15614 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. BESLUIT

Op 17 april 2019 is van

Valto B.V.
Leehove 81
2678 MB DE LIER
Nederland

een aanvraag tot wijziging van de gewasbeschermingsmiddeltoelating met Nederland als zonaal rapporteur op basis van een laag-risico-stof ontvangen als bedoeld in artikel 47 en artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

V10

op basis van de werkzame stoffen Mild Pepino Mosaic Virus isolate VX1 en Mild Pepino Mosaic Virus isolate VC1. De wijziging betreft de uitbreiding van de toelating met het gebruik van het middel gedurende de kweekfase van tomaat.

HET COLLEGE BESLUIT tot toelating van de uitbreiding van de toelating van bovenstaand middel.

Alle bijlagen, waaronder registratierapport deel A en deel B, vormen een onlosmakelijk onderdeel van dit besluit.

1.1 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.2 Gebruik

Het middel mag slechts worden gebruikt volgens het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.

1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen conform de geldende regelgeving op of bij de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.
- De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II en in hoofdstuk 2 van deel A van het registratierapport.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Het gebruik wordt bij dit besluit alleen uitgebreid. Er wordt een nieuw gebruiksvoorschrift aangemaakt met volgnummer W.1, maar respijttermijnen zijn niet van toepassing.

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. De te hanteren w-coderingen en aflever- en opgebruiktermijnen voor oude verpakkingen staan vermeld onder “toelatingsinformatie” in bijlage I.

2. WETTELIJKE GRONDSLAG

Besluit	Artikel 47 van de verordening
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Bgb en Rgb d.d. 16 december 2011 en de voor dit aanvraagtype van toepassing zijnde Evaluation en Registration Manual op de dag van ontvangst van deze aanvraag.

3. BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.2 Analysemethoden.

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

3.6 Overige overwegingen

De toepassing van het middel V10 heeft in de opkweekfase het beste resultaat. Omdat uitgangsmateriaal doorgaans verhandeld en verplaatst wordt van opkweekbedrijf naar productiebedrijf is er een risico op onbedoelde verspreiding van de milde stammen van het pepinomozaïkvirus (Mild Pepino Mosaic Virus isolate VX1 en isolate VC1). Met dit besluit is toepassing in de opkweekfase van tomaat mogelijk, mits de toelatinghouder en de gebruiker van V10 in de opkweekfase van tomaat een contract afsluiten met een voorgeschreven protocol over de toepassing van het middel en verdere opkweek en logistiek van behandelde planten. Deze contractuele verplichting vormt de basis voor de mitigerende maatregelen voor een veilig gebruik van V10 in de opkweekfase van tomaat en het voorkomen van het onbedoeld verspreiden van de milde virusstammen daarna.

In Part A van het RR is een standaard contract en protocol opgenomen. De delen van het contract en protocol die opgenomen zijn op het WG kunnen niet zonder goedkeuring van het Ctgb worden gewijzigd.

Voor nadere onderbouwing van de beoordelingen verwijzen wij u naar deel A en B van het registration report als toegevoegd aan de bijlagen van dit besluit overeenkomstig Besluit beleidsregel bekendmaken delen A en B van het Registration Report.

15614 N

Bezwaarmogelijkheid.
Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 8030, 6710 AA, EDE. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Ede, 25 september 2020

Het College voor de toelating van
gewasbeschermingsmiddelen en biociden,
voor deze:
de voorzitter,

Ir. J.F. de Leeuw

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraaginformatie

Aanvraagnummer:	20190787 ZWTG-LR
Type aanvraag:	Aanvraag tot wijziging van de gewasbeschermingsmiddeltoelating met Nederland als zonaal rapporteur op basis van een laag risico stof.
Middelnaam:	V10
Verzenddatum aanvraag:	17 april 2019
Formele registratiedatum: *	13 mei 2019

* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

2.2 Stofinformatie

Werkzame stof	Gehalte
Mild Pepino Mosaic Virus isolate VX1	0,005-0,025 g/L
Mild Pepino Mosaic Virus isolate VC1	0,005-0,025 g/L

- De stoffen Mild Pepino Mosaic Virus isolate VX1en Mild Pepino Mosaic Virus VC1 zijn goedgekeurd per 29 maart 2017 krachtens Verordening (EG) No 1107/2009 (Uitvoeringsverordening (EU) 2017/408 d.d. 8 maart 2017) als laag risico stoffen. De goedkeuring van deze werkzame stoffen expireert op 29 maart 2032.

2.3 Toelatingsinformatie

Toelatingsnummer:	15614 N
Expiratiedatum:	29 maart 2033 (ongewijzigd)
Afgeleide parallel of origineel:	Wijziging Middel
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel

W-coderingen en aflever- en opgebruiktermijnen:

W-codering professioneel gebruik:	W.1
Vorige w-codering professioneel gebruik:	-
Aflevertermijn professioneel gebruik:	nvt
Opgebruiktermijn professioneel gebruik:	nvt

2.4 Verpakkingsinformatie Aard van het preparaat: Suspensie concentraat

Uiterste gebruiksdatum 6 maanden na productiedatum, indien opgeslagen bij temperaturen onder -15°C.

15614 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel V10

Professioneel gebruik

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:

Pictogram		
Signaalwoord		
Gevarenaanduidingen		
Voorzorgsmaatregelen	P280C	Beschermende handschoenen en beschermende kleding dragen.
	SP 1	Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Aanvullende etiketelementen	EUH401	Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.

Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

REGISTRATION REPORT

Part A

Risk Management

Product code: V10

Active Substance: 5-25 mg/L Mild Pepino Mosaic Virus isolate VX1 & 5-25 mg/L Mild Pepino Mosaic Virus isolate VC1

Interzonal

NATIONAL ASSESSMENT

Applicant: Valto B.V.

Date: September 2020

Table of Contents

PART A – Risk Management

1 Details of the application

This document describes the acceptable use condition required for the label extension of V10 containing Mild Pepino Mosaic Virus VX1 and Mild Pepino Mosaic Virus VC1 in The Netherlands. This evaluation is required subsequent to the EU approval under EU Regulation 1107/2009 of Mild Pepino Mosaic Virus VX1 and Mild Pepino Mosaic Virus VC1.

V10 is authorised in the Netherlands for the use in the protected cultivation of tomato (registration number 15614 N) since 2018. This label extension concerns the use in the nursery phase of tomato. The GAP for the Netherlands is covered by the GAP evaluated in the course of the original core assessment for V10.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to V10 where that data has not been considered in the EU review. Otherwise assessments for the safe use of V10 have been made using endpoints agreed in the EU review of Mild Pepino Mosaic Virus VX1 and Mild Pepino Mosaic Virus VC1.

This document describes the specific conditions of use and labelling required for The Netherlands for the registration of V10.

