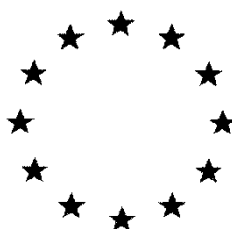


# ***European Commission***



**Draft Assessment Report prepared according to the Commission  
Regulation (EU) N° 1107/2009**

**Pepino Mosaic Virus, EU strain, mild isolate  
Abp1  
Pepino Mosaic Virus, CH2 strain, mild isolate  
Abp2  
Product data: AbioProtect®  
Volume 3 – Annex B.8 Fate and behavior in the  
environment**

**Rapporteur Member State: Spain**

**July 2019**

## Version History

When	What
	Completeness check report of the dossier submitted by the notifier
March 2019	DAR submitted to the Notifier. Reception of comments
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## B8. FATE AND BEHAVIOUR IN THE ENVIRONMENT

PepMV was first isolated in 1974 in Peru from Pepino (*Solanum muricatum* Ait.) plants showing symptoms of yellow mosaic (Jones *et al.*, 1980). It was not reported as a pathogen of tomato (*Solanum lycopersicum* L.) until 1999 (van der Vlugt *et al.*, 2000), in greenhouses in The Netherlands, but has since spread rapidly in Europe (Aguilar *et al.*, 2002; Cotillon *et al.*, 2002; López *et al.*, 2005; Mumford and Metcalfe, 2001; Pagan *et al.*, 2006; Pospieszny *et al.*, 2008; Roggero *et al.*, 2001) and beyond (French *et al.*, 2001; Ling 2007; Ling *et al.*, 2008; Maroon-Lago *et al.*, 2005; Soler *et al.* 2002).

PepMV belongs to the genus Potexvirus of the Alphaflexiviridae family; which include plant viruses only. It is widespread in Europe, its presence is described in 19 countries and is included in the European and Mediterranean Plant Protection Organization EPPO A2 of pests recommended for regulation as quarantine pest. Table 8-1 summarised the geographical distribution of PepMV in Europe from EPPO Global database webpage<sup>1</sup>.

**Table 8-1** geographical distribution of PepMV in Europe.

Country	Current status (2017)
Austria	Present, few occurrences
Belgium	Present, restricted distribution
Bulgaria	Present, few occurrences
Cyprus	Present, restricted distribution
Denmark	Present, few occurrences
France	Present, few occurrences
Germany	Present, few occurrences
Greece	Present, restricted distribution
Hungary	Present, few occurrences
Ireland	Present, few occurrences
Italy	Present, few occurrences
Italy (Sicilia)	Present, widespread
Lithuania	Present, few occurrences
Netherlands	Present, restricted distribution
Poland	Present, few occurrences
Spain	Present, widespread
Spain (Islas Canarias)	Present, restricted distribution
Switzerland	Present, restricted distribution
Turkey	Present, few occurrences
Ukraine	Present, no details
United Kingdom	Present, few occurrences

Four main PepMV genotypes can be distinguished, the original Peruvian genotype (LP), the European genotype (EU), the American genotype (US1), and the Chilean genotype (CH2), with an intergenotype RNA sequence identity ranging from 78% to 96% (Hanssen and Thomma, 2010). More recently (Moreno-Pérez *et al.*, 2014) reported the occurrence in wild tomatoes of isolates belonging to a new PepMV genotype, not yet reported in domestic tomato and named the South Peruvian genotype (PES).

<sup>1</sup> EPPO. (2018) Pepino mosaic virus (PepMV): Overview, distribution and Host plants, EPPO Global Database, <https://gd.eppo.int/taxon/PEPMV0>.

The PepMV EU genotype was the first to appear in Europe, although the CH2 genotype is currently the most frequent (Gómez et al., 2009, Hanssen & Thoma 2010), while isolates of the EU genotype are persisting both in single and mixed infections (Gómez et al., 2009). The EU genotype was predominant in North America (Ling et al., 2008), though a recent shift toward the CH2 genotype has been described (Ling et al., 2013).

