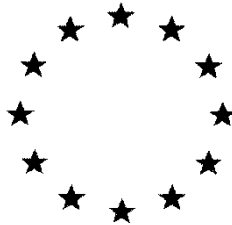


European Commission



**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
Active organism data**

**Volume 3 – Annex B.10 Summary and
evaluation of environmental impact**

Rapporteur Member State: Spain

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B.10. SUMMARY AND EVALUATION OF ENVIRONMENTAL IMPACT

B.10.1. DISTRIBUTION AND FATE IN THE ENVIRONMENT

PepMV presence is described in 19 countries in Europe and is included in the European and Mediterranean Plant Protection Organization EPPO A2 list of pest recommended for regulation as quarantine pest. Of the different PepMV genotypes that can be distinguished the European (EU) genotype was the first to appear in Europe, although the Chilean (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). 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.

PepMV is very efficiently transmitted mechanically in tomato plants 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). 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).

PepMV host range is mainly restricted to plant species from the family Solanacea. However, infections, symptomless or with mild symptoms of PepMV have been observed in weed species (Papayiannis et al., 2012; Soler et al., 2002; Stobbs et al., 2009, and others). 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).

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 (please refer to Document K-MA 7.1/01, Agüero, 2017b). This study has shown that the risk of spread of PepMV infection from weeds surrounding tomato greenhouses treated with PepMV is not higher than the risk of infection from weeds surrounding tomato greenhouses not treated with PepMV and treatment (or vaccination) of tomato plants in a greenhouse with PepMV does not appear to affect the level of natural occurrence of the virus. As PepMV is widespread in Europe introduction of PepMV, EU strain, mild isolate Abp1 and/or PepMV, CH2 strain, mild isolate Abp2 in greenhouse (protected) tomato crops is therefore not expected to affect the level of natural occurrence of the virus.

It has been described that PepMV can be spread from plant to plant by recirculating water (Schwarz et al., 2010) and that PepMV can survive and be transmitted in water (Mehle et al., 2014), implying that PepMV might be persistent to a certain extent outside its host cell. Three GEP studies to assess the risk of PepMV transmission through water, through soil and from the substrates of tomato plants in greenhouses treated with PepMV have been conducted and the results of those GEP studies (please refer to Document K-MP 6.2/04, Prats, 2017a; Document K-MP 6.2/05, Prats, 2017b; Document K-MA 7.1.1/02, Céspedes, 2015a), have shown that there is no risk of PepMV infection from the leachate or from the soil or substrate of the plants treated.

Regarding the interference of microorganism with methods of analysis for pathogens in drinking water, the EFSA¹² 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. Therefore, this principle should be applied for PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2.

¹ 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.

² 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.

According to the information and data provided the use of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 in greenhouse (protected) tomato crops is not expected to have any relevant effect on the distribution or fate in the environment of PepMV.

B.10.2. NON TARGET SPECIES AND POPULATIONS AT RISKS

PepMV belongs to the *Alphaflexiviridae* family order *Tymovirales* that include plant viruses only. For this virus family a qualified presumption of safety has been found at the European level (EFSA BIOHAZ Panel, 2013)³. 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).

Plant pathogenic viruses can usually only replicate in living plant cells and the virus can usually only be produced in plants. Therefore, plant viruses are generally considered to be pathogenic towards plant species only and not towards other organisms, like humans. Human exposure to plant pathogenic viruses is enormous and human illnesses caused by plant pathogenic viruses have not been described. A focussed search for scientific peer review literature on pathogenicity of plant viruses to animals or humans or other non-target organisms has been conducted and is included (Document K-MA 5.2.5, Hernando, 2017). Such search has not retrieved any relevant summary report related to any effect of PepMV, Potexvirus or other members of the family *Alphaflexiviridae* on humans or mammals, on fish, or any other aquatic organisms, on fresh water invertebrates or in algae growth or any aquatic plants other than algae. The results of the search for scientific peer review literature supports the general assumption that plant viruses are considered to be pathogenic to plant species only and not towards other organisms. For other plant virus families, such search has pointed out that some authors have reported the presence of RNA from pepper mild mottle virus (PMMoV) and pepper mottle virus (PMV) in human feces (Colson *et al.*, 2010; Zhang *et al.*, 2006) and in human serum (Tobacco mosaic virus, TMV) (Liu *et al.*, 2013). However, no information or cases on multiplication of these or other plant viruses in vertebrate or human tissues has been reported in the scientific literature.

