oilseed rape.	A	A	A	A	A	R Aquatic org. bees NTAs  A Re- main- ing species	A	N
32	POL	Mustard, spring (SINSS)	F	MELIAE	spraying (foliar)	50-57 50-59	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600	as per growth stage	possible regis- tration as mi- nor uses ac- cording to Ar- ticle 51 (Part B3)  In area of efate and ecotox, exposure and risk covered	A	A	A	A	A	R Aquatic org. bees NTAs	A	N

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. *	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between appli- cations (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology ***	Relevance of metabolites in groundwater	Efficacy
													by evaluation performed for oilseed rape.  Application not later than 10 days before flowering  NDE exposure covered by evaluation performed for oilseed rape.						A Re- main- ing species		
33	ROU	Mustard, winter (SINSS)	F	MELIAE	spraying (foliar)	50-57 <del>50-59</del>	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600	as per growth stage	In area of efate and ecotox, exposure and risk covered by evaluation performed for oilseed rape.  Application not later than 10 days before flowering  NDE exposure covered by evaluation performed for oilseed rape.	A	A	A	A	A	R Aquatic org. bees NTAs  A Re- main- ing species	A	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
Use- No. *	Member state(s)	Crop and/ or situation  (crop destina- tion / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: de- velopmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ sea- son	Min. interval between appli- cations (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology ***	Relevance of metabolites in groundwater	Efficacy
34	ROU	Mustard, spring (SINSS)	F	MELIAE	spraying (foliar)	50-57 <del>50-59</del>	a) 2 b) 2	14	a) 0.75 b) 1.5	a) DLT 7.5 + FPF 56.25 b) DLT 15 + FPF 112.5	200- 600	as per growth stage	In area of efate and ecotox, exposure and risk covered by evaluation performed for oilseed rape.  Application not later than 10 days before flowering  NDE exposure covered by evaluation performed for oilseed rape.	A	A	A	A	A	R Aquatic org. bees NTAs  A Re- main- ing species	A	C

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application.

\*\*\* The risk assessment for aquatic organisms and bees could not be finalised at this stage and further calculations should be submitted by the Applicant during the commenting period.

- |   |     |   |     |   |
|---|-----|---|-----|---|
| <b>Re-<br/>marks<br/>table<br/>heading:</b> | (a) | e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  | (d) | Select relevant   |
|   | (b) | Catalogue of pesticide formulation types and international coding system<br>CropLife<br>International Technical Monograph n°2, 6th Edition Revised May 2008 | (e) | Use number(s) in accordance with the list of all intended GAPs in Part B, Section<br>0 should be given in column 1                                    |
|   | (c) | g/kg or g/l   | (f) | No authorization possible for uses where the line is highlighted in grey, Use should<br>be crossed out when the notifier no longer supports this use. |

<b>Re- marks col- umns:</b>	1	Numeration necessary to allow references	8	The maximum number of application possible under practical conditions of use must be provided.
	2	Use official codes/nomenclatures of EU Member States	9	Minimum interval (in days) between applications of the same product
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
	7	Growth stage at first and 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	14	Remarks may include: Extent of use/economic importance/restrictions
			15	Overall conclusions - explanation for the column 15 is below ***
			n/a	Not applicable

\*\*\* Explanation for column 15 “Overall conclusions”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible

**Comments of zRMS – corrigendum to the GAP table:**

In the GAP table above, for each one of the cMSs except for HU, PL and RO, the applicant had listed 2 application windows for the use in the oilseed rape, and had included the maximum of 2 applications per each use, *i.e.* *per* application window, as well as 2 applications *per* season. This notation is inconsistent with the anti-resistance strategy declared by the applicant further in the dRR (a total of 2 applications *per* growth season) and it should have been corrected in the course of evaluation.

As the zRMS, we apologize for the inconvenience. However, presenting the applicant’s claim properly, in the GAP table, it would require remodelling of the table, first by altering the sequence of the uses to make all winter form uses or spring form uses neighbouring, and then by collating rows in columns 8-10, separately for winter and spring uses, in order to place one common statement for 2 or 3 uses, concerning no. of applications, interval and maximum dose rate *per* season. As it might be inappropriate to interfere so extensively with the GAP’s original layout, we decided to make the corrigendum textual, without changing the GAP notation.

The GAP table must be interpreted as follows:

- 1) A single application of Sivanto Energy should be authorized in each separate application window / for each group of target pests, in the oilseed rape. At the same time, the maximum of two applications of Sivanto Energy *per* growth season must be authorized overall.
- 2) The interval between the applications carried out within the neighbouring application windows is claimed as  $\geq 14$  days, which is correct in the cMSs, in which only two relatively distant application windows are envisaged, one for the stem weevils and the other one - for the pod weevil and the pod midge.
- 3) The anti-resistance strategy assumed by the applicant, and explained in the respective chapter (B3), holds it that no two consecutive applications should use Sivanto Energy. Therefore, in the cMSs with two application windows, one application must use an insecticide showing different MoA (MoAs listed in the zRMS comments to resistance chapter, B3). The recommendation of 2 applications per season using Sivanto energy may only suggest, that in those cMSs an additional, second application is allowed within the first window, or - preceding the second application of Sivanto - in the second window, with other MoA product, thus fulfilling the requirement of MoA rotation.
- 4) To the opinion of zRMS the single application window, that is provided for the control of stem weevils in Hungary, may not be long enough to contain repeated application, and even though, such application should then be using another product, if the assumptions of anti-resistance strategy are to be respected. Therefore the zRMS presumes that only a single application might have been meant, by the applicant, for Hungary.
- 5) In Poland and in Romania, where the additional application window is envisaged for MELIAE, the GAP has been interpreted as allowing choice of the maximum two application options, out of the three available, using Sivanto Energy, with a product of another MoA being used in between, as the third application, while still respecting the interval  $\geq 14$  days.
- 6) For the mustard crop (PL, RO), the number of applications with Sivanto Energy: “2” must be considered an error either, because it is the only pest claimed in that crop and the single application window envisaged, both in PL and in RO. As MELIAE is the important pest with high risk of resistance to pyrethroids, the proper anti-resistance strategy should be also extended over other crops infested by the species. Therefore if necessary, the second application in mustard must use an insecticide showing different MoA. The number of applications allowed in the mustard crop should be therefore 1 *per* growth season.

**According to Commission Regulation (EU) No 2018/62, the complete list of the crops that may be considered are listed below.**

- 0401060 (Rapeseeds/canola seeds), 0401060-001 (Radish seeds), 0401060-002 (Turnip rape seeds)
- 0401080 (Mustard seeds)

**Please refer to the national application for the complete list of crops considered at country level.**