PepMV, mild isolate Abp1 belongs to the EU genotype (or strain), and PepMV, mild isolate Abp2 belongs to the CH2 genotype (or strain). Mild and aggressive isolates are known from both the EU and the CH2 strains. Mild isolates will induce in tomato crop a symptomless infection without damage to the fruit, while an aggressive isolate will induce symptoms leading to economic losses in the crop.

Table 8-1 shows that PepMV is widespread in Europe. Introduction of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 in (permanet) tomato crops is therefore not expected to affect the level of natural occurrence of the virus.

PepMV is a plant virus, which can only replicate in their host plant living cell. Tomato is the most suitable host for PepMV, so production of PepMV, EU strain, mild isolate Abp1 and PepMV CH2 strain, mild isolate Abp2, are performed in tomato plants.

On the other hand, it should be noticed that viruses do not produce metabolites as they can only modify host cell metabolism. PepMV infection and replication is known to be very specific to plants and has not been reported to occur in other organisms, including humans or animals. Furthermore, PepMV belongs to the Alphaflexiviridae family of plant viruses for which a qualified presumption of safety has been found at the European level (EFSA BIOHAZ Panel, 2013)<sup>2</sup>.

### **B.8.1 PERSISTENCE AND MULTIPLICATION**

Viruses can only reproduce inside their host cells, plant viruses can only reproduce in plant living cells and PepMV can only reproduce inside its host plants. Multiplication in soil, water or air is therefore of little relevance.

PepMV is very efficiently transmitted mechanically in tomato by standard crop handling through contaminated tools, hands and clothing and by direct plant-to-plant contact (Spence et al., 2006; Van der Vlugt, 2009; Wright & Mumford, 1999). Bumblebees use as pollinators in tomato crops can spread the virus mechanically. However, no specific vector-plant virus relation is known and PepMV is not known to be harmful to bumblebees or any other insects. Plant viruses enter cells only through wounds made mechanically or by vectors or by deposition into an ovule by an infected pollen grain (Agrios, 2005).

It was described that recirculating water can also spread the virus from plant to plant (Schwarz et al., 2010) and that PepMV can survive and be transmitted in water (Mehle et al., 2014). This implies that PepMV might be persistent to a certain extent outside its host cell.

On the other hand, the virus could be transmitted by seed, although PepMV on tomato is localized on seed coat and not in embryo, mechanical transmission from a contaminated seed could easily induce a new infection. A low rate (0.0026%) of PepMV seed transmission in tomato has already been observed (Ling et al., 2013).

Infections, symptomless or with mild symptoms of PepMV have been observed in weed species which are members of families of *Amaranthaceae*, *Asteraceae*, *Boraginaceae*, *Brassicaceae*, *Chenopodiaceae*, *Compositae*, *Convolvulaceae*, *Malvaceae*, *Plantaginaceae*, *Polygonaceae* and *Solanaceae* (Córdoba et al., 2004; Jordá et al., 2001; Kazinczi et al., 2005; Papayiannis et al., 2012; Salomone and Roggero 2002; Soler et al., 2002; Stobbs et al., 2009). Most of these infections were found in the vicinity of tomato greenhouses. Weeds may play an important role in virus epidemiology by acting as virus reservoirs in crop-free period (Jorda et al., 2001; Córdoba et al., 2004).

PepMV host range is mainly restricted to plant species from the family Solanaceae, but it can also be found in weed species which were growing in or around tomato greenhouse.

A study on the presence of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 on alternative non-tomato host plants has been undertaken.

#### **B.8.1/01**

<sup>2</sup> EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2013. Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2013 update). EFSA Journal 2013;11(11):3449, 107 pp. doi:10.2903/j.efsa.2013.3449

**Reference:** K-MA 7.1/01

**Author(s); year:** Agüero (2017b).

**Title:** Study of the presence of *Pepino mosaic virus* (PepMV) on alternative and potential non-tomato host plants.

**Organisation:** Abiopep S.L.

**Report No:** ABP03/2017. (Unpublished report).

**Guidelines:** Guidelines are not available.

**GEP:** No. Research facilities.

#### Material and methods

A survey of weeds in the surroundings of a tomato greenhouse treated (V) with the formulation AbioProtect® (PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2) in July 2016 and in the surroundings of a tomato greenhouse not treated (NV) with the formulation was conducted on March 6<sup>th</sup>, 2017.