Appendix 1 of this document provides a copy of the final product authorisation for The Netherlands.

Appendix 2 of this document is a copy of the approved product label for The Netherlands.

Appendix 3 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.

1.1 Application background

This application was submitted by Valto B.V. in April 2019.

The application was for the label extension of V10, a suspension concentrate containing 5-25 mg/L Mild Pepino Mosaic Virus isolate VX1 and 5-25 mg/L Mild Pepino Mosaic Virus isolate VC1 (equivalent to $1.5x10^{11}$ and $7.5x10^{11}$ virus particles per mL) for use as an elicitor that induces resistance to virulent Pepino Mosaic Virus in commercial greenhouse areas.

1.2 Annex I inclusion

Mild Pepino Mosaic Virus VX1 and Mild Pepino Mosaic Virus VC1 are approved under EU Regulation 1107/2009.

1.3 Regulatory approach

To obtain approval the product V10 must meet the condition of EU-approval under EU Regulation 1107/2009 and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using EU approved end-points.

This application was submitted in order to allow the label extension of product V10 in the Netherlands in accordance with the above.

1.4 Data protection claims

Data protection is claimed for newly submitted study reports.

1.5 Letters of Access

No letter of access was submitted as Valto B.V. is notifier of the active substances.

2 Details of the authorisation

2.1 Product identity

Product Name	V10
Authorization Number (for re-registration)	Not applicable
Function	Elicitor
Applicant	Valto B.V.
Composition	5-25 mg/L Mild Pepino Mosaic Virus isolate VX1 and 5-25 mg/L Mild Pepino Mosaic Virus isolate VC1 (equivalent to $1.5x10^{11}$ and $7.5x10^{11}$ virus particles per mL)
Formulation type	SC
Packaging	5L black rectangular plastic jerry can made of HDPE, Hostalen ACP 5331 A. The tank dimensions are 190mm x 160mm x 237 mm (l·w·h). Tank closure has a size of the opening equal to 51 mm, and it is made with a plastic screw lid (material: HDPE 40055E colour: green) 1 L round container made of HDPE. The container dimensions are 86mm x 85mm x 232mm (l-w-h). Tank closure has a size of the opening equal to 28 mm, and is made with a HDPE with PE insert screw cap (colour: black)

2.2 Classification and labelling

2.2.1 Classification and labelling under Regulation (EC) No 1272/2008

The current classification and labelling can be maintained:

The identity of all substances in the mixture that contribute to the classification of the mixture *:
-
Pictogram: - Signal word: -

H-statements:	-	
P-statements:	P280c	Wear protective gloves and protective clothing.
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
	SP1	Do not contaminate water with the product or its container.
Child-resistant fastening obligatory?		Not applicable
Tactile warning of danger obligatory?		Not applicable

2.2.2 R and S phrases under Directive 2003/82/EC (Annex IV and V)

The current classification and labelling can be maintained.

2.2.3 Other phrases

The current classification and labelling can be maintained:

Contains Mild Pepino Mosaic Virus VX1 and Mild Pepino Mosaic Virus VC1: Microorganisms may have the potential to provoke sensitising reactions.

2.3 Product uses

GAP rev. date: 10-04-2019

PPP (product name/code):	V10	Formulation type:	SC
Active substance 1:	Mild Pep MV isolate VC1	Conc. of as 1:	5-25 mg/L $7.5x10^{10}$ to $3.75x10^{11}$ virus particles / mL
Active substance 2:	Mild PepMV isolate VX1	Conc. of as 2:	5-25 mg/L $7.5x10^{10}$ to $3.75x10^{11}$ virus particles / mL
Applicant:	Valto B.V.	Professional use:	☒
Zone(s):	interzonal	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-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)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between appli-cations (days)	kg or 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		
New 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)													
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 g VC1/ha ($2.63x10^{16}$ particles/ha) per crop cycle 1.75 g VX1/ha ($2.63x10^{16}$ 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.	-	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 ($3x10^{14}$ particles/ha) per crop cycle 0.02 g VX1/ha ($3x10^{14}$ particles/ha) per crop cycle b) 0.16 g VC1/ha per 12 months 0.16 g VX1/ha per 12 months	8 L/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

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

Overall summary: V10, an SC preparation with the microbial pest control agents Mild Pepino Mosaic Virus mild isolate VC1 and mild isolate VX1 is not reactive, not oxidizing, not explosive and not flammable. It has a wet cortex/grass odour and is an olive green liquid with slight suspension (turbid). The preparation has a pH of 7.45 and a kinematic viscosity of 1.104 mm^2/s at 20°C and 0.734 mm^2/s at 40°C. The foam volume of 40 ml after 1 minute is acceptable. The suspensibility of the preparation is 101% for VX1 (2% and 10% concentration) and 102 and 101% for VC1 (2% and 10% concentration). Relative density is 1.020-1.019 (20°C and 40°C, CIPAC 3.2.1) to 1.140 (CIPAC 3.2.2).
At room temperature this biological plant protection product is not stable. When stored at < -15°C the preparation has a shelf life of 6 months in HDPE.

Implications for labelling:
Label prescriptions to ensure physical compatibility of the tank mix:
Use preferably a piston pump, clean filter every time, synthetic sand will deposit in the spray solution, therefore make sure of movement in the tank.
Be aware of obstruction of the nozzles. This is easy to see because the spray jet is no longer parallel. Also control this before spraying the tomato plants.

In Dutch:
Het gebruik van een zuigerpomp verdient de voorkeur. Het filter moet na elk gebruik gereinigd worden. Om te voorkomen dat het zand neerslaat moet de spuitvloeistof continu geroerd worden.
Pas op voor het verstoppen van de spuitkoppen. Controleer voor het spuiten of de spuitstraal parallel is.

Compliance with FAO specifications: The product V10 complies with FAO specifications.

Compatibility of mixtures: V10 is a 1:1 mixture Mild Pepino Mosaic Virus isolates VC1 & VX1. Synthetic sand should be added to the spray solution to create some minor damage on leaves, enabling the virus to enter the plant.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment: Information regarding the required protective clothing and equipment for the safe handling of V10 has been provided and is considered to be acceptable.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

V10 was the representative formulation in the EU review of Mild Pepino Mosaic Virus isolates VC1 & VX1. Analytical methods for determination of Mild Pepino Mosaic Virus isolates VC1 & VX1 and

impurities were evaluated as part of the EU review of Mild Pepino Mosaic Virus isolates VC1 & VX1. All data are considered adequate.

3.1.2.2 Analytical methods for residues

Viable residues:

Routine monitoring and MRL setting are not proposed since the virus is not toxic and not infective to humans. Mild variants occur in nature as well. Although positive determination of VC1 and VX1 is not suitable for concluding on treatment of tomato plants with V10, samples can be tested by ELISA and by real-time PCR for the presence of the specific mild virus variant (VX1 and/or VC1) and for the ratio of the mild variants to the total amount of PepMV (ratio's VX1 : total PepMV and VC1 : total PepMV).

