SANCO/12544/2014 rev. 2 26 May 2018

# Template to notify intended zonal applications under Article 33 of Regulation (EC) No 1107/2009

## 1. Background

At least six months before the application is due to be made it is recommended that the applicant should submit to all zonal contact points in MSs in the zone a summary of the products for which authorisation will be sought, detailing in which MSs the authorisation is envisaged. This applies to regular products and low-risk products (Article 47).

A common format ("notification form") has been developed which should be used by applicants (see Appendixes). This will help to organise the allocation of work to MSs and speed up the process. In future, the applicant shall also feed this information into the authorisation database.

#### Implementation schedule

Revision 1 of this document has been finalised in the Standing Committee on Plants, Animals, Food and Feed on 13 December 2017. The new revision can be used as soon as possible for notification of new intended applications.

# Form to notify intended zonal applications under Article 33 of Regulation (EC) No 1107/2009

Send to contact points of zonal Rapporteur(s) (zRMS) and concerned MS (cMS) <sup>1</sup> preferably via e-mail

Please use one sheet for every product

## 1. Product name(s)

V10

## 2. Product code(s):

## **3. Type of formulation:**

SC

4a. Name and content of the active substance(s) (name all active substances); are the active substance(s) approved as low-risk active substances?:

5-25 mg/L Mild Pepino Mosaic Virus isolate VX1
5-25 mg/L Mild Pepino Mosaic Virus isolate VC1
Both active substances are approved as low risk active substances

4b. Is authorisation sought for a low-risk product? (Is the product expected to meet the requirements of Article 47?)

Yes

## 5. EU countries, in which authorisation is granted (authorisation status):

NL, pending in BE, AT, DE, UK, FR, ES, IT, PL, SE

<sup>&</sup>lt;sup>1</sup> For list of contact points see European Commission Website

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\_legis\_national-authorities\_en.pdf

## 6. Applicant/authorisation holder:

Company name: Valto B.V.
Company address: Leehove 81, 2678 MB, De Lier
Name contact:
Tel.no. contact:
Email contact: <u>@valto.nl</u>

7. Intended zones, proposal for zRMS of each zone (for possible work sharing of zonal independent assessments) and indicative date for submission of the application to zRMS and cMS

Northern zone: zRMS: cMS:	indicative/estimated submission date:
Central zone:	indicative/estimated submission date:
zRMS:	
cMS:	
Southern zone:	indicative/estimated submission date:
zRMS:	
cMS:	
22 	
EU-wide zone:	indicative/estimated submission date: April 2019
izRMS: The Netherlands	
cMS:	
Planned MR (mutual recognition)	submission date:
MS:	

8. If interzonal worksharing is possible, please indicate proposal for zRMS of section 1 (i.e. phys-chem properties), section 2 (i.e. analytical methods), section 3 (i.e. study evaluation without risk assessment) and part C (confidential information)

#### 9. Studies to be provided:

The applicant is the owner of the studies for the active substance?

yes <del>no</del>

If NO, please indicate data access to studies necessary:

Letter of access

Alternative and equivalent studies

**Out-of-protection studies (indicate which reference product)** 

Other (indicate, what)

None of the above

### 10. Summary of uses

- a. For details of all national GAPs within the zone, please complete table in appendix A.
- b. For the zone, which MS authorised use represents the critical GAP and thus can be used to establish the risk envelope. Please complete table in appendix B.

see Appendix A and B

# 11. Is the source of the active substance(s) identical with the one(s) evaluated for the (renewal of the) approval?

If the source has been assessed previously please, provide information which MS carried out an equivalence assessment and when.

If not, an equivalence assessment has to be carried out according to Article 38 of Regulation 1107/2009 (in line with Article 43 of 1107/2009). In that case appendix C would need to be completed and should be sent separately or provided at the pre-submission meeting<sup>2</sup>.

Yes

<u>Please note</u>:

A short but sufficiently descriptive summary should be provided together with this form highlighting critical aspects and potential areas of concern.

Detailed technical questions should be submitted separately in time prior to presubmission meetings with zRMS (or cMS, if relevant).

 $<sup>^2</sup>$  In cases that the applicant has no access to these data, the specification could be sent directly from the respective applicant/manufacturer to the zRMS/cMS with a clear reference.