Each weed sample was taxonomically ascribed with the advised of an expert. 12 weeds belonging to 8 different families were sampled in the surrounding of greenhouse treated (V) and 10 weeds belonging to 8 different families were sampled in the surrounding of greenhouse not treated (NV).

Samples were also taken from the tomato plants inside both greenhouses, 8 tomato plants in each case.

The presence/absence of PepMV in the tomato samples was analysed by molecular hybridization. While in the weeds samples it was analysed by a PepMV test AgriStrip Kit (Bioreba AG, Reinach, Switzerland), based on antibodies against different isolates of the EU, CH2 and US1 genotypes or strains.

#### Findings

Analysis of tomato plants showed 100% infection with both EU and CH2 strain (mild isolate Abp1 and mild isolate Abp2) in plants treated with the preparation AbioProtect® and infection with the EU strain in 2 out of 8 plants and with the CH2 strain in 8 out of 8 plants in the greenhouse not treated.

Analysis of alternative and potential non-tomato host plants resulted in absence of PepMV in all analysed samples but one, corresponding to the species *Solanum nigrum*, which showed presence of PepMV. This plant was sampled in the surrounding of the non-treated greenhouse; no PepMV-infected weed was sampled in the surroundings of the treated greenhouse. None of the weeds sampled showed symptoms of PepMV infection.

#### Conclusion

- In this study PepMV was detected in only one weed sampled outside the non-treated greenhouse and in none of the weeds sampled outside the treated greenhouse.
- The risk of spread of PepMV infection from weeds surrounding tomato greenhouses treated with PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 is not higher than the risk of infection from weeds surrounding tomato greenhouses not treated according to this study.
- In this study vaccination of a tomato greenhouse with PepMV does not appear to affect the level of natural occurrence of the virus.

More data and detailed information is included in Document K-MA 7.1/01 (Agüero, 2017b).

All this information, together with the fact already mentioned that PepMV is widespread in Europe, indicates that introduction of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 in (high technology permanent greenhouse) tomato crops is therefore not expected to affect the level of natural occurrence of the virus. Without treatment, the crop will most probably be infected with natural occurring mild or aggressive isolates of PepMV.

#### **RMS Comments:**

The presence of Pepino mosaic virus (PepMV) in weeds surrounding tomato greenhouse treated (V) with the formulation AbioProtect® and not treated (NV) with the formulation was studied.

PepMV was not detected in weeds sampled in the surrounding of the tomato greenhouse treated with AbioProtect®. However, PepMV was detected in only one weed sampled in weeds growing next to tomato greenhouse that had not been treated with the formulation.

PepMV was detected in all the tomato plants sampled in both the vaccinated and the nonvaccinated greenhouse, the Chilean (CH2) strain of PepMV was detected in all the samples, while the European (EU) strain of PepMV was detected in all the samples from the vaccinated greenhouse and only in 2 out of 8 samples of the non-vaccinated greenhouse.

RMS has found some uncertainties regarding the methodology of the study:

RMS considered that the number of weeds sampled in the surrounding of tomato greenhouse was small: 12 weeds belonging to 8 different families of tomato greenhouses treated (V) and 10 weeds belonging to 8 different families of tomato greenhouse not treated.

The distance between the tomato greenhouse and the sampling was not indicated.

The date from the treatment to the sampling was not specified. RMS thought that weeds should have been sampling at different dates after the treatment with AbioProtect®.

The weeds samples were analysed by a PepMV test AgriStrip Kit (Bioreba AG, Reinach, Switzerland), based on antibodies against different isolates of the EU, CH2 and US1 genotypes or strains. In the case of the weed where PepMV was found, the genotype and the isolate was not checked.

Although, the RMS is not agree with the methodology of the study K-MA 7.1/01 (Agüero, 2017b), confirms that the vaccination of a tomato greenhouse with PepMV does not appear to affect the level of natural occurrence of the virus.

**The treatment of tomato plants with the Plant Protection Product AbioProtect® has not effect in the natural occurrence of the virus in weeds surrounding of tomato greenhouse.**

#### **B.8.1.1 Soil**

A study on the persistence of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 in the soil next to the plants treated with both isolates has been undertaken, the complete report is included in Document K-MP 6.2/05 (Prats, 2017b) and its summarized below.