Two GLP studies on the effect of PepMV on algae growth and on aquatic plants other than algae have been conducted to assess the potential effect of the virus on those non-target organisms. Both studies (Documents K-MA 8.2.3/01, Schuster, 2017a, and K-MA 8.2.4/01, Schuster, 2017b) have shown that there is no risk to algae or to aquatic plants other than algae of the use of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 in greenhouse (protected) tomato crops.

Regarding other non-target organisms such as bees or other arthropods, earthworms and non-target soil microorganisms the focussed search for scientific peer review literature included (Document K-MA 5.2.5, Hernando, 2017), has retrieved documents showing that bumblebees can transmit PepMV (Shipp *et al.*, 2008; Stobbs *et al.*, 2009; Stobbs and Greig, 2014); however, a specific PepMV-bumblebee vector relation does not appear to exist. These publications do not mention any adverse effects on bumblebees and there were not found other reports on negative effects of PepMV on bumblebees. Regarding other arthropods the possibility that PepMV could be transmitted by whiteflies has been studied without reporting any negative effect on the insect (Noël *et al.*, 2014). It has been reported that PepMV can also be transmitted by the soil fungus *Olpidium virulentus* (Alfaro-Fernández *et al.*, 2010) without describing any negative effect on the soil fungus. All this data supports the general assumption that plant pathogenic viruses are only pathogenic to their host plants and that PepMV does not have any effect on non-target organisms.

Besides, the risk to birds, fish, aquatic invertebrates, bees and other non-target arthropods, earthworms and soil microorganisms of the use of PepMV (mild isolates VX1 and VC1) in greenhouses was concluded as low by the European Food Safety Authority (EFSA). EFSA also concluded that the risk from the representative use of those PepMV isolates to algae and aquatic plants is low (EFSA)^{1,2}.

Therefore, it could be concluded that the use of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 in greenhouse (protected) tomato crops is not expected to have any relevant effect on non-target species and that there are no populations at risk of its use.

³ 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.

B.10.3. PRECAUTIONS NECESSARY TO AVOID OR MINIMIZE CONTAMINATION OF THE ENVIRONMENT

PepMV is widespread in Europe, there is no higher risk of PepMV infection from weeds surrounding tomato greenhouses treated with PepMV than from those surrounding tomato greenhouses not treated, the risk of PepMV infection from the leachate of the tomato plants treated with PepMV, or from the substrate or soil of the plants treated is negligible. Besides PepMV has no effect on animals or humans, or any other non-target organisms or species. Introduction of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 in greenhouse (protected) tomato crops is not expected to affect the level of natural occurrence of the virus, nor the distribution or fate on the environment of PepMV or have any relevant effect on non-target species and that there are no populations at risk of its use. Identification of precautions necessary to avoid or minimize contamination of the environment is not necessary. Nonetheless the formulation consisting of PepMV, EU strain, mild isolate Abp1 and PepMV, CH2 strain, mild isolate Abp2 would always be applied by Abiopep own trained and qualified personnel, would never be for sale to be applied by farmers or third parties. Application would always be done inside the greenhouse or in a close facility near it, never in the nursery, when the tomato plants have 3-5 leaves (BBCH 13-15) minimizing its spread to the environment.