#### Appendix A - details of all intended national GAPs within the zone (to be sorted by crop);

(For further information regarding filling the table see guidance provided in the technical guidelines on the presentation and evaluation of plant protection product dossiers in the format of a (draft) Registration Report. The tables below are excerpted from revision 2.2 of these technical guidelines. Please check and use the latest version of the GAP table provided in these guidelines)

			OAF IEV. 2019-04-10, date. year-month-day
PPP (productname/code):	V10	Formulation type:	SC
Active substance 1:	Mild Pep MV isolate VC1	Conc. of as 1:	$5\text{-}25mg/L7.5x10^{10}to3.75x10^{11}virusparticles/mL$
Active substance 2:	Mild PepMV isolate VX1	Conc. of as 2:	$5\text{-}25mg/L7.5x10^{10}to3.75x10^{11}virusparticles/mL$
Applicant:	Valto B.V	Professionaluse:	X
Zone(s):	interzonal <sup>(d)</sup>	Non professional use:	
Verified by MS:	yes		

Field of use:

elicitor

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-	Member	Crop and/	F,	Pests or Group of pests		Applic	ation		Application rate			PHI	Remarks:
No. (*)	state(s)	or situation (crop destination / purpose of crop)	Fn, Fpn G, Gn, Gpn or I	(additionally: developmental stages of the pest or pest group) ment, in greenhouses (	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	(days)	e.g. g safener/synergist per ha
New	Interzona	ll uses (use as seed	l treat	ment, in greenhouses (	(or other cl	osed places of p	olant produc	tion), as post	t-harvest treat	ment or for tre	atment	ofemp	ty storage rooms)
1	NL	Solanum lycopersicum (nursery phase of tomato)	G	Pepino mosaic virus	Downward spraying	Young tomato plants (BBCH 13-51, 10-30 cm high) Jan-Dec	a) 1 per crop cycle b) 8 per 12 months (8 crops cycles per year)	-	a) 70 L product/ha per appl. b) 560 L product/ha per 12 months	a) $1.75 \text{ g}$ VC1/ha (2.63x10 <sup>16</sup> particles/ha) per crop cycle 1.75  g VX1/ha (2.63x10 <sup>16</sup> particles/ha) per crop cycle b)14 g VC1/ha per 12 months 14 g VX1/ha per 12 months	3500 L/ha per appl.	-	Plant propagation companies can have up to 8 productions per 12 months. V10 is applied in combination with 800 grams of synthetic sand per 100 litres of spray liquid

2	NL	Solanum lycopersicum (nursery phase of tomato)	G	Pepino mosaic virus	Rubbing individual plants	Young tomato plants (BBCH 13-61) Jan-Dec	a) 1 per crop cycle b) 8 per 12 months (8 crops cycles per year)	-	a) 0.8 L product/ha per appl. b) 6.4 L product/ha per 12 months	a) 0.02 g VC1/ha (3x10 <sup>14</sup> particles/ha) per crop cycle 0.02 g VX1/ha (3x10 <sup>14</sup> particles/ha) per crop cycle b) 0.16 g VC1/ha per 12 months 0.16 g VX1/ha per 12 months	8L/ha per appl.	-	Plant propagation companies can have up to 8 productions per 12 months. V10 is applied in combination with 15 grams of synthetic sand per 1 litre of liquid
Autho	orised inter	zonal uses (use as s	eed tre	eatment, in greenhouses (	(or other clo	sed places of plan	t production)	, as post-harv	est treatment or	for treatment o	f empty :	storage	rooms)
1	NL	Solanum lycopersicum (production phase of tomato)	G	Pepino mosaic virus	Downward spraying	Young tomato plants (BBCH 13-51, 10-30 cm high) Jan-Dec	a) 1 per crop cycle b) 8 per 12 months (8 crops cycles per year)	-	a) 70 L product/ha per appl. b) 560 L product/ha per 12 months	a) $1.75 \text{ g}$ VC1/ha ( $2.63 \times 10^{16}$ particles/ha) per crop cycle 1.75  g VX1/ha ( $2.63 \times 10^{16}$ particles/ha) per crop cycle b)14 g VC1/ha per 12 months 14 g VX1/ha per 12 months	3500 L/ha per appl.	-	Tomato producing companies have 1-3 crop cycles per year. V10 is applied in combination with 800 grams of synthetic sand per 100 litres of spray liquid
2	NL	Solanum lycopersicum (production phase of tomato)	G	Pepino mosaic virus	Rubbing individual plants	Young tomato plants (BBCH 13-61) Jan-Dec	a) 1 per crop cycle b) 8 per 12 months (8 crops cycles per year)	-	a) 0.8 L product/ha per appl. b) 6.4 L product/ha per 12 months	a) $0.02 \text{ g}$ VC1/ha $(3x10^{14} \text{ particles/ha})$ per crop cycle 0.02  g VX1/ha $(3x10^{14} \text{ particles/ha})$ per crop cycle b) $0.16 \text{ g}$ VC1/ha per 12 months 0.16  g VX1/ha per 12 months	8L/ha per appl.	-	Tomato producing companies have 1-3 crop cycles per year. V10 is applied in combination with 15 grams of synthetic sand per 1 litre of liquid