##### **B 8.1.1/01**

**Reference:** K-MP 6.2/05

**Author(s); year:** Prats (2017b).

**Title:** Field study to evaluate the crop safety and the efficacy of the Plant Protection Product (PPP) AbioProtect®, and its components or agents (PPA1 and PPA2), for the control of PepMV in tomato crop (Southern Spain, 2016).

**Organisation:** Abiopep S.L.

**Report No:** ACEX1277/AB. (Unpublished report).

**Guidelines:** EPPO Guidelines PP 1/152(3), PP 1/1841(3), PP/135(3).

**GEP:** GEP certified by Agrocolor.

##### **Material and methods:**

The trial took place from November 14<sup>th</sup>, 2016 until June 8<sup>th</sup>, 2017

The persistency of the components of AbioProtect® (PepMV, EU strain, mild isolate Abp1, and PepMV, CH2 strain, mild isolate, Abp2) in soil was assessed by studying the presence of PepMV in samples of soil taken from Tr. 4 (tomato plants treated with AbioProtect®) and from Tr. 1 for comparison (control).

Soil samples were taken on 26/05/2017 from 2 depths (5 and 35 cm) from Tr.4 (AbioProtect®, containing PepMV, EU strain, mild isolate Abp1 and PepMV, CH2, mild isolate Abp2) with 3 replicates each depth. One sample was taken from Tr. 1 as control. An extract was prepared from soil samples with buffer (1:3 w/v) and the presence of PepMV was analyzed by a PepMV test AgriStrip Kit (Bioreba AG, Reinach, Switzerland), based on antibodies against different isolates of the EU, CH2 and US1 genotypes or strains. In addition, 3 plants were inoculated manually by rubbing the leaves of the plants, previously sprinkled with silicon carbide, with each replicate sample. On 7/06/2017 (12 days after inoculation) the plants were evaluated. Analysis of virus presence and assessments of PepMV symptoms were conducted. The analysis was performed by molecular hybridization

with PepMV RNA probe. 3 tomato plants were also inoculated with AbioProtect® as positive control, 3 plants with AbioProtect® added to soil extract from Tr.1 (control) as control of inoculation and 3 plants were left without inoculation.

#### Findings

Results of the samples from Tr. 4 (AbioProtect®) were negative; the analyses did not detect the presence of PepMV in the soil samples taken from Tr. 4 or in the plants inoculated with extracts from the soil samples taken from Tr. 4.

#### Conclusion

It can be concluded that the Plant Protection Product AbioProtect® (formulated with equivalent amounts of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2) has no persistency in the soil next to tomato plants treated with AbioProtect®. Therefore, there is no risk of PepMV infection from this soil.

#### **RMS Comments:**

The study was conducted to evaluate the efficacy of Prepotec® and AbioProtect®, and the components of AbioProtect® (Abp1 and Abp2) for the control of PepMV in tomato crop. A study to evaluate the persistence of AbioProtect® in soil was also performed.

In this section RMS will only evaluate the study of persistence of the Plant Protection Product AbioProtect® in soil.

The study concludes that the formulated is not persistence in soil.

**PepMV was not persistent in soil next to tomato plants treated with the Plant Protection Product AbioProtect®.**

#### **B 8.1.1/02**

**Reference:** K-MA 7.1.1/02

**Author(s); year:** Céspedes (2015)

**Title:** Evaluación de diferentes desinfectantes con y sin solarización para la desinfección de sacos de sustrato de fibra de coco de un cultivo de tomate inoculado con PepMV.

**Organisation:** Estación Experimental Las Palmerillas (El Ejido, Almería) Spain.

**Report:** Final Report on Project LPA/2015-23/S

**Guidelines:** Guidelines are not available.

**GEP:** GEP certified by Agrocolor.

Furthermore, a GEP study on the persistence of PepMV in hydroponic grow bags, failed to detect any viable PepMV on roots from plants infected with mild isolate Abp1 and mild isolate Abp2, 30 days after removal of the crop indicating that PepMV is not persistent in the substrate from tomatoes treated with PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 (details in Document K-MA 7.1.1/02, Céspedes, 2015a).