Non-viable residues

Not relevant. Pepino Mosaic Virus does not produce metabolites.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

For the acute toxicity of the product V10 reference is made to the evaluation for the original authorization.

3.1.3.2 Operator Exposure

The label extension concerns the use during the nursery phase of tomatoes. The application rate applied for is exactly the same as the current authorized use in the production phase of tomatoes. No new Guidance documents have been adopted that affect the risk assessment and therefore it is concluded that the new use is covered by the risk assessment of the original authorization.

3.1.3.3 Bystander Exposure

The label extension concerns the use during the nursery phase of tomatoes. The application rate applied for is exactly the same as the current authorized use in the production phase of tomatoes. No new Guidance documents have been adopted that affect the risk assessment and therefore it is concluded that the new use is covered by the risk assessment of the original authorization.

3.1.3.4 Worker Exposure

The label extension concerns the use during the nursery phase of tomatoes. The application rate applied for is exactly the same as the current authorized use in the production phase of tomatoes. No new Guidance documents have been adopted that affect the risk assessment and therefore it is concluded that the new use is covered by the risk assessment of the original authorization.

3.1.4 Residues and Consumer Exposure

Residue data and consumer safety considerations are addressed in the EU review for Mild Pepino Mosaic virus VC1 & VX1. It is concluded that there are no acute and/or chronic effects expected from exposure to V10. The acute and chronic risk for consumer is negligible.

3.1.4.1 Residues

Validated methods are not required for micro-organisms. No new residue trials have been submitted. No MRL is needed for the micro-organism and Mild Pepino Mosaic virus VX1 and VC1 are candidates for inclusion in Annex IV to Regulation (EC) 396/2005.

3.1.4.2 Consumer exposure

As no acute reference has been set for Mild Pepino Mosaic virus VC1 & VX1, there is no need to evaluate the acute risk for this active substance. Use of V10 does not lead to unacceptable risk for consumers when applied according to the recommendations. Plant viruses like Pepino Mosaic Virus are ubiquitous in plants and fruits and therefore humans are continuously exposed. There are no documented cases of plant viruses causing diseases in humans. Viruses are not able to produce metabolites. Moreover, the toxicity studies demonstrate the Pepino Mosaic Virus isolate VX1 & VC1 were not acutely toxic.

As the product contains nicotine as impurity consumers may be exposed to non-viable residues. The consumer exposure assessment shows that the exposure is well below the ADI.

3.1.5 Environmental fate and behaviour

No new studies are presented, all data were reviewed in the EU review for Mild Pepino Mosaic virus isolates VX1 and VC1. The summary presented is the same as for the initial product registration of V10 (15614 N).

The impact of formulants is limited to short-term effects such as formation of stable spray dispersions or to facilitate uptake by target organisms, while their influence on long-term processes, such as degradation and distribution is negligible. Therefore, for the purposes of this risk assessment it is assumed that formulants do not influence the fate and behaviour of an active substance in the environment and are not considered further in this document. The risk assessment therefore can be based on endpoints derived for the active substances Mild Pepino Mosaic Virus isolate VX1 and Mild Pepino Mosaic Virus isolate VC1, except for nicotine which is a relevant impurity present in formulation V10 at 0.1 mg/L and which needs separate consideration next to the active substances.

3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil)

Pepino Mosaic Virus can only reproduce inside its host. Multiplication in soil is not relevant. Persistence in soil has not been quantified. It is unlikely that Pepino Mosaic Virus will be mobile in the environment via soil, or air.

V10 - The maximum applied dose of V10 in the greenhouse is 70 L/ha, equal to maximal 1.75 g/ha VC1 and 1.75 g/ha VX1. Interception by tomatoes at BBCH 13 is 50%, which results in an initial PEC_{soil} of 0.0012 mg/kg. Since viruses will not survive in soil only initial PEC_{soil} is calculated.

Nicotine - The ECHA soil DT_{50} value for readily biodegradable compounds of 30 days was proposed for nicotine. The PIECs is calculated with this DT_{50}-value, application rate of 7 mg/ha nicotine and interception value of 50% for tomatoes at BBCH stage 13. The worst case application of 8 applications per year with 45 days interval were used for the PECs calculations. $PIEC_{max,soil}$: 0.007 µg/kg.

3.1.5.2 Predicted Environmental Concentration in Surface water (PECsw)

Pepino Mosaic Virus can only reproduce inside its host. Multiplication in water is not relevant. Persistence in nutrient solution up to 3 weeks (20ºC).

V10 - A worst-case initial exposure value for surface water for Pepino Mosaic Virus VC1 and VX1 can be estimated. Drift from a greenhouse is assumed to be 0.1%. The maximum applied dose of V10 in the greenhouse is 70 L/ha, equal to maximal 1.75 g/ha VC1 and 1.75 g/ha VX1. As a result a maximum amount of 0.00175 g VC1/ ha (corresponding to 1.75×10^{-7} g VC1/m^2) and 0.00175 g VX1/ ha

(corresponding to $1.75x10^{-7}$ g VX1/m^2). This total amount is assumed to reach a standard ditch of 0.3 m depth, 1 m wide and 1 m length, which leads to a predicted initial concentration of 5.8×10^{-4} µg VC1/L water and 5.8×10^{-4} µg VX1/L water.

Nicotine - The maximum applied dose of V10 in the greenhouse is 70 L/ha, equal to maximal 0.007 g nicotine/ha. Drift from a greenhouse is assumed to be 0.1%. As a result a maximum amount of $7x10^{-6}$ g nicotine/ ha (corresponding to 7×10^{-10} g nicotine/m^2) is assumed to be present outside the greenhouse. This total amount is assumed to reach a standard ditch of 0.3 m depth, 1 m wide and 1 m length, which leads to a predicted initial concentration of $2.3x10^{-12}$ g nicotine/L water. As a worst case all the 8 applications are dosed at once this will result in a PECsw of 1.9×10^{-11} g nicotine/l water (18.6 pg/L).

PECgw
The PECgw for nicotine was calculated based on worst case input parameter assumptions as proposed by EFSA (DT_{50} of 30 days and a Koc of 48.23 l/kg, 1/n = 1) and 12 applications per year using FOCUS PEARL v4.4.4. Application dates for groundwater risk assessment were set on the 1st day of each month. The maximum applied dose of V10 in the greenhouse is 70 L/ha, equal to maximal 7 mg nicotine/ha (purified TGAI). V10 is applied at BBCH 13-51, so before flowering, when plants are 10-30cm high. Crop interception is therefore set at 50%. Crop used in FOCUS PEARL is winter cereals, which is considered worst case. The PECgw calculations were initially performed with 12 applications per year. However, the total amount of applications was lowered to 8 applications per year resulting in even lower PECgw. For each scenario PECgw <0.001 µg/L.

