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CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance *Pepino mosaic* virus strain CH2 isolate 1906[1]

European Food Safety Authority[2]

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ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Belgium for the pesticide active substance *Pepino mosaic* virus strain CH2 isolate 1906, and the assessment of the application to include *Pepino mosaic* virus strain CH2 isolate 1906 in Annex IV of Regulation (EC) No 396/2005, are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative use of *Pepino mosaic* virus strain CH2 isolate 1906 as a virus inoculation for cross protection of tomatoes under glasshouse application. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed.

KEY WORDS

Pepino mosaic virus strain CH2 isolate 1906, peer review, risk assessment, pesticide, virus inoculation, cross protection

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SUMMARY

Pepino mosaic virus strain CH2 isolate 1906 is a new active substance for which in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (hereinafter referred to as 'the Regulation'), the rapporteur Member State (RMS) Belgium received an application from De Ceuster NV on 30 July 2012 for approval. In accordance with Article 8(1)(g) of the Regulation, De Ceuster NV submitted an application to include *Pepino mosaic* virus strain CH2 isolate 1906 in Annex IV of Regulation (EC) No 396/2005. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 10 January 2013.

The RMS provided its initial evaluation of the dossier on *Pepino mosaic* virus strain CH2 isolate 1906 in the Draft Assessment Report (DAR), which was received by EFSA on 8 January 2014. The DAR included a proposal to include *Pepino mosaic* virus strain CH2 isolate 1906 in Annex IV of Regulation (EC) No 396/2005. The peer review was initiated on 27 January 2014 by dispatching the DAR for consultation of the Member States and the applicant De Ceuster NV.

Following consideration of the comments received on the DAR, it was concluded that additional information should be requested from the applicant, and that there was no need to conduct an expert consultation.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether *Pepino mosaic* virus strain CH2 isolate 1906 can be expected to meet the approval criteria provided for in Article 4 of the Regulation taking into consideration recital (10) of the Regulation and give a view concerning the application to include *Pepino mosaic* virus strain CH2 isolate 1906 in Annex IV of Regulation (EC) No 396/2005. The conclusions laid down in this report were reached on the basis of the evaluation of the representative use of *Pepino mosaic* virus strain CH2 isolate 1906 as a virus inoculation for cross protection of tomatoes under glasshouse application, as proposed by the applicant. Full details of the representative use can be found in Appendix A to this report.

A data gap was identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites.

Additional trials are required to confirm the efficacy of *Pepino mosaic* virus strain CH2 isolate 1906 when used according to the proposed GAP.

In the area of identity of the microorganism/biological properties/physical and technical properties and methods of analysis, no data gaps were identified.

In the area of mammalian toxicology, a data gap was set for the assessment of the pathogenicity of coliforms found in the analysed batches.

The consumer risk assessment can be finalised and a quantitative risk assessment is not necessary. EFSA would therefore recommend the inclusion of *Pepino mosaic* virus strain CH2 isolate 1906 in Annex IV of Regulation (EC) No 396/2005, providing that it could be guaranteed that the active substance can be produced free of potential microbial contaminants that could be pathogenic for humans.

A formal data gap has been identified for evidence that the studies not published in scientific peer review journals or performed under GLP, have been performed in an officially recognised testing facility or organisation satisfying at least the requirements under points 2.2 and 2.3 of the introduction of the Annex to Commission Regulation (EU) No 545/2011 in order to fully support the environmental risk assessment with respect to the use in soil greenhouses (no hydroponic cultivation).

In the area of ecotoxicology, a data gap for a risk assessment for algae and aquatic plants was identified.

TABLE OF CONTENTS

BACKGROUND

Regulation (EC) No 1107/2009 of the European Parliament and of the Council[3] (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure and conditions for approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant(s) for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation where appropriate.

In accordance with Article 12 of the Regulation, EFSA is required to adopt a conclusion on whether an active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation (also taking into consideration recital (10) of the Regulation) within 120 days from the end of the period provided for the submission of written comments, subject to an extension of 30 days where an expert consultation is necessary, and a further extension of up to 150 days where additional information is required to be submitted by the applicant(s) in accordance with Article 12(3).