#### **RMS Comments:**

This study was conducted to evaluate the efficacy of different disinfectants, with or without solarization, on the inactivation of PepMV on the substrate (coconut fiber) where infected tomato crop was grown. The substrates had been inoculated with different PepMV viruses isolates: La Palma (aggressive isolate) CASI (mild isolate) and vaccine.

The disinfectants evaluated were: calcium hypochlorite, ozone, TERRA DIS (chlorine dioxide), HUGASAN- 50 (hydrogen peroxide + silver chloride), Metam sodium, Agrocelhone (dichloropropene + chloropicrin ). Each disinfectant was checked in 2 conditions: with plastic cover for solarization and without plastic cover.

The presence and infectivity of PepMV was studied in three different bioassays:

- The first one consists in inoculating the virus from the infected roots of the tomato plants in healthy tomato seedling.
- In the second one the inoculation is carried out with the remaining roots after the disinfection treatments.



- Finally, in the third bioassay tomato seedling were planting in the disinfected sacks.

The first bioassay had to be repeated due to problems with the greenhouse air conditioning.

The virus was not infective in any bioassays. Therefore, the effectiveness of the different treatments could not be evaluated. However, the virus was detected in the remained roots of tomato plants.

A Summary of this study should be submitted by the applicant.

Differences were not observed between the sacks inoculated with vaccinated plants and the other isolates.

This study could be considered additional information.

#### **B.8.1.1.1. Predicted Environmental concentrations in Soil (PECsoil)**

The initial PEC:  $PiEC_{soil} = D \cdot (1 - f_{int}) / 100 \cdot d \cdot \rho$

PiECsoil = Predicted Initial Environmental Concentration (mg Abioprotect®/kg soil);

D = dose (g/ha);

f<sub>int</sub> = crop interception (fraction);

d = depth (cm);

ρ = dry bulk density of the soil (g/cm<sup>3</sup>).

A dry bulk density of the soil of 1.5 g/cm<sup>3</sup> and a dose reaching the top 5 cm of the soil (d = 5 cm) is assumed.

Interception by tomatoes at BBCH 13 is 50%.

The maximum applied dose of AbioProtect® in the greenhouse is 8 L/ha, equal to a range from 51.2 to 512 g product/ha (>4x10<sup>12</sup> genome copies/ha).

**PECsoil initial = 0.34 mg Abioprotect®/kg soil**

Corresponding to >0.26x10<sup>3</sup> genome copies of PepMV/kg soil:

- **>0.13x10<sup>3</sup> genome copies of PepMV, EU strain, mild isolate Abp1/kg of soil, and**
- **>0.13x10<sup>3</sup> genome copies of PepMV, CH2 strain, mild isolate Abp2/kg of soil.**

### **|Water**

The virus is transmitted between plants most effectively via mechanical plant-to-plant contact, contact between equipment and tools and plants (Jones et al., 1980) and to a lesser extent via recirculation water (Schwarz et al., 2010). Mehle et al. (2014) confirms survival and transmission of PepMV in water. A study on the persistence of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 in the leachate from the plants treated with both isolates has been undertaken, the complete report is included in Document K-MP 6.2/04 (Prats, 2017a) and its summarized below.

#### **B 8.1.2/01**

**Reference:** K-MP 6.2/04

**Author(s); year:** Prats (2017a).

**Title:** Field study to evaluate the crop safety and the efficacy of the Plant Protection Product (PPP) AbioProtect®, and its components or agents (PPA1 and PPA2), for the control of PepMV in tomato crop (Southern Spain, 2016).

**Organisation:** Abiopep S.L.

**Report No:** ACEX1274/AB. (Unpublished report).

**Guidelines:** EPPO Guidelines PP 1/152(3), PP 1/1841(3), PP/135(3).

**GEP:** GEP certified by Agrocolor.

#### **Material and methods:**

The trial took place from September 6<sup>th</sup>, 2016 until March 24<sup>th</sup>, 2017

The persistency of the components of AbioProtect® (PepMV, EU strain, mild isolate Abp1, and PepMV, CH2 strain, mild isolate, Abp2) in water was assessed by studying the presence of PepMV in the leachate of Tr. 4 (tomato plants treated with AbioProtect®).