Drinking water
The risk of nicotine to the consumer via drinking water is considered negligible.
The realistic worst case expected surface water concentration is $1.9x10^{-11}$ g/L (0.019 ng/L). In the production of drinking water from surface water this amount is not detectable and will not result in problems regarding drinking water production.

3.1.5.3 Predicted Environmental Concentration in Air (PECair)

It is unlikely that Pepino Mosaic Virus will be mobile in the environment via soil, or air.

Nicotine is readily biodegradable. It can be degraded easily by photo oxidation with a DT_{50} of 1.411 hours (EPI Suite) based on 12 h light/dark periods per day. Nicotine degradation is concluded to be fast. Nicotine accumulation in the air compartment does not have to be expected and nicotine transportation by air is expected to be minimal.

Implications for labelling resulting from environmental fate assessment:
None

3.1.6 Ecotoxicology

The impact of formulants is limited to short-term effects such as formation of stable spray dispersions or to facilitate uptake by target organisms, while their influence on long-term processes, such as degradation and distribution is negligible. Therefore, for the purposes of this risk assessment it is assumed that formulants do not influence the fate and behaviour of an active substance in the environment and are not considered further in this document. The risk assessment therefore can be based on endpoints derived for the active substances Mild Pepino Mosaic Virus isolate VX1 and Mild Pepino Mosaic Virus isolate VC1, except for nicotine which is a relevant impurity present in formulation V10 at 0.1 mg/L and which needs separate consideration next to the active substances.

Exposure to birds and mammals through drinking water as a result of exposure of surface water to recirculation water, is also considered low. Like all viruses (both plant and animal/human pathogenic) Pepino Mosaic Virus can only reproduce inside its host. And in any case: any exposure due to release from the greenhouse will only add to the exposure that will already take place via naturally present Pepino Mosaic Virus strains, which are ubiquitous in the environment.
Direct exposure to nicotine is not considered relevant for the same reason. From the information provided in Section B5 it is demonstrated nicotine will not persist in the environment.

For aquatic organisms, plant pathogenic viruses are generally considered not to be toxic. However, nicotine can be effective to aquatic organisms. An initial PECsw of $1.9x10^{-5}$ µg/L has been calculated for nicotine. Toxicological endpoints are available for fresh water fish, aquatic invertebrates and algae. Risk assessment revealed that TER values are well above Annex VI trigger values for fish, aquatic invertebrates (Daphnia), algae (*Selenastrum)* and aquatic plants (*Lemna*). No risk has to be expected for aquatic organisms upon the use of V10 at the recommended dose rate in greenhouses according to Appendix 2.

Chronic exposure due to repeated applications cannot be excluded, however considering the very low exposure to surface water that is predicted taking into account the extra purification of the TGAI which results in a nicotine concentration in the product ≤ 0.1 mg/L product, the RMS considered in the DAR that no further data is required.

For bees and non-target arthropods, plant pathogenic viruses are generally considered not to be toxic. However, nicotine can be effective to bees and non-target arthropods. Exposure is not foreseen to bees and non-target arthropods in the greenhouse. Tomato plants are treated between BBCH 13-61. Bumble bees can be introduced for pollination purposes, however, this will be > BBCH 61. Nicotine is expected to be at the level of the natural background at this timing, and no risk is expected for bumble bees in greenhouses.

For bees and other non-target arthropods in the off-field environment (outdoor), no exposure to V10 is expected. The risk to bees and non-target arthropods outside the greenhouse is considered to be low.

Exposure of soil organisms in greenhouse soils is not relevant since tomato plants are generally sown in pots and treatment with V10 is foreseen before small plants are transplanted. The use of V10 on tomatoes in greenhouses does not require a risk assessment for soil organisms.

According to the presented risk assessment, the use of V10 at the proposed label rates according to good agricultural practice poses no risk to any of the non-target species.

No additional safety measures are needed.

3.1.7 Efficacy

The Netherlands are the ZRMS for the evaluation of this label extension; there are no concerned member states, however the international trade of treated tomato plants and the regulation thereof is an important topic of the current label extension. As such the dossier may be of relevance for member states that are not designated as an officially concerned member state.

Minimum effective dose and efficacy

No new data was submitted as the efficacy was already evaluated during the original authorisation of the product. It is relevant to note that, in the trials underlying the original dossier, the product was applied on very young plants (BBCH 12-14). The restriction to not apply the product during the nursery

stage that was included as part of the original evaluation was imposed for reasons other than product effectiveness. In fact, application of the product during the nursery stage more closely resembles the trial setup in the original dossier. There is no need to submit additional efficacy or dose justification trials, these data requirements are covered by the original evaluation.

Monitoring
The applicant has submitted monitoring data based on quantitative reverse transcriptase PCR. While these trials are not GEP, they provide insight on inoculation efficiency and product efficacy. As the product is currently only authorised in the production phase the tested plants were inoculated in the production phase, not the nursery phase. Data show that the majority of plants was successfully inoculated. Based on the data however a point can be made that according to the monitoring results, the product was not always effective, possibly because aggressive strains had already had a chance to infect the plants before the product was applied. As explained before, efficacy and crop safety of the product in small plants was already addressed during the original authorisation of V10.

Adverse effects.
Because the unconventional mode of action, and possible adverse effects, the submitted data do not fall precisely within the standard subjects of an adverse effects evaluation, the normal chapter layout has been dispensed with in favour of an adapted chapter layout.

Proposed measures
With the current dossier the applicant wants to remove the restriction that forbids product use in the nursery phase of tomatoes. The mild strains in the product can produce mild virus symptoms. The restriction was put in place to prevent distribution of plants that are infected/inoculated with VC1 and VX1 to member states or areas where the aggressive strains do not occur, or where the product is not authorised. Such distribution could take place directly/intentionally, because plants that have been inoculated could be sold and transported to such areas, or unintentionally, because the mild strains can unintentionally infect plant material that is supposed to be clean, and be distributed to the aforementioned destinations.
It should be noted that no new studies have been submitted, therefore the conclusion of the efficacy evaluation remains the same as in the original evaluation. Mitigation measures are needed to prevent the distribution of virus inoculated material. The current mitigation is that use of the product in the nursery phase is prohibited. The applicant has now proposed alternative restrictions to make an authorisation of the product in the nursery phase possible.