Pepino mosaic virus strain CH2 isolate 1906 is a new active substance for which in accordance with Article 7 of the Regulation, the rapporteur Member State (RMS) Belgium (hereinafter referred to as the 'RMS') received an application from De Ceuster NV on 30 July 2012 for approval of the active substance *Pepino mosaic* virus strain CH2 isolate 1906. In accordance with Article 8(1)(g) of the Regulation, De Ceuster NV submitted an application to include *Pepino mosaic* virus strain CH2 isolate 1906 in Annex IV of Regulation (EC) No 396/2005[4] as an active substance for which no MRLs are required. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 10 January 2013.

The RMS provided its initial evaluation of the dossier on *Pepino mosaic* virus strain CH2 isolate 1906 in the DAR, which was received by EFSA on 8 January 2014 (Belgium, 2014a). The DAR included a proposal to include *Pepino mosaic* virus strain CH2 isolate 1906 in Annex IV of Regulation (EC) No 396/2005, in accordance with Article 11(2) of the Regulation. The peer review was initiated on 27 January 2014 by dispatching the DAR to the Member States and the applicant De Ceuster NV, for consultation and comments. EFSA also provided comments. In addition, EFSA conducted a public consultation on the DAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 12(3) of the Regulation were considered in a telephone conference between EFSA, the RMS, and the European Commission on 19 May 2014. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicant, and that there was no need to conduct an expert consultation.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, were compiled by EFSA in the format of an Evaluation Table.

[3] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table were reported in the final column of the Evaluation Table.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether *Pepino mosaic* virus strain CH2 isolate 1906 can be expected to meet the approval criteria provided for in Article 4 of the Regulation taking into consideration recital (10) of the Regulation and give a view concerning the application to include *Pepino mosaic* virus strain CH2 isolate 1906 in Annex IV of Regulation (EC) No 396/2005. A final consultation on the conclusions arising from the peer review of the risk assessment and on the proposal to include *Pepino mosaic* virus strain CH2 isolate 1906 in Annex IV of Regulation (EC) No 396/2005 took place with Member States via a written procedure in December 2014.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative use of *Pepino mosaic* virus strain CH2 isolate 1906 as a virus inoculation for cross protection of tomatoes under glasshouse application as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A.

In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2015) comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the comments received on the DAR,
- the Reporting Table (20 May 2014),
- the Evaluation Table (5 December 2014),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its final addendum (compiled version of November 2014 containing all revisions to the DAR (Belgium, 2014b)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

THE IDENTITY OF THE MICROORGANISM AND THE PROPERTIES OF THE FORMULATED PRODUCT

Pepino mosaic virus isolate CH2 isolate 1906 is deposited in GenBank, under accession number JN835466 and it is a wild-type avirulent strain isolated from a commercial crop of tomatoes in Belgium.

The representative formulated product for the evaluation is 'PMV-01', a suspension concentrate (SC), homogenised filtered tomato leaves, containing minimum 5 x 10^5 viral genome copies per µL.

The representative uses evaluated comprise applications by low-volume spraying of tomato seedlings as an elicitor to provide protection against the severe strain of *Pepino mosaic* virus. Full details of the GAP can be found in the list of end points in Appendix A.

A data gap has been identified for a search of the scientific peer-reviewed 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 dossier, to be conducted and reported in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011). The literature search provided does not comply with the EFSA guidance document.

The recommendations of the guidance document SANCO/10054/2013-rev. 3 (European Commission, 2013) have been considered for the assessment of the effectiveness of the active substance. Insufficient information was reported in the DAR (Belgium, 2014a) to conclude that the use of the *Pepino mosaic* virus strain CH2, isolate 1906 according to the proposed GAP results in an acceptable efficacy. Additional efficacy trials are needed.

CONCLUSIONS OF THE EVALUATION

1. Identity of the microorganism/biological properties/physical and technical properties and methods of analysis

Pepino mosaic virus belongs to the family *Alphaflexiviridae*, genus *potexvirus*.

Pepino mosaic virus strain CH2 isolate 1906 can be differentiated from virulent strains using TaqMan real-time quantitative reverse transcription PCR. This method is also used for quantification.