From the start of the trial the leachate from Tr. 4 (AbioProtect®, containing PepMV, EU strain, mild isolate Abp1 and PepMV, CH2, mild isolate Abp2) was collected. On 02/03/2017 a sample of this leachate (5 litres) was taken and preserved at 20°C. 5 tomato plants (BBCH: 18) were inoculated with the sample at 1, 3 and 10 days after the sample was taken (5 plants at each moment). 2 plants were inoculated by irrigation and 3 plants were inoculated manually by rubbing the leaves of the plants, previously sprinkled with silicon carbide, with the sample. On 24/03/2017 (21, 19 and 12 days after each inoculation) the plants were evaluated. Analysis of virus presence and assessments of PepMV symptoms were conducted. The analysis was performed by molecular hybridization with specific RNA probes. 2 tomato plants were also inoculated, one with PepMV aggressive EU isolate and one with PepMV aggressive CH2 isolate, and used as controls for the virus analysis.

#### Findings

None of the inoculated tomato plants showed symptoms associated with a PepMV infection.

The analysis did not detect the presence of PepMV in the plants inoculated with the leachate of Treatment 4. In the case of the tomato plants used as controls, the analysis detected the presence of PepMV.

#### Conclusion

It can be concluded that the Plant Protection Product AbioProtect® (formulated with equivalent amounts of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2) has no persistency in the leachate from tomato plants treated with AbioProtect®. Therefore, there is no risk of PepMV infection with this leachate.

#### **RMS Comments:**

The study was conducted to evaluate the efficacy of AbioProtect®, and its components (Abp1 and Abp2) for the control of PepMV in tomato crop. A study to evaluate the persistence of AbioProtect® in water was also performed.

In this section, RMS will only evaluate the study of persistence of the Plant Protection Product AbioProtect® in the leachate of tomato plants treated with AbioProtect®. PepMV was not detected in plants inoculated with the leachate from tomato plants vaccinated with AbioProtect®. The formulated product has not been found persistent in the leachate.

PepMV, EU strain mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 are plant viruses already naturally present on tomato plants in greenhouse today. The virus does not multiply outside its plant host, it only survives short periods outside the host cell since it is broken down by proteases, RNases and UV light. Persistence in water of the product Abioprotec has been evaluated in this GEP trial and found that PepMV was not persistent in the leachate from the tomato plants treated, concluding that there is no risk of infection from this leachate (Prats, 2017a). Furthermore, as viruses have no metabolism of their own are not able to produce secondary metabolites. Thus, the risk of the product Abioprotec to consumers is negligible and impact of water treatment processes on the active substance and its metabolites in water abstracted for drinking water is not foreseen.

The study concludes that the formulated Abioprotec is not persistence in the leachate from tomato plants.

**PepMV has not persistency in the leachate from tomato plants treated with the Plant Protection Product AbioProtect®.**

#### **B.8.1.2.1. Predited Environmental Concentrations in Surface Water (PEC<sub>sw</sub>)**

Predicted environmental concentration PEC for the worst-case scenario is estimated as follows:

Drift from a greenhouse is assumed to be 0.1%.

The maximum applied dose of AbioProtect® in the greenhouse is 8 L/ha, equal to a range from 51.2 to 512 g/ha ( $>4 \times 10^{12}$  genome copies/ha).

As a result, a maximum amount per application of 0.512 g AbioProtect®/ha (corresponding to  $5.12 \times 10^{-5}$  g AbioProtect®/m<sup>2</sup>,  $>4 \times 10^8$  genome copies of PepMV/m<sup>2</sup>) could be considered.

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:

**PECgw initial =  $17.06 \times 10^{-2}$  µg Abioprotect®/L water**

Corresponding to  $1.33 \times 10^6$  genome copies of PepMV/L water

- **$6.66 \times 10^6$  genome copies of PepMV, EU strain, mild isolate Abp1/L water, and**
- **$6.66 \times 10^6$  genome copies of PepMV, CH2 strain, mild isolate Abp2/L water.**

#### **RMS Comments:**

RMS agrees with PECsw proposed by the applicant has been calculated for high technology permanent greenhouse

On the other hand, regarding the interference of microorganism with methods of analysis for pathogens in drinking water, the EFSA<sup>34</sup> concluded that PepMV isolates VX1 and VC1 are related to other plant viruses commonly found in surface water and that it is unlikely to interfere with the analytical systems intended for bacteria. Therefore, no further information or data were requested regarding the potential interference of PepMV isolates VX1 and VC1 with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC.

