REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: ADM.4651.H.1.A (former A18032E)

Product name: NIKITA

Chemical active substances:

Dicamba, 312.5 g/kg

Mesotrione,150 g/kg

Nicosulfuron,100 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Sponsor: ADAMA

Applicant: ADAMA

Submission date: June 2020

MS Finalisation date: March 2022 (initial Core Assessment)

June 2022 (final Core Assessment)

Version history

When	What
June 2020	Applicant initial dRR
March 2022	Initial assessment by the zRMS 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 highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
June 2022	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.

ADAMA use the code ADM.4651.H.1.A for the formulation but for consistency the former Syngenta code A18032E is used throughout the dRR.

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0 Product background, regulatory context and GAP information

0.1 Introduction

This application is submitted by ADAMA.

The application is for the approval of the herbicide A18032E (NIKITA), a water dispersible granule (WG) containing 150 g/kg mesotrione, 312.5 g/kg dicamba and 100 g/kg nicosulfuron for use in maize to control annual and perennial broadleaved weeds and grass weeds.

0.1.1 Reason for application

This is an application for the approval of A18032E under Regulation (EC) No. 1107/2009.

An assessment of equivalence is not required since sources for the active substances have been approved and are considered as chemically equivalent. Refer to Part C of this dossier for further details.

This application follows the data requirements for the active substance 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.

All data relied on are provided with this application. The reference list at **Appendix 1** of dRR B. 1-10 define the data owner and data access. Data protection is a national concern and is addressed in Part A, **Appendix 4**.

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 applicable)**
Northern zone	Not applicable	Not applicable
Central zone	Poland – NIKITA	none
Southern zone	Not applicable	Not applicable
Inter-zonal	Not applicable	Not applicable

0.1.3 Regulatory history of the actives

0.1.3.1 Dicamba

Table 0.1-2: Summary of regulatory history of CAS No: 1918-00-9

Status	
Approved in EU	Y
Commission Implementing Regulation	Commission Implementing Regulation (EU) No 1100/2011 of 31 October 2011 (amending Implementing Regulation (EU) No 540/2011 of 25 May 2011, which repealed Commission Directive 2008/69/EC of 1 July 2008)
RMS	DK

Status	
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	1th January 2009
Date of first Commission (re-registration) deadline (Step 1)	
Date of final Commission (re-registration) deadline (Step 2)	31st December 2013
Current expiration of approval	31st December ~~2020~~ 2022
Low risk substance or Candidate for Substitution?	N/A

Regulation (EU) No 1100/2011 of 31 October 2011 provides specific provisions for dicamba which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

Member States shall pay particular attention to the protection of non-target plants. Conditions of use shall include adequate risk mitigation measures, where appropriate. This specific concern is addressed in the current submission.

An EFSA Scientific Report was published on 17 December 2010. **The EFSA conclusion** on dicamba (**EFSA Scientific Report (2011); 9(1):1965**) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. The final review report for dicamba (**SANCO/829/08 rev.2**), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 July 2016 , provides additional information.

Table 0.1-3: Information on minimum purity of dicamba

EU agreed minimum purity **Reference: Commission Implementing Regulation (EU) 820/2011**	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **** **Reference: Confidential Volume 4 Annex C (Revision, October 2010) and Annex I Renewal dossier submitted June 2016**
850g/kg	880 g/kg~~ǂ~~

* 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.

~~ǂ~~ Commission Directive 2008/69/EC, Commission Implementing Regulation (EU) 540/2011 of 25 May 2011 and subsequent amendment in Commission Implementing Regulation (EU) No. 1100/2011 of 31 October 2011 specifies the minimum purity of dicamba technical material as 850 g/kg, but as agreed between the notifiers during the EU Review in 2010, a revised specification of 880 g/kg was proposed and accepted by the RMS as part of a revised Document J (September 2009). The change in specification was formally published in the Confidential Volume 4 Annex C (Revision, October 2010).

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

Table 0.1-4: Summary of deviations from EU endpoints for dicamba

Endpoint	Dicamba		
	EU agreed endpoint from EFSA scientific report Reference: EFSA Scientific Report (2011); 9(1):1965	**Endpoint used***	**zRMS comment**
Non-target arthropods	All non-target arthropod data undertaken with representative formulation Banvel 480 SL (foliar spray)	Tier I and II data for the mixture formulation A18032E. Risk assessment based on endpoints for the formulated mixture product A18032E.	Consideration of the formulation data in the risk assessment for non-target arthropods and non-target terrestrial plants is not considered to be deviation from the EU endpoints since evaluation for these groups of species is always based on the toxicity data generated for the formulation for which authorisation is sought.
Non-target plants	All non-target terrestrial plant data undertaken with representative formulation Banvel 480 SL (foliar spray)	Tier II data for the mixture formulation A18032E. Risk assessment based on endpoints for the formulated mixture product A18032E.	