The technical concentrate is produced as a filtered tomato leaf homogenate, which is also the plant protection product. The microbial contamination complied with the OECD position paper (OECD, 2011) except for total coliforms and this issue is considered further in section 2.

Pepino mosaic virus is closely related to the plant pathogens *Narcissus mosaic* virus (NMV), *Scallion* virus X (SVX), *Cymbidium mosaic* virus (CymMV) and *Potato aucuba mosaic* virus (PAMV). It is not pathogenic to humans or animals.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity of the microorganism/biological properties/physical and technical properties of the representative formulation; however it should be mentioned on the label that the formulation can be stored at maximum of 4 ^{o}C for 3 weeks.

2. Mammalian toxicity

With regard to the potential microbial contaminants that could be pathogenic for humans, the performed 5 batch analysis revealed the presence of total coliforms for 3 out of the 5 batches exceeding the limits. As a contamination by faecal pathogens (other than *E. Coli*, which was not

found) could not be excluded, the assessment of the pathogenicity of the coliforms should be provided (data gap).

As all other viruses, also *Pepino mosaic* virus does not produce antimicrobial substances, toxins or secondary metabolites and cannot become resistant to antibiotics or spread resistance.

As a default for the microorganisms the following warning phrase is applicable for reactions by inhalation as well as by dermal exposure: "Microorganisms may have the potential to provoke sensitising reactions". All the Tier I studies including a recently submitted *in vitro* study on human cells indicated that *Pepino mosaic* virus is devoid of any potential of toxicity, infectivity and pathogenicity. An *in vitro* study to provide information on the ability of viral pest control agents to infect, replicate in, transform or cause toxicity in mammals was submitted after the commenting phase: the results indicate that *Pepino mosaic* virus did not multiply in human alveolar epithelial cell type 2 A549; it is also unlikely that the virus entered the cells, as shown by the significant decrease in the viral concentration.

Considering all the available information, it is not necessary to derive reference values for *Pepino mosaic* virus, as well as no quantitative operator, worker, resident and bystander risk assessment is needed.

3. Residues

As this virus is not pathogenic to humans, and will not produce any toxins, it can be concluded that the consumer risk assessment is not needed. A quantitative risk assessment is not necessary. Furthermore, since a qualified presumption of safety was concluded to be applicable to alphaflex viruses such as *Pepino mosaic virus* strain CH2, isolate 1906 (EFSA BIOHAZ Panel, 2013), EFSA would recommend inclusion in Annex IV of Regulation (EC) No 396/2005, provided that it could be guaranteed that the active substance can be produced free of potential microbial contaminants that could be pathogenic for humans.

4. Environmental fate and behaviour

4.1. Fate and behaviour in the environment of the microorganism

Information on persistence and multiplication of *Pepino mosaic* virus strain CH2, isolate 1906 in soil is not needed for those situations when the product is used in high-technology greenhouses with hydroponic culture (EFSA PPR Panel, 2010). However, investigation of the fate and behaviour in soil is relevant for greenhouses with cultivation in soil. The fate and behaviour (persistence and mobility) of *Pepino mosaic* virus strain CH2, isolate 1906 in soil was investigated in one laboratory experiment and in one greenhouse experiment. In the laboratory experiment at 4 ^{o}C and 20 ^{o}C a stable period of 14 d for the viral concentration was observed followed by a steady decline. The virus remained present up to a period of 31 d (at 20 ^{o}C) and up 52 d (at 4 ^{o}C). Furthermore, it was demonstrated that phosphate buffer suspension from the soils stored at 4 ^{o}C (during 3 d, 7 d and 14 d) were unable to infect tomato plants. Samples from a greenhouse treated with the formulation 'PMV-01' revealed that no viral particles are detectable eight months after application. Therefore, it may be concluded that "background levels" (assuming those not causing infection to plants) will be recovered in soils of treated crops well within the one year period after application. The studies as described are performed with high quality state of the art methodology and are well reported. However, a formal data gap has been identified for evidence that the studies not published in scientific peer review journals or performed under GLP, have been performed in an officially recognised testing facility or organization satisfying at least the requirements under points 2.2 and 2.3 of the introduction of the Annex to Commission Regulation (EU) No 545/2011 (as required by when the GLP condition cannot be satisfied; derogation specific for microbial active substances including viruses). This data gap is identified in order to fully support the environmental risk assessment with respect to the use in soil greenhouses (no hydroponic cultivation). Worst case PEC soil was calculated and reported in the DAR and Appendix A.