B.10.4. REFERENCES RELIED ON

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 10.1 B 10.2	Agrios	2005	Plant diseases caused by virus. Plant Pathology. Fifth Edition. Chapter 14, pp 722-820 (pp731) Elsevier Academia Press No GLP Published	N		
B 10.1 K-MA 7.1/01	Agüero J.	2017b	Study of the presence of Pepino mosaic virus (PepMV) on alternative and potential non-tomato host plants. Abiopep S.L., Spain Report number: ABP03/2017 No GLP Not published	N		Abiopep S.L.
B 10.1 K-MA 7.1.1/02	Céspedes A.	2015	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. Estación Experimental Las Palmerillas (El Ejido, Almería), Spain. Fundación Cajamar Report number: LPA/2014-23/S GEP Not published	N		
B 10.1	Córdoba M.C., Martínez-Priego L., Jordá C	2004	New natural hosts of <i>Pepino mosaic virus</i> in Spain. Plant Disease 88:906. DOI: 10.1094/PDIS.2004.88.8.906D No GLP Published	N		
B 10.1	Gómez P. Sempere R., Elena S.F. Aranda M.A.	2009	Mixed infections of <i>Pepino mosaic virus</i> strains modulate the evolutionary dynamics of this emergent virus. Journal of Virology 83:12378-12387 No GLP Published	N		
B 10.1	Hanssen	2010	Pepino mosaic virus: a successful pathogen that	N		

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
	I.M., Thomma B.P.H.J.		rapidly evolved from emerging to endemic in tomato crops. Molecular Plant Pathology 11:179-189. DOI: 10.1111/j.1364-3703.2009.00600.x. No GLP Published			
B 10.1	Jordá C., Perez A.L., Martínez- Culebras P., Abad P., Lacasa A., Guerrero M.	2001	First report of <i>Pepino mosaic virus</i> on tomato in Spain. Plant Disease 85:1292 No GLP Published	N		
B 10.1	Ling K.S., Li R., Bledsoe M.	2013	<i>Pepino mosaic virus</i> genotype shift in North America and development of a loop-mediated isothermal amplification for rapid genotype identification. Virology Journal 10. DOI: 10.1186/1743-422x-10-117 No GLP Published	N		
B 10.1	Mehle N., Gutiérrez- Aguirre I., Prezelj N., Delić D., Vidic U., Ravnikar M.	2014	Survival and transmission of <i>Potato virus Y</i> , <i>Pepino mosaic virus</i> , and Potato Spindle Tuber Viroid in Water. Applied and Environmental Microbiology 80:1455-1462. DOI: 10.1128/aem.03349-13 No GLP Published	N		
B 10.1	Papayiannis L.C., Kokkinos C.D., Alfaro- Fernández A.	2012	Detection, characterization and host range studies of <i>Pepino mosaic virus</i> in Cyprus. European Journal of Plant Pathology 132:1-7. DOI: 10.1007/s10658-011-9854-7 No GLP Published	N		
B 10.1 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. Report number: ACEX/1277/AB GEP Not published	Y	Proprietary information	Abiopep S.L.
B 10.1 K-MP 6.2/04	Prats C.	2017a	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). Agrocolor S.L. Report Number ACEX/1274/AB GEP Not published	Y	Proprietary information	Abiopep S.L.
B 10.1	Schwarz D., Beuch U., Bandte M., Fakhro A., Büttner C., Obermeier C.	2010	Spread and interaction of <i>Pepino mosaic virus</i> (PepMV) and <i>Pythium aphanidermatum</i> in a closed nutrient solution recirculation system: effects on tomato growth and yield. Plant Pathology 59:443-452. DOI: 10.1111/j.1365-3059.2009.02229.x No GLP Published	N		
B 10.1	Soler S., Prohens J., Díez M.J., Nuez F.	2002	Natural occurrence of <i>Pepino mosaic virus</i> in <i>Lycopersicon</i> species in central and southern Peru. Journal of Phytopathology 150:49-53. DOI: 10.1046/j.1439-0434.2002.00712.x. No GLP Published	N		