* Studies with non-target arthropods & non-target terrestrial plants are always conducted with a formulated product and no testing is carried out with unformulated technical material. Therefore it may not be appropriate to rely on the data from the individual solo formulations submitted as representative formulations for the EU review for the risk assessment for non-target terrestrial plants.

0.1.3.2 Mesotrione

Table 0.1-5: Summary of regulatory history of CAS No: 104206-82-8

Status	
Approved in EU	Y
Commission Implementing Regulation	Commission Implementing Regulation (EU) 2017/725 of 24 April 2017
RMS	UK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	1st June 2017
Date of deadline for renewal of authorization (renewal)	
Date of final Commission (re-registration) deadline	
Current expiration of approval	31st May 2032
Low risk substance or Candidate for Substitution?	N/A

Regulation (EU) 2017/725 of 24 April 2017 provides specific provisions for mesotrione which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

Member States shall pay particular attention to the protection of operators, the protection of groundwater in vulnerable regions, the protection of mammals, aquatic and non-target plants. Conditions of use shall include risk mitigation measures, where appropriate.

The applicant shall submit confirmatory information as regards:

1. the genotoxic profile of the metabolite AMBA;

2. the potential endocrine disrupting mode of action of the active substance in particular level 2 and 3 tests, currently indicated in the OECD Conceptual framework (OECD 2012) and analysed in the EFSA Scientific opinion on the hazard assessment of endocrine disruptors;

3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water.

The applicant shall submit to the Commission, the Member States and the Authority the relevant information requested under point 1 by 1 July 2017 and the relevant information requested under point 2 by 31 December 2017. The applicant shall submit to the Commission, the Member States and the Authority the confirmatory information requested under point 3 within a period of two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater be made public by the Commission.

These specific concerns will be addressed in accordance with the timelines set out in the implementation regulation.

The European Commission Final Renewal report for the active substance MESOTRIONE is SANTE/11654/2016 (23 March 2017).

An EFSA Scientific Report was published on 7 March 2016. **The EFSA conclusion** on mesotrione **(EFSA Journal 2016;14(3):4419)** is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

Table 0.1-6: Information on minimum purity of mesotrione

EU agreed minimum purity Reference: Commission Implementing Regulation (EU) 2017/725	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
920 g/kg‡	n.a.

‡ In the RAR Volume 4 (11 November 15) and the EFSA Conclusions (EFSA Journal 2016;14(3):4419), the minimum purity is given as 930 g/kg, however this is superceded by the **COMMISSION IMPLEMENTING REGULATION (EU) 2017/725** which states 920 g/kg.

* 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.

Table 0.1-7: Summary of deviations from EU endpoints for mesotrione

Endpoint	Mesotrione		
	EU agreed endpoint from EFSA scientific report Reference: EFSA Journal 2016;14(3):4419	Endpoint used*	zRMS comment
Lemna gibba**	E_bC_{50} frond no.= 0.022 mg a.s./L $_{mm}$ E_bC_{50} dry weight = 0.0077 mg a.s./L $_{mm}$	E_rC_{50} frond no or biomass = 0.028 mg a.s./L $_{nom}$ E_bC_{50} yield = 0.0052 mg a.s./L $_{nom}$	Consideration of the new endpoint for *L. gibba* was agreed by the zRMS. For details, please refer to Core Assessment, Part B, Section 9, point 9.5.
*Myriophyllum spicatum****	None (data gap)	E_rC_{50} total shoot length = 0.0339 mg a.s./L $_{nom}$ E_yC_{50} yield = 0.00301 mg a.s./L $_{nom}$	Consideration of the new endpoint for *M. spicatum* was agreed by the zRMS. For details, please refer to Core Assessment, Part B, Section 9, point 9.5.

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

** The laboratory study for Lemna was repeated due to issues in the original study submitted in which concentrations were not maintained within 20% of nominal throughout the exposure period, and endpoints were not reported in terms of growth rate. The new 7d study (Hengsberger & Wydra 2015) fulfils all the current acceptability criteria, and concentrations were maintained within 20% of nominal throughout the study. The biomass endpoints of the Hengsberger & Wydra study (2015, $E_bC_{50\ dry\ weight}$ = 0.0052 mg a.s./L) and the previous study of Smyth et al. (1997c, E_bC_{50} = 0.0077 mg a.s./L) are very similar, and the new endpoints will be used in the risk assessment, in preference, as they are considered more reliable.

*** In the EU review a data gap was identified for a dicot aquatic macrophyte, and therefore a new test has been carried out

with *Myriophyllum spicatum*.