Contamination of surface water through drainage water by *Pepino mosaic* virus strain CH2, isolate 1906 can be excluded when the product is used in high-technology greenhouses with hydroponic culture and water recirculation with disinfection systems in place (eg. UV treatment). However, contamination through aerosols or drainage in low-technology greenhouses cannot be excluded. Fate and behaviour (persistence and mobility) of *Pepino mosaic* virus strain CH2, isolate 1906 in surface was investigated in one study in a laboratory experiment by application of the virus (at a rate 7 orders of magnitude higher than the calculated worst case PEC SW) to distilled water and maintained at 4 °C and 20 °C. In this experiment the *Pepino mosaic* virus strain CH2, isolate 1906 was present for a period of 31 d (at 20 °C) and 90 d (at 4 °C). However, samples stored at 20 °C for 3 d or more and samples stored at 4 °C for 90 d or more were not able to infect tomato plants. The studies as described are performed with high quality state of the art methodology and are well reported. However, a formal data gap has been identified for evidence that the studies not published in scientific peer review journals or performed under GLP, have been performed in an officially recognised testing facility or organization satisfying at least the requirements under points 2.2 and 2.3 of the introduction of the Annex to Commission Regulation (EU) No 545/2011 (as required when the GLP condition cannot be satisfied; derogation specific for microbial active substances including viruses). This data gap is identified in order to fully support the environmental risk assessment with respect to use in soil greenhouses (no hydroponic cultivation). Worst case PEC surface water based on an assumed 0.2 % emission was calculated and reported in the DAR and Appendix A.

No information has been provided in relation to potential interference of *Pepino mosaic* virus strain CH2, isolate 1906 with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC[5]. This is a specific decision-making criterion for the authorisation of plant protection products containing microorganisms (see specific Annex VI decision-making criteria in Directive 2005/25/EC[6]). However, as a virus, *Pepino mosaic* virus strain CH2, isolate 1906 is related to other plant viruses commonly found in surface water and unlikely to interfere with the analytical systems intended for bacteria. Therefore, no further information or data have been requested.

No information has been provided on the potential transfer of genetic material from *Pepino mosaic* virus strain CH2, isolate 1906 to other organisms. However, for *Pepino mosaic* virus strain CH2, isolate 1906 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 (EFSA BIOHAZ Panel, 2013).

It is considered that no further information on potential groundwater contamination by *Pepino mosaic* virus strain CH2, isolate 1906 is required at EU level since a qualified presumption of safety has been found to be applicable to alphaflex viruses such as *Pepino mosaic* virus strain CH2, isolate 1906 (EFSA BIOHAZ Panel, 2013).

4.2. Fate and behaviour in the environment of any relevant metabolite formed by the microorganism under relevant environmental conditions

Virus metabolites cannot be formed in environmental matrices. Viruses do not produce metabolites, they can only modify host cell metabolism, as they self-replicate within host organisms. The information available on the metabolism changes in cells infected by *Pepino mosaic* virus strain CH2, isolate 1906 does not suggest the production of metabolites that could be of relevance to human and animal health. It is considered that no further information is required at EU level since a qualified presumption of safety has been found to be applicable to alphaflex viruses such as *Pepino mosaic* virus strain CH2, isolate 1906 (EFSA BIOHAZ Panel, 2013).

[5] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.98, p.32.

[6] Council Directive 2005/25/EC of 14 March 2005 amending Annex VI to Directive 91/414/EEC as regards plant protection products containing micro-organisms. OJ L 90, 8.4.2005, p.1-34.

5. Ecotoxicology

No specific data on infectiveness or pathogenicity were available for the ecotoxicological assessments. However, some data on potential transmission of the virus were available in the dossier (in the section for fate and behaviour in the environment of the microorganism).