It is proposed by the applicant that the intentional, or direct distribution of plants will be prevented by limiting the distribution of V10 for use in nurseries to companies that have signed a legal agreement to adhere to phytosanitary protocols for use of V10 in nursery tomato. Furthermore, inoculated plants would be clearly labelled in the proposal.
The legal agreement, the possibilities for enforcement, and the final decision on its acceptability is outside of the scope of the efficacy evaluation and conclusions will be drawn in paragraph 3.2 under Conclusions.

In addition, there is the distribution through accidental inoculation of plant material.

Under the new proposal nurseries will have to work with batches inoculated with V10 and batches that are not treated with V10, and infections of the latter should be prevented. The protocol can be found in appendix 6.
The applicant proposes that certified companies have to follow proposed protocols. The protocols address several pathways through which virus free plants could get inoculated with V10, and includes a general clause that unintended distribution of the mild strains in V10 should be prevented at all times.

Further analysis was submitted exploring if proposed protocols can prevent contamination between batches. The applicant refers to a study by Li et al. (2014)
In an experimental setup it was shown that several methods for disinfection were successful in de-activating pepino mosaic virus. Virkon S (1% and 2%), Lysol all-purpose cleaner (50%), nonfat dry milk (20%), and Clorox regular bleach showed the most promising results. Several infections where still seen in some of the experiments with nonfat dry milk, Lysol all-purpose cleaner and Clorox regular bleach, but the experiment was set up with very short contact times. This is realistic for work within a batch of plants such as grafting, but for assessing the risks of inoculation between inoculated and virus free batches longer contact times would be more realistic, and the trial setup can be considered worst case.

It should be noted that not all these methods are registered as plant protection products, a number of them are registered as biocides. Skimmed milk is authorised in the Netherlands for use against viruses under the RUB, a national authorisation scheme that is being phased out. Uses authorised under RUB are being evaluated for a regular authorisation as a PPP or basic substance. It should be noted that in this article Benzoic Acid (Menno Florades) was only tested at rates that are considered inadequate for control of viruses (it was tested at 1% whereas the label prescribes 2-4%, and the tomato hygiene protocol prescribes 4%). It can be concluded that efficacious products are available on the market as biocides, but that availability as registered PPP's is in some cases a concern, the registration status of disinfectants available for greenhouses and the borderline area between biocides and PPP products is an issue that is not only relevant to this dossier but to disinfection in these circumstances in general.

Resistance management.
No new data has been submitted. Conclusions are the same as for the original authorisation, as the proposed label change (application in nursery phase, instead of during the production phase) is not expected to have an impact on resistance risks.

3.2 Conclusions

For a safe use in the germination phase of V10, extra mitigation measures are needed to prevent the unintended distribution of virus inoculated material. For the use of V10 the mitigation measure has been up till now that use of the product in the nursery phase was prohibited. The authorisation holder has currently proposed alternative restrictions to authorise the product in the nursery phase of tomato. A specified legal agreement between the supplier of V10 and the user of V10 in the nursery phase, including a strict hygiene protocol, should ensure the specific conditions to avoid any unintended spread of the mild virus isolates VX1 and VC1.
Because the normal hygienic standards in both nursery and tomato cultivation are so high, it is expected that these conditions are realistic and that compliance with these conditions is close to current practise in these cultivations. The authorisation holder Valto is the sole distributor of V10, and is therefore able to indicate which parties have concluded the aforementioned contract. Valto is obliged to share this information with dedicated enforcement agencies.
The most crucial components of the legal agreement are also part of the instruction of use (WG), and as such recognisable for all stakeholders. These include the strict hygiene procedures during the whole cultivation and sale, the recognisability of treated plants and the limitation that treated plants can only be sold in countries where V10 is authorised by the national authority.
The following (in Dutch) is therefore part of the instruction of use:

Planten in de productiefase behandeld met V10 mogen niet verplaatst worden naar andere bedrijven, uitgezonderd voor afvalverwerking.

Het middel mag in de opkweek van tomatenplanten uitsluitend toegepast worden door bedrijven die met de toelatingshouder een contract hebben over de toepassing van V10 in de opkweekfase van tomaat. Op verzoek van de verantwoordelijke toezichthouder stelt de toelatingshouder een actuele lijst met gecontracteerde bedrijven ter beschikking.
Toepassing in de opkweek van tomatenplanten is uitsluitend toegestaan onder de volgende voorwaarden:

- Alle hygiëne maatregelen en voorschriften tijdens de teelt zoals beschreven in het protocol voor gebruik van V10 in opkweek tomaten moeten worden nageleefd om onbedoelde besmetting met V10 van niet behandelde planten te voorkomen,

- Met V10 behandelde planten moeten permanent zichtbaar gemarkeerd zijn,

- Met V10 behandelde kweekplanten mogen alleen doorverkocht worden aan landen waar V10 is toegelaten voor gebruik in de productiefase van de teelt.

Deze voorwaarden zijn opgenomen in het contract tussen de toelatinghouder en de bedrijven die V10 gebruiken in de kweekfase van tomaat.

Voor aanvullende informatie en de te volgen procedure wordt verwezen naar het protocol voor gebruik van V10 in opkweek tomaten.

The authorisation holder will only deliver the product to companies that have made the aforementioned contract and have adopted the protocol for use of V10 in nursery tomato. This legal agreement and the protocol can be found in appendix 5 and 6 of this document. Changes in the legal agreement and protocol which are part of the instructions of use can only be made with consent of the Ctgb.
An evaluation of efficacy related aspects of this proposal can be found in the efficacy section. The outline of the agreements on the protocol and the extra conditions of use are the result of a dialogue between the authorisation holder and the authority in consultation with the Food and Consumer Product Safety Authority.
For users of V10 in the production phase of tomato nothing changes.

3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

No further information.

Appendix 1 – Copy of the product authorisation

A copy of the product authorisation (in Dutch) is included at the beginning of this document.

Appendix 2 – Copy of the product label

Wettelijk Gebruiksvoorschrift **W.1**

Het middel is uitsluitend toegelaten als virusbestrijdingsmiddel voor het professionele gebruik in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.1 Ctgb juni 2015) onder de hierna vermelde toepassingsvoorwaarden.

Toepassingsvoorwaarden:

Toepassingsgebied	Type toepassing	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximaal aantal toepassingen per teeltcyclus
Tomaat	Bespuiting	Pepinomozaïekvirus [1]	70 L/ha[2]	1
	Inwrijven	Pepinomozaïekvirus [1]	0,8 L/ha[3]	

* Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is vastgesteld voor de genoemde dosering per toepassing en niet voor verlaagde doseringen.

[1] Pepinomozaïekvirus, Europese stam en Chileense stam van Pepinomozaïekvirus

[2] in combinatie met 800 gram synthetisch zand per 100 L spuitvloeistof.

[3] in combinatie met 15 gram synthetisch zand per 1 L inwrijfvloeistof.