In accordance with the specific provisions of approval, the applicant, Syngenta, submitted an updated dossier to address the confirmatory data requirement 1) on 15 June 2017, and to address the confirmatory data requirement 2) on 21 December 2017. The updated dossier was evaluated by the designated rapporteur Member State (RMS), the United Kingdom, in the form of an addendum to the draft renewal assessment report. In compliance with guidance document SANCO 5634/2009-rev.6.1, the RMS UK distributed the addendum to Member States, the applicant and EFSA for comments on 18 July 2018. The RMS UK collated all comments in the format of a reporting table, which was submitted to EFSA on 12 November 2018. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table.

The outcome of the consultation process organised by the RMS UK, and EFSA's scientific views and conclusions on the individual comments received is reported in EFSA Supporting publication 2018:EN-1527, Technical Report entitled 'Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for mesotrione in light of confirmatory data'.

There was no overall consensus within the peer review to conclude on the endocrine disrupting properties of mesotrione, although there was a general agreement with the RMS assessment that the testis and epididymides findings reported in the multigeneration study should be considered unrelated to mesotrione administration. It is therefore proposed to further discuss the endocrine disrupting properties of the active substance in an experts' consultation. It was agreed that the metabolite AMBA is unlikely to be genotoxic, however it is proposed to further discuss its toxicological profile in an experts' consultation since the metabolite is relevant to consumer exposure.

The guidance document on renewal of authorisations (SANCO/2010/13170 rev. 14 specify "the assessment of the application should be undertaken without referral to the confirmatory information provided that the requirements of Article 29 are met". The confirmatory data has been addressed and further data to address pending questions is included in dRR and submitted to the RMS (Original RMS did not consider the additional data as part of the confirmatory data evaluation).

0.1.3.3 Nicosulfuron

Table 0.1-8: Summary of regulatory history of CAS No: 111991-09-4

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 (repealing Commission Directive 2008/40/EC of 28 March 2008)
RMS	Current RMS: Latvia Original RMS: UK ~~UK~~
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	1th January 2009
Date of first Commission (re-registration) deadline (Step 1)	
Date of final Commission (re-registration) deadline (Step 2)	31st October 2012
Current expiration of approval	31st December 2022 ~~2020~~
Low risk substance or Candidate for Substitution?	CfS

Regulation (EU) No 540/2011 of 25 May 2011 provides specific provisions for nicosulfuron which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

Member States shall pay particular attention to:

- the potential exposure of the aquatic environment to metabolite DUDN when is applied in regions with vulnerable soil conditions,
- the protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones,
- the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no-spray buffer zone,
- the protection of groundwater and surface water under vulnerable soil and climatic conditions.

These specific concerns are addressed within the current submission.

An EFSA Scientific Report was published on 29 November 2007. **The EFSA conclusion** on nicosulfuron (**EFSA Scientific Report (2007) 120, 1-91**) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. The final review report for nicosulfuron (**SANCO/3780/07 rev.1**), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008, provides additional information.

ADAMA has an independent position on nicosulfuron and the data associated with first approval of nicosulfuron no longer had data protection.

Table 0.1-9: Information on minimum purity of nicosulfuron

EU agreed minimum purity Reference: COMMISSION DIRECTIVE 2009/51/EC and Commission Implementing Regulation (EU) No. 540/2011	Proposed EU minimum purity – pending June 2016 Annex I Renewal
910 g/kg	938 g/kg*

* The Syngenta/Cheminova joint source of nicosulfuron, with minimum purity 938 g/kg has been declared equivalent after evaluation by the former RMS; CRD (UK) in May 2013. The equivalence report is available on CIRCA. The confirmatory data required was submitted to UK CRD in June 2016. The min. purity of 938 g/kg has also been proposed in AIR3 dossier submitted to the current RMS LV in June 2016.

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

Table 0.1-10: Summary of deviations from EU endpoints for Nicosulfuron

Endpoint	Nicosulfuron		
	EU agreed endpoint from EFSA scientific report Reference: EFSA Scientific Report (2007) 120, 1-91 + Graham & Strachan (2008)	**Endpoint used***	**zRMS comment**
K_{FOC} (mL/g)	**EFSA(2007)** Arithmetic mean (n=4): 20.7; 1/n=0.93 Geometric mean (n = 4): 15.4; - **Graham&Strachan (2008)** Arithmetic mean (n=10): 55; 1/n= 0.9559 Geometric mean (n=10): 29.7; -	**EFSA Scientific Report, 2007 + Graham&Strachan (2008)** 24.6 (geomean, n= 14)*	Consideration of the new soil sorption study by Graham & Strachan (2008) was not agreed by the zRMS since sufficient information was available from the EU review and the study have not provided any new information.
DT_{50} (days)	Geomean 16.4 d (n=7) no pH-dependency	**EFSA Scientific Report, 2007** Laboratory data, normalisation to 10 kPa or pF2, 20°C with Q_{10} of 2.2.	In the exposure assessment the EU agreed soil DT_{50} was used.