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 10.1	Spence N.J., Basham J., Mumford R.A., Hayman G., Edmondson R., Jones D.R.	2006	Effect of <i>Pepino mosaic virus</i> on the yield and quality of glasshouse-grown tomatoes in the UK. Plant Pathology 55:595-606. DOI: 10.1111/j.1365-3059.2006.01406.x. No GLP Published	N		
B 10.1 B 10.2	Stobbs L., Greig N., Weaver S., Shipp L., Ferguson G	2009	The potential role of native weed species and bumble bees (<i>Bombus impatiens</i>) on the epidemiology of <i>Pepino mosaic virus</i> . Canadian Journal of Plant Pathology 31:254-261 No GLP Published	N		
B 10.1	Van der Vlugt R.	2009	<i>Pepino mosaic virus</i> . Hellenic Plant Protection Journal 2:47-56 No GLP Published	N		
B 10.1	Wright D., Mumford R.	1999	<i>Pepino mosaic Potexvirus</i> (PepMV): first records in tomato in the United Kingdom Central Science Laboratory. No GLP Published	N		
B 10.2	Colson P., Richet H., Desnues C., Balique F., Moal V., Grob J.-J., Berbis P., Lecoq H., Harlé J.-R., Berland Y	2010	<i>Pepper mild mottle virus</i> , a plant virus associated with specific immune responses, fever, abdominal pains, and pruritus in humans. PloS one 5:e10041. No GLP Published	N		
B 10.2	Alfaro- Fernández A., Del Carmen Córdoba- Sellés M., Herrera- Vásquez José Á., Cebrián M.d.C., Jordá C.	2010	Transmission of <i>Pepino mosaic virus</i> by the fungal vector <i>Olpidium virulentus</i> . Journal of Phytopathology 158:217-226. DOI: 10.1111/j.1439-0434.2009.01605.x No GLP Published	N		
B 10.2 K-MA 5.2.5	Hernando Y.	2017	Focused search of scientific peer review literature for <i>Pepino mosaic virus</i> . CEBAS-CSIC, Murcia. Spain No GLP Not published	N		
B 10.2	Liu R., Vaishnav R.A., Roberts A.M., Friedland R.P.	2013	Humans have antibodies against a plant virus: evidence from <i>Tobacco mosaic virus</i> . PloS one 8:e60621. No GLP Published	N		
B 10.2	Noël P., Hance T., Bragard C.	2014	Transmission of the <i>Pepino mosaic virus</i> by whitefly. European Journal of Plant Pathology 138:23-27. DOI: 10.1007/s10658-013-0313-5. No GLP Published	N		
B 10.2 K-MA 8.2.3/01	Schuster A.K.	2017a	AbioProtect® and its components PepMV-Abp1 and PepMV-Abp2: Toxicity to the Single Cell Green Alga <i>Pseudokirchneriella subcapitata</i> Hindák under Laboratory Conditions.	Y	Proprietary information	Abiopep S.L.

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
			Eurofins Agrosience Services EcoChem. Report number: S17-03474 GLP Not published			
B 10.2 K-MA 8.2.4/01	Schuster A.K.	2017b	AbioProtect® and its components PepMV-Abp1 and PepMV-Abp2: Toxicity to the Duckweed <i>Lemna gibba</i> under Laboratory Conditions (Acute Test – Static). Report number: S17-03475 GLP Not published	Y	Proprietary information	Abiopep S.L.
B 10.2	Shipp J.L., Buitenhuis R., Stobbs L., Wang K., Kim W.S., Ferguson G	2008	Vectoring of <i>Pepino mosaic virus</i> by bumble-bees in tomato greenhouses. <i>Annals of Applied Biology</i> 153:149-155. DOI: 10.1111/j.1744-7348.2008.00245.x No GLP Published	N		
B 10.2	Stobbs L., Greig N., Weaver S., Shipp L., Ferguson G	2009	The potential role of native weed species and bumble bees (<i>Bombus impatiens</i>) on the epidemiology of <i>Pepino mosaic virus</i> . <i>Canadian Journal of Plant Pathology</i> 31:254-261 No GLP Published	N		
B 10.2	Stobbs L.W., Greig N.	2014	First report of bumblebee (<i>Bombus impatiens</i> Cresson) transmission of <i>Pepino mosaic virus</i> between tomato (<i>Solanum lycopersicum</i> L.) and perennial climbing nightshade (<i>Solanum dulcamara</i> L.). <i>Canadian Journal of Plant Pathology</i> 36:529-533. DOI: 10.1080/07060661.2014.954625 No GLP Published	N		
B 10.2	Zhang T., Breitbart M., Lee W.H., Run J.-Q., Wei C.L., Soh S.W.L., Hibberd M.L., Liu E.T., Rohwer F., Ruan Y.	2006	RNA viral community in human feces: prevalence of plant pathogenic viruses. <i>PLoS biology</i> 4:e3. No GLP Published	N		