Overige toepassingsvoorwaarden

In de teelt van tomaat dient V10 verspoten te worden met een volume van 3500 L water per ha.
Voor de inwrijftoepassing dient V10 te worden toegevoegd aan 8 L water per ha.

Het gebruik van een zuigerpomp verdient de voorkeur. Het filter moet na elk gebruik gereinigd worden. Om te voorkomen dat het zand neerslaat moet de spuitvloeistof continu geroerd worden.

Pas op voor het verstoppen van de spuitkoppen. Controleer voor het spuiten of de spuitstraal parallel is.

Bevat Mild pepinomozaïekvirus, isolaat VC1 en VX1. Micro-organismen kunnen mogelijk sensibiliserende reacties veroorzaken.

De milde virusstammen in V10 kunnen aangrenzende gewassen en volggewassen van vruchtgroenten van *Solanaceae* infecteren en zich daarin verder verspreiden.

Het product kan milde virussymptomen op de plant veroorzaken.

Planten in de productiefase behandeld met V10 mogen niet verplaatst worden naar andere bedrijven, uitgezonderd voor afvalverwerking.

Het middel mag in de opkweek van tomatenplanten uitsluitend toegepast worden door bedrijven die met de toelatingshouder een contract hebben over de toepassing van V10 in de opkweekfase van tomaat. Op verzoek van de verantwoordelijke toezichthouder stelt de toelatingshouder een actuele lijst met gecontracteerde bedrijven ter beschikking.

Toepassing in de opkweek van tomatenplanten is uitsluitend toegestaan onder de volgende voorwaarden:

- Alle hygiëne maatregelen en voorschriften tijdens de teelt zoals beschreven in het protocol voor gebruik van V10 in opkweek tomaten moeten worden nageleefd om onbedoelde besmetting met V10 van niet behandelde planten te voorkomen,
- Met V10 behandelde planten moeten permanent zichtbaar gemarkeerd zijn,
- Met V10 behandelde kweekplanten mogen alleen doorverkocht worden aan landen waar V10 is toegelaten voor gebruik in de productiefase van de teelt.

Deze voorwaarden zijn opgenomen in het contract tussen de toelatinghouder en de bedrijven die V10 gebruiken in de kweekfase van tomaat.

Voor aanvullende informatie en de te volgen procedure wordt verwezen naar het protocol voor gebruik van V10 in opkweek tomaten.

Appendix 3 – Letter of Access

No letter of access was submitted as Valto B.V. is notifier of the active substance.

Appendix 4 – List of data submitted in support of the evaluation

List of additional information

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Study used y/n	Data protection granted y/n
6.0-01	Looije, Th	2019	Biological Assessment Dossier V10 – nursery tomato Valto B.V - -, unpublished	Y	Valto B.V	y	No, can not have data protecio n on BAD.
6.4-01	Looije, Th	2018	Data Valto 2015-2018_TL20180820 Valto B.V. - -, unpublished, non GEP	Y	Valto B.V	y	y

Appendix 5 : Agreement for use of V10 in nursery phase of tomato

PROPOSED CONTRACT VALTO B.V. – NURSERIES

PARTIES INVOLVED:
Authorisation holder and distributer Valto B.V, (seated in De Lier, the Netherlands) legally represented by…, further referred to as "the supplier"

and

Nursery …. (company name, legal form, location) legally represented by…., further referred to as "the nursery grower".

TAKING INTO ACCOUNT THAT:

- the supplier commits itself to the production and sale of the plant protection product V10 (authorisation number NL: 15614N) and wishes to sell this to customers of the nursery grower under the conditions that are defined hereafter;
- the nursery grower wishes to use the plant protection product V10 in the nursery phase of tomato under the conditions that are defined hereafter;

ARE AGREED AS FOLLOWS:

Article 1: Goals
The supplier and the nursery grower agree to enable the use of V10 in the nursery phase of tomato.

Article 2: Conditions for use
V10 can be used by nursery growers in the nursery phase of tomato under the conditions that:

- the protocol "V10 in the nursery phase of tomato" is adhered to; this protocol is added to this contract as an appendix and is an integral part of this contract
- plants can only be treated with V10 on the specific request of the customer of the nursery grower;
- V10 will only be delivered to the nursery growers after presentation with the work order of the customer;
- plants destined for treatment with V10 will be potted in marked rockwool, and this mark will remain visible during the whole nursery phase and transport of the plants;
- plants will only be treated with V10 when they are destined for customers of the nursery growers located in European countries in which V10 is authorised for use in the production phase of tomato;
- all precautions for the prevention of infection with diseases or pests prescribed by the supplier and/or involved authorities are taken;
- all precautions are taken with the transport of V10 treated plants to prevent spread of the virus isolates;
- the nursery grower accepts that the supplier shares the name and address details of the nursery grower with the responsible authority like the Netherlands Food and Consumer Product Safety Authority (NVWA) on the request of this authority.

Article 3: Commitments of the nursery grower

The nursery grower commits himself to the following:

- on agreement between the nursery grower and his customer, an explicit mention will be made in the confirmatory work order that plants will be treated with V10 and that treated plants cannot be resold or transported to other entities than those of the customer of the nursery grower;

- the nursery grower informs the supplier of all batches that are treated with V10 and to which customers the treated plants are delivered;
- the nursery grower allows the supplier to take a sample after approx. 3 weeks after treatment with V10, to analyse the genetic profile of the present virus;
- when analysis by the supplier shows that the concerned batch of plants is infected with the aggressive Pepino Mosaic Virus, the nursery grower will directly notify his customer in writing.

Article 4: Commitments of the supplier

- the supplier will take samples of each treated batch of plants approx. 3 weeks after treatment with V10, to analyse the genetic profile of the present virus;
- when analysis shows the aggressive strain of Pepino Mosaic Virus is present in the plants, the nursery grower will be directly notified;
- when the results of the analysis are ambiguous, new samples will be taken and the analysis will be repeated;
- the supplier will inform the nursery grower in a timely manner, of any changes in the authorisation of V10
- the supplier will take care of an independent analysis of the samples
- the supplier will share the name and contact details of the nursery grower on the request of the responsible authority like the Netherlands Food and Consumer Product Safety Authority (NVWA)

Article 5: Duration and termination of contract

The contract is valid for 1 year. When the conditions of this contract are violated by a party of the contract, the contract will be suspended or terminated with direct effect by the other party.

Article 6: Confidentiality agreement

The nursery grower is aware that information and tools provided by the supplier are of a confidential nature and the nursery grower declares to respect and adhere to this confidentiality and will do everything in his power to accomplish this confidentiality and confidential treatment of the provided information and tools. The nursery grower vouches that the same confidentiality will be imposed on all employees involved and that these employees shall adhere to this confidentiality.

The supplier commits himself to confidentiality of all information of confidential nature concerning the methods of the nursery grower.