Endpoint	Nicosulfuron		
	EU agreed endpoint from EFSA scientific report Reference: EFSA Scientific Report (2007) 120, 1-91 + Graham & Strachan (2008)	**Endpoint used***	**zRMS comment**
1/n (-)	0.952 Arithmetic mean, n=14	**EFSA Scientific Report, 2007 + Graham & Strachan (2008)**	Consideration of the new soil sorption study by Graham & Strachan (2008) was not agreed by the zRMS since sufficient information was available from the EU review and the study have not provided any new information.

0.1.4 Regulatory history of the product

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-11: Summary of regulatory history of the product A18032E/Nikita

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
A18032E	NIKITA	Czech Republic	5129-2	17.02.2016	Not applicable
A18032E	Meso Trio	Hungary	04.2/1636-2/2018	12.05.2016	Not applicable
A18032E	Nikita / Pyxides	Romania	188PC/03.06.2016	03.06.2016	Not applicable
A18032E	NIKITA	Slovakia	18-00278-AU	01.07.2015	Not applicable
A18032E	NIKITA	Slovenia	U34330-46/17/5	03.03.2016	Not applicable
A18032E	Callisto Turbo	Bulgaria	Authorization pending		Not applicable
A18032E	Nikita	Croatia	UP/I-320-20/13-01/331	13.06.2018	Not applicable
A18032E	NIKITA	France	2170358	29.05.2017	Not applicable
A18032E	PYXIDES WG	Greece	70228	28.07.2017	Not applicable
A18032E	PYXIDES WG	Italy	15909	19.09.2018	Not applicable
A18032E	NIKITA	Portugal	0984	26.07.2017	Not applicable
A18032E	NIKITA	Spain	ES-00474	05.07.2018	Not applicable

A18032E was not the representative formulated product during the EU review of mesotrione.

0.2 zRMS conclusion

Authorisation of the product A18032E / NIKITA is recommended to the control annual/perennial grass and broadleaved weeds in Maize (ZEAMX).

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

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

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP , date: 2022-06-~~03~~

PPP (product name/code):	NIKITA/A18032E	Formulation type:	WG [a, b]
Active substance 1:	Mesotrione	Conc. of as 1:	150 g/kg [c]
Active substance 2:	Dicamba	Conc. of as 2:	312.5 g/kg [c]
Active substance 3:	Nicosulfuron	Conc. of as 3:	100 g/kg [c]
Safener:	None	Conc. of safener:	Not applicable
Synergist:	None	Conc. of synergist:	Not applicable
Applicant:	ADAMA	Professional use:	☒
Zone(s):	Central	Non professional use:	☐
Verified by MS:	Yes		
Field of use:	Herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15*							
Use -No. [e]	**Member 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: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]	**Overall conclusions**							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg 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 & bevaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					

1	Poland	Maize (ZEAMX)	F	Annual/perennial grass and broadleaved weeds	Foliar, spraying, overall	- / BBCH 12-14 Spring	a) 1 b) 1	n.a.	a) 0.4 b) 0.4	1) Mesotrione a) 60 b) 60 2) Dicamba a) 125 b) 125 3) Nicosulfuron a) 40 b) 40	200-300	n.a.	Tank-mixed adjuvant needed (e.g. Adigor: 1.0 - 1.5 L/ha, Olejan: 1.5 L/ha, Styk (Insert): 0,2 L) Application every 3 years	A	A	A	A	R	R Aquatics NTTP A Remaining species	A	A
2	Poland	Maize (ZEAMX)	F	Annual/perennial grass and broadleaved weeds	Foliar, spraying, overall	- / BBCH 12-14 Spring	a) 1 b) 1	n.a.	a) 0.4 b) 0.4	1) Mesotrione a) 60 b) 60 2) Dicamba a) 125 b) 125 3) Nicosulfuron a) 40 b) 40	200-300	n.a.	Application in tank mix with 0.8 L/ha Efica 960 EC Application every 3 years Risk mitigation measures identified for Efica 960 EC must be combined with RMM identified for A18032E	A	A	A	A	R	R Aquatics NTTP A Remaining species	A	A
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
None																				
Minor uses according to Article 51 (zonal uses)																				
None																				
Minor uses according to Article 51 (interzonal uses)																				
None																				

Remarks table heading:

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

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
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)
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
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.
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.
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
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions
15 Overall conclusions - explanation for the column 15 is below*

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

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use