Remarks	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
table	(b)	Catalogue of pesticide formulation types and international coding system CropLife
heading:		International Technical Monograph n 2, 6th Edition Revised May 2008
	(c)	g/kg or g/l

- **Remarks** 1 Numeration necessary to allow references
- columns:
- s: 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 nonprofessional 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.

- (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 authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
- 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/m<sup>3</sup> 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

Appendix B – critical intended uses within each zone; for existing authorisations this should be based on the based on the existing uses in the zone (Note: The tables below are excerpted from revision 2.2 of these technical guidelines. Please check and use the latest version of the GAP table provided in these guidelines)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-	Member	Crop and/	F,	Pests or Group of pests		Appli	cation		Ар	plication rate		PHI	Remarks:
No. (°)	state(s)	or situation (crop destination/ purpose of crop)	Fn, Fpn G, Gn, Gpn or I	controlled (additionally: developmental stages of the pest or pest group)	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	(days)	e.g. g safener/synergist per ha ()
1	NL	Solanum lycopersicum	G	Pepino mosaic virus	Downwar d spraying	Young tomato plants (BBCH 13-51, 10-30 cm high) Jan-Dec	a) 1 per crop cycle b) 8 per 12 months (8 crops cycles per year)	-	a) 70 L product/ha per appl. b) 560 L product/ha per 12 months	a) $1.75 \text{ g}$ VC1/ha ( $2.63 \times 10^{16}$ particles/ha) per crop cycle 1.75  g VX1/ha ( $2.63 \times 10^{16}$ particles/ha) per crop cycle b)14 g VC1/ha per 12 months 14 g VX1/ha per 12 months	3500 L/ha per appl.	-	Tomato producing companies have 1-3 crop cycles per year. Plant propagation companies can have up to 8 productions per 12 months. V10 is applied in combination with 800 grams of synthetic sand per 100 litres of spray liquid
2	NL	Solanum lycopersicum	G	Pepino mosaic virus	Rubbing individua l plants	Young tomato plants (BBCH 13-61) Jan-Dec	a) 1 per crop cycle b) 8 per 12 months (8 crops cycles per year)	-	a) 0.8 L product/ha per appl. b) 6.4 L product/ha per 12 months	a) $0.02 \text{ g}$ VC1/ha $(3x10^{14})$ particles/ha) per crop cycle 0.02  g VX1/ha $(3x10^{14})$ particles/ha) per crop cycle b) $0.16 \text{ g}$ VC1/ha per 12 months 0.16  g VX1/ha per 12 months	8L/ha per appl.	-	Tomato producing companies have 1-3 crop cycles per year. Plant propagation companies can have up to 8 productions per 12 months. V10 is applied in combination with 15 grams of synthetic sand per 1 litre of liquid

Table A: Operator/worker/bystander/resident exposure risk assessment (copy of relevant use(s) from appendix A)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-	Member	Crop and/	F,	Pests or Group of pests		Appli	cation		Ар	plication rate		PHI	Remarks:
No. (*)	state(s)	or situation (crop destination / purpose of crop)	Fn, Fpn G, Gn, Gpn or I	(additionally: developmental stages of the pest or pest group) Pepino mosaic virus	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	(days)	e.g. g safener/synergist per ha
1	NL	Solanum lycopersicum	G	Pepino mosaic virus	Downwar d spraying	Young tomato plants (BBCH 13-51, 10-30 cm high) Jan-Dec	a) 1 per crop cycle b) 8 per 12 months (8 crops cycles per year)	-	a) 70 L product/ha per appl. b) 560 L product/ha per 12 months	a) $1.75 \text{ g}$ VC1/ha ( $2.63 \times 10^{16}$ ) per crop cycle 1.75  g VX1/ha ( $2.63 \times 10^{16}$ ) per crop cycle b)14 g VC1/ha per 12 months 14 g VX1/ha per 12 months	3500 L/ha per appl.	-	Tomato producing companies have 1-3 crop cycles per year. Plant propagation companies can have up to 8 productions per 12 months. V10 is applied in combination with 800 grams of synthetic sand per 100 litres of spray liquid