**The Plant Protection Product Abioprotect® is unlikely to interfere with the analytical systems intended for bacteria in drinking water.**

#### **Air**

PepMV can only reproduce inside its host plants, it is not an airborne agent and it is a sap or mechanically transmitted virus. In the tomato cultures in greenhouses the release of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 mild isolate Abp2 to the environment through air is very limited. Even in the unlikely event that aerosols containing PepMV particles would be formed, exposure of the environment is not expected as the only air-exchange with the outside is located at the ventilation windows several meters above the plants. The virus does not survive long outside plant material and is broken down by UV light.

The spray application is done only once per production cycle and only inside the greenhouse or in a close facility near the greenhouse, so exposure to the air is extremely limited. Since the virus is degraded by UV light, virus particles in aerosols that might be formed during spraying will be deactivated very rapidly.

Exposure of the environment through air is thus considered insignificant.

**The Plant Protection Product Abioprotect® is unlikely to be release to the environment through air.**

#### **B.8.2. MOBILITY**

Given the information above, it is unlikely that PepMV will be mobile in the environment via soil, or air. As the virus can infect plants through circulation water in the greenhouse (Schwarz et al., 2010), the possibility that the virus can infect host plants outside the greenhouse via drainage water was assessed (see B 8.1.2) and found that PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2, have no persistency in the leachate from the tomato plants treated. Therefore, there is no risk of PepMV infection with this leachate. Besides, according to the results of the persistence in soil study there is no risk of PepMV spread from the soil or the substrate of the plants treated (see B 8.1.1).

Furthermore, as the more severe variants of PepMV are already widespread, and the above-mentioned characteristics for persistence and replication of the virus, the risk to the environment from a possible temporary increase in the natural background concentration of PepMV is expected to be negligible.

**The Plant Protection Product Abioprotect® is unlikely to be mobile in the environment via soil, water or air.**

<sup>3</sup> EFSA. (European Food Safety Authority), 2017a Peer review of the pesticide risk assessment of the active substance Mild *Pepino mosaic virus* isolate VX1. EFSA Journal 15:4650. DOI: doi:10.2903/j.efsa.2017.4650.

<sup>4</sup> EFSA. (European Food Safety Authority), 2017b Peer review of the pesticide risk assessment of the active substance Mild *Pepino mosaic virus* isolate VC1. EFSA Journal 15:4651. DOI: doi:10.2903/j.efsa.2017.4651.



### B.8.3. REFERENCES RELIED ON

The applicant has provided summaries and results of the scientific peer-review open literature, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier. There is no information whether this literature search was performed in accordance to the provisions of the EFSA Guidance “Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) 1107/2009”.

The literature search provided was conducted in accordance to the guidelines set up in document European Food Safety Authority; Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p.1-50), (EFSA Journal 2011; 9(2):2092. [49pp.]. doi:10.2903/j.efsa.2011.209)2. Full details and justification of how the literature search was performed could be found in Document K-MA 5.2.5 Hernando 2017.

Reference list ordered by data point

Data point	Author(s)	Year	Title Source (where different from company) Company, Report Number GLP or GEP status Published or not	Data Protection claimed Y/N	Justification if data protection is claimed	Owner
B 8	Aguilar J., Hernandez-Gallardo M., Cenis J., Lacasa A., Aranda M.	2002	Complete sequence of the <i>Pepino mosaic virus</i> RNA genome. Archives of virology 147:2009-2015. No GLP Published	N		
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B 8.1.1 <b>B.8.1.1/01</b> (K-MP 6.2/05)	Prats C.	2017b	Field study to evaluate the crop safety and the efficacy of the Plant Protection Product (PPP) AbioProtect®, and its components or agents (PPA1 and PPA2), for the control of PepMV in tomato crop (Southeast Spain, 2016). Agrocolor S.L., Spain. Report number: ACEX/1277/AB GEP Not published	Y	Proprietary information	Abiopep S.L.
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