The above mentioned obligation of confidentiality does not apply to information that:
Is or became common knowledge and that this common knowledge is not the consequence of a break of confidentiality.

This confidentiality remains valid, indefinitely, after termination of this contract.

Article 7: Dispute settlement

This contract and disputes that arise from it, fall under Dutch Law. Potential disputes are only settled via the competent court in the district where the supplier is located.

Appendix 5 continued: Dutch translation agreement for use of V10 in nursery phase of tomato

MODEL -OVEREENKOMST VALTO B.V – PLANTENKWEKERS

PARTIJEN:
Toelatingshouder en distributeur Valto B.V, gevestigd in De Lier, Nederland) ten deze rechtsgeldig vertegenwoordigd door …., verder te noemen "de leverancier"

en

Plantenkweker ….(firmanaam, rechtsvorm, zetel) ten deze rechtsgeldig vertegenwoordigd door ….., verder te noemen "de plantenkweker".

OVERWEGENDE DAT:

- de leverancier zich toelegt op de productie en verkoop van het gewasbeschermingsmiddel V10 (toelatingsnummer: 15614N) en deze wenst te verkopen aan de klanten van de plantenkweker onder voorwaarden zoals hierna gedefinieerd;
- de plantenkweker het gewasbeschermingsmiddel V10 wenst te gebruiken bij de opkweek van tomatenplanten onder voorwaarden zoals hierna gedefinieerd;

ZIJN ALS VOLGT OVEREENGEKOMEN:

Artikel 1: Doelstellingen
De leverancier en de plantenkweker komen overeen om het gecontroleerde gebruik van V10 in de opkweek van tomaten planten mogelijk te maken.

Artikel 2: Voorwaarden voor gebruik
V10 mag worden gebruikt door de plantenkweker in de opkweek van tomatenplanten onder de voorwaarden dat:

- het protocol "V10 in opkweek tomaten" wordt nageleefd; dit protocol is als bijlage aan dit contract toegevoegd en maakt integraal onderdeel uit van dit contract
- planten alleen op bestelling met V10 worden behandeld op specifiek verzoek van de klant van de plantenkweker;
- V10 pas wordt geleverd aan de plantenkweker na overleg van een opdrachtbrief van de klant;
- planten bestemd voor behandeling met V10 in gemarkeerde steenwol worden opgepot, en dat deze markering tijdens de duur van opkweek en transport zichtbaar blijft;
- planten alleen worden behandeld met V10 wanneer deze bestemd zijn voor klanten van de plantenkweker uit Europese landen waar V10 is toegelaten in de productieteelt van tomaat;
- alle door de leverancier en/of door betrokken autoriteiten voorgeschreven voorzorgs maatregelen ter voorkoming van besmetting met ziektes en plagen in acht worden genomen;
- alle voorzorgsmaatregelen worden genomen bij transport van met V10 behandelde planten ter voorkoming van verspreiding van de virus-isolaten;
- de plantenkweker gaat ermee akkoord dat zijn naam, adres en woonplaats gegevens door de leverancier gedeeld worden met de verantwoordelijke toezichthouder, zoals de Nederlandse Voedsel en Waren Autoriteit (NVWA) op verzoek van deze autoriteit;

Artikel 3: Verplichtingen plantenkweker
De plantenkweker verplicht zich tot het volgende:

- bij overeenkomst tussen de plantenkweker en haar klant wordt in de orderbevestiging naar haar klant expliciet vermeld dat planten worden behandeld met V10 en dat behandelde planten niet nader mogen worden verhandeld en niet naar andere entiteiten dan die van de klant van de plantenkweker mogen worden getransporteerd;
- de plantenkweker bericht de leverancier van alle partijen planten die worden behandeld met V10 en aan welke klanten die worden geleverd;
- de plantenkweker staat toe dat de leverancier ±3 weken na behandeling met V10, monsters neemt ter analyse van het genetische profiel van het aanwezige virus;
- wanneer uit analyse van de leverancier blijkt dat de desbetreffende partij planten is geïnfecteerd met agressief Pepino Mosaic Virus, dan stelt de plantenkweker hiervan zijn klant direct schriftelijk op de hoogte.

Artikel 4: Verplichtingen leverancier

- de leverancier neemt van iedere behandelde partij planten ±3 weken na behandeling met V10, monsters ter analyse van het genetische profiel van het aanwezige virus;
- wanneer bij analyse de agressieve variant van het Pepino Mosaic virus wordt aangetroffen, wordt de plantenkweker hiervan direct op de hoogste gesteld;
- wanneer de resultaten van de analyse niet eenduidig zijn worden nieuwe monsters genomen en wordt de analyse herhaald
- de leverancier stelt de plantenkweker tijdig op de hoogte van wijzigingen in de toelating van V10.
- de leverancier zorgt voor een onafhankelijke analyse van de monsters
- de leverancier deelt de naam, adres en woonplaats gegevens van de plantenkweker op verzoek van de verantwoordelijke toezichthouder, zoals de NVWA

Artikel 5: Duur en beëindiging van de overeenkomst
De overeenkomst is geldig voor 1 jaar. Wanneer de voorwaarden van deze overeenkomst worden geschonden wordt door een partij wordt de overeenkomst met onmiddellijke ingang opgeschort of ontbonden door de andere partij.

Artikel 6: Geheimhouding
Plantenkweker is zich ervan bewust dat alle door de leverancier aan haar verstrekte informatie en hulpmiddelen een vertrouwelijk karakter draagt en de plantenkweker verklaart dat zij deze vertrouwelijkheid zal respecteren en in acht nemen en al het nodige zal doen teneinde geheimhouding als vernoemd en een vertrouwelijke behandeling van de verstrekte gegevens en hulpmiddelen te bewerkstelligen. Plantenkweker staat ervoor in dat aan ieder van haar in deze betrokken medewerkers dezelfde geheimhoudingsverplichting opgelegd zal worden en deze geheimhoudingsverplichting zal naleven.

Leverancier verplicht zicht tot geheimhouding van alle informatie van vertrouwelijke aard betreffende de werkwijze van plantenkweker.

De bovengenoemde geheimhoudingsverplichting geldt niet voorzover de informatie:
Van algemene bekendheid is of is geworden en deze bekendheid niet het gevolg is van niet naleving van deze overeenkomst.

Deze geheimhoudingsbepaling blijft ook, voor onbepaalde tijd, gelden na beëindiging van deze overeenkomst.

Artikel 7: Geschillenregeling

Deze overeenkomst en geschillen die daaruit voortvloeien worden beheerst door het Nederlandse recht. Eventuele geschillen zullen bij uitsluiting worden beslecht door de bevoegde rechter in het arrondissement waarbinnen de leverancier is gevestigd.