 $Table \, B: Dietary risk \, assessment \, (copy of relevant use(s) \, from \, appendix \, A)$ 

Table C: Environmental risk assessment (copy of relevant use(s) from appendix A)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
U N	Jse- No. <sup>(e)</sup>	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)	Method / Kind	Appli Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	Ap kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	plication rate g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ max	PHI (days)	Remarks: e.g. g safener/synergist per ha
1	-	NL	Solanum lycopersicum	G	Pepino mosaic virus	Downwar d	Young tomato plants	a) 1 per crop cycle	-	a) 70 L product/ha	a) 1.75 g VC1/ha	3500 L/ha	-	Tomato producing companies have 1-3

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-	Member	Crop and/	F,	Pests or Group of pests		Appli	cation		Application rate			PHI	Remarks:
No. <sup>(e)</sup>	state(s)	or situation (crop destination / purpose of crop)	Fn, Fpn G, Gn, Gpn or I	controlled (additionally: developmental stages of the pest or pest group)	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	(days)	e.g. g safener/synergist per ha
					spraying	(BBCH 13-51, 10-30 cm high) Jan-Dec	b) 8 per 12 months (8 crops cycles per year)		per appl. b) 560 L product/ha per 12 months	$\begin{array}{c} (2.63 \times 10^{16} \\ \text{particles/ha}) \\ \text{per crop cycle} \\ 1.75 \text{ g VX1/ha} \\ (2.63 \times 10^{16} \\ \text{particles/ha}) \\ \text{per crop cycle} \\ \text{b)14 g VC1/ha} \\ \text{per 12 months} \\ 14 \text{ g VX1/ha} \\ \text{per 12 months} \end{array}$	per appl.		crop cycles per year. Plant propagation companies can have up to 8 productions per 12 months. V10 is applied in combination with 800 grams of synthetic sand per 100 litres of spray liquid

## Table D: Ecotoxicological risk assessment\* (copy of relevant use(s) from appendix A)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-	Member	Crop and/	F,	Pests or Group of pests		Appli	cation		Application rate			PHI	Remarks:
No. (*)	state(s)	or situation (crop destination / purpose of crop)	Fn, Fpn G, Gn, Gpn or I	n, (additionally: n, (additionally: developmental stages of pn the pest or pest group) r	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	(days)	e.g. g safener/synergist per ha <sup>(f)</sup>
1	NL	Solanum lycopersicum	G	Pepino mosaic virus	Downwar d spraying	Young tomato plants (BBCH 13-51, 10-30 cm high) Jan-Dec	a) 1 per crop cycle b) 8 per 12 months (8 crops cycles per year)	-	<ul> <li>a) 70 L</li> <li>product/ha</li> <li>per appl.</li> <li>b) 560 L</li> <li>product/ha</li> <li>per 12 months</li> </ul>	a) $1.75 \text{ g}$ VC1/ha (2.63x10 <sup>16</sup> particles/ha) per crop cycle 1.75  g VX1/ha (2.63x10 <sup>16</sup> particles/ha) per crop cycle	3500 L/ha per appl.	-	Tomato producing companies have 1-3 crop cycles per year. Plant propagation companies can have up to 8 productions per 12 months. V10 is applied in

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-	Member	Crop and/	<b>F</b> ,	Pests or Group of pests		Appli	cation		Ар	plication rate		PHI	Remarks:
No. <sup>(e)</sup>	state(s)	or situation (crop destination / purpose of crop)	Fn, Fpn G, Gn, Gpn or I	i,     controlled     N       in     (additionally:     K       n,     developmental stages of     F       pn     the pest or pest group)     K	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	(days)	e.g. g safener/synergist per ha
										b)14 g VC1/ha per 12 months 14 g VX1/ha per 12 months			combination with 800 grams of synthetic sand per 100 litres of spray liquid bees*

\*) For the ecotoxicological risk assessment the critical organism should be indicated under remarks.

## Appendix C - Specification of the used technical material

(Document should be sent separately or provided at the pre-submission meeting)

Name of the active substance or variant:

Manufacturer:

Location of the manufacturing site:

Chemical name/code	CAS number, if available	Structural formula	Specified levels Minimum purity (as) Maximum content (impurities) [g/kg]
			s Adda - Scialain