Appendix 6: Protocol for use of V10 in nursery tomato

A Dutch translation is given below

Terms

Batch: A batch is understood to mean plants that are grown at the same time and are destined for one and the same customer of the nursery

Hygiene measures

- All visitors to the nursery have to be announced.
  Visitors cannot enter the greenhouses without escort of authorized personnel;
- All visitors wear suitable disposable overalls and overshoes;
- Visitors enter the greenhouses through a hygiene lock where shoes and hands are disinfected;
- Personnel of the nursery wears suitable workwear. Workwear is changed when maintenance work is performed on a different batch;
- Before entering of every greenhouse or greenhouse compartment, shoes and hands are disinfected;
- All water that is used with the plants is disinfected;
- All instruments and objects that come in contact with plants are cleaned and disinfected after finishing the activities;
- After transport, trolleys and trucks that were used are cleaned and disinfected.
- The greenhouse or greenhouse compartment where the treated plants were located is cleaned and disinfected.
- Any unintended spreading of the mild virus isolates in V10 should be prevented at all times.

Requirements during cultivation

- Sowing is done mechanically, to prevent hand contact;
- Only certified Pepino Mosaic Virus-free tomato seeds are used;
- After sowing of one batch, the sowing machine and sowing room are cleaned and disinfected according to the protocol of the nursery;
- Every tray with sown tomato plants are labelled. The label contains at least the date of sowing and the details of the customer;
- After grafting, every tray with grafted tomato plants is labelled. In case no grafting is performed, the plants are labelled during repotting. The label contains at least the date of grafting and the details of the customer;
- After grafting or repotting, the tomato plants are transferred to rockwool blocks provided with a distinctive V10 label. The labels that are used are pre-printed rockwool sleeves; These sleeves will never be used for batches that will not be treated;
- Per greenhouse or greenhouse compartment only one batch of tomato plants is placed, plants of different batches are not mixed or combined to form new batches;
- It is indicated at the entry door of the greenhouse or greenhouse compartment that the room contains plants treated with V10, and that there is risk of contamination;
- A log is kept inside the greenhouse or greenhouse compartment with the details of the batch, containing at least the details of the customer;
- Treatment with V10 is made by authorized personnel in possession of a license to use ppp;
- Treatment with V10 is made according to the label requirements;
- When plants are topped, the required hygiene measures are taken to prevent spread of infection from one plant to the other; meaning that employees clean and disinfect their hands and tools regularly;

- For transport of plants, trolleys are used that are covered in foil and marked to contain V10 treated plants and that contamination should be prevented;
- For transport to the customer the foil covered trolleys are transported in clean, disinfected trucks;
- After transport the trolleys and trucks are cleaned and disinfected by the nursery.

Appendix 6 continued: Dutch translation of Protocol for use of V10 in nursery tomato

MODEL PROTOCOL voor gebruik van V10 IN OPKWEEK TOMATEN

Begrippen

Batch Onder een batch worden de planten verstaan die tegelijkertijd opgekweekt worden en bestemd zijn voor één en dezelfde klant van plantenkweker

Hygiëne maatregelen

- Alle bezoekers van de plantenkweker moeten worden aangekondigd aan plantenkweker. Bezoekers mogen de kassen niet zonder begeleiding betreden;
- Alle bezoekers van de plantenkweker dragen geschikte wegwerp overalls en overschoenen;
- Bezoekers van de plantenkweker betreden de kassen door een hygiëne sluis waarbij schoenen en handen worden gedesinfecteerd;
- Medewerkers van plantenkweker dragen bedrijfskleding. Kleding wordt gewisseld wanneer er werkzaamheden moeten worden uitgevoerd aan een andere batch;
- Voor het betreden van ieder(e) kas(compartiment), worden schoenen en handen gedesinfecteerd;
- Al het water dat wordt gebruikt bij de planten is gedesinfecteerd;
- Alle instrumenten en voorwerpen waarmee de planten in contact komen worden na afloop schoongemaakt en gedesinfecteerd;
- Na het transport worden de trolleys en vrachtwagens schoongemaakt en gedesinfecteerd.
- De kas of het kascompartiment waar de behandelde planten hebben gestaan moeten worden schoongemaakt en gedesinfecteerd.
- Elke vorm van ongewenste verspreiding van de milde virus isolaten in V10 moet te allen tijde worden voorkomen.

Voorschriften tijdens de teelt

- Zaaien wordt machinaal gedaan, om handcontact te voorkomen;
- Alleen gecertificeerd Pepino Mosaic Virus-vrij tomatenzaad wordt gebruikt;
- Na het zaaien van één batch wordt de zaaimachine en ruimte waarin is gezaaid schoongemaakt en gedesinfecteerd conform het protocol van de plantenkweker;
- Iedere tray met daarin gezaaide tomatenplanten is gelabeld met tenminste de datum van het zaaien en de gegevens van de klant van de plantenkweker;
- Na het enten is iedere tray met daarin geënte tomatenplanten gelabeld. Wanneer niet geënt wordt, worden de trays tijdens het overpotten gelabeld. Het label bevat tenminste de datum van het enten en de gegevens van de klant van de plantenkweker;
- Na het enten worden de tomatenplanten opgepot op steenwol voorzien van een speciale V10 markering; de speciale markering zijn voorgedrukte steenwol wikkels. De gemarkeerde V10 steenwolwikkels zullen nooit gebruikt worden voor batches die niet worden behandeld;.
- Per kas(compartiment) wordt maar één batch van tomatenplanten geplaatst. Planten van verschillende batches worden niet door elkaar gehaald of samengevoegd tot nieuwe batches.;
- Op de toegangsdeur van de kas/het kascompartiment is aangegeven dat de planten behandeld zijn met V10 en dat planten mogelijk besmettelijk zijn;

- In een logboek aanwezig in de kas/het kascompartiment zijn de details van de batch beschreven met hierin tenminste de gegevens van de klant van de plantenkweker;
- Behandeling met V10 vindt plaats door een medewerker van de plantenkweker met geldig spuitdiploma;
- Behandeling met V10 vindt plaats volgens de etiketvoorschriften van V10;
- Wanneer planten worden getopt, worden hierbij de nodige hygiëne maatregelen genomen om besmetting van de ene naar de andere plant te voorkomen; hiermee wordt bedoeld het regelmatig schoon beginnen van de medewerkers van de plantenkweker
- Bij transport worden de trolleys waarop de planten staan bedekt met folie waarop staat aangegeven dat de trolley met V10 behandelde planten bevat en dat besmetting dient te worden voorkomen;
- Voor transport naar de klant van de plantenkweker worden de met folie bedekte trolleys vervoerd in schone vrachtwagens;
- Na het transport worden de trolleys en vrachtwagens schoongemaakt en gedesinfecteerd door plantenkweker.