Pepino mosaic virus strain CH2, isolate 1906 is a naturally occurring plant virus strain. Its host plants are mainly from the *Solanaceae* family. As indicated in section 4, for *Pepino mosaic* virus 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 (see also section 2). Therefore, even if the virus is released outside the greenhouse, it will unlikely infect the wild fauna or communities of microorganisms. On the basis of this information and considering that the representative use is a greenhouse use, the risk to birds and mammals, fish, aquatic invertebrates, honey bees, non-target arthropods, soil micro- and macroorganisms was concluded as low. Some information was available on bumble bees from a literature study where bumble bees were used as vectoring agent. This study indicated no visible effects on bumble bee colonies after two weeks foraging on treated crops. The exposure of the bees was proven by isolating the virus from worker bees.

Considering that the representative use is a greenhouse use, the exposure of non-target terrestrial plants is generally considered as limited. However, some information and a study was available that indicated the presence of the virus in different plant species around the greenhouses. Information on the virulence of *Pepino mosaic* virus in these contaminated plants and crops was also available. This confirmed that the host-range of the virus is mainly restricted to *Solanaceae*. However, samples from a wide range of weeds outside the greenhouses were also found positive in diagnostic tests. In non-*Solanaceae* plants, the infection appeared latent, without overt symptoms. Therefore it was concluded that the risk from non-*Solanaceae* plants serving as a reservoir for virus transmission, is very limited. On balance, it was concluded that the risk from the representative use of *Pepino mosaic* virus strain CH2, isolate 1906 to non-target terrestrial plants is low.

No information was available on the virulence or transmission of the virus to algae or aquatic plants. Considering the information available for terrestrial plants, it may be concluded that the risk from the representative use of *Pepino mosaic* virus strain CH2, isolate 1906 to algae or aquatic plants is low. However, this extrapolation includes some uncertainties. Also, some uncertainties were identified in the data used for the assessments of the fate and behaviour of the virus in soil and surface water (see data gap identified in section 4). Moreover, it was indicated that specific studies for algae and aquatic plants are on-going. These studies may potentially address the uncertainties described above. Therefore a data gap for a risk assessment for algae and aquatic plants was identified.

No specific assessments for toxicity were available since metabolites are not formed.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Pepino mosaic virus strain CH2, isolate 1906	Virus present in soil up to a period of 31 d (at 20 °C) and up to 52 d (at 4 °C).	The risk to soil organisms was concluded as low.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Not applicable [(a)]	-	-	-	-	A data gap was identified for algae and aquatic plants.

(a): Qualified presumption of safety has been found to be applicable to alphaflex viruses such as *Pepino mosaic virus* strain CH2 isolate 1906 (EFSA BIOHAZ Panel, 2013)

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Pepino mosaic virus strain CH2, isolate 1906	A data gap was identified for algae and aquatic plants.

6.4. Air

Compound (name and/or code)	Toxicology
Pepino mosaic virus strain CH2, isolate 1906	No potential for toxicity, infectivity or pathogenicity; may provoke sensitisation reactions via inhalation.

7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of the Regulation concerning information on potentially harmful effects).

- A search of the scientific peer-reviewed open literature on the active substance, 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 dossier, to be conducted and reported in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011; relevant for the representative use evaluated; submission date proposed by the applicant: unknown).

- Additional efficacy trials are needed to confirm the effectiveness of the *Pepino mosaic* virus strain CH2, isolate 1906, when applied according to the proposed GAPs (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see above section on the active substance and the formulated product).

- The pathogenicity assessment of the coliforms potentially present in the production batches (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 2).

- A data gap has been identified for evidence that the studies authored by Hanssen and by Ortega Parra, not published in a scientific peer review journals or performed under GLP, have been performed in an officially recognised testing facility or organization satisfying at least the requirements under points 2.2 and 2.3 of the introduction of the Annex to Commission Regulation (EU) No 545/2011 (as required when the GLP condition cannot be satisfied; derogation specific for microbial active substances including virus; relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 4).

- A risk assessment for algae and aquatic plants (relevant for the representative use evaluated; submission date proposed by the applicant: November 2014; see section 5).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- The analysis of the microbial contaminants should be regularly performed in the quality control phase to exclude the batches exceeding the threshold limits fixed for microbials (see section 2).

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011[7] and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

[7] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127-175.

An issue is also listed as an issue that could not be finalised where the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation.

No issue that could not be finalised were identified.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where in the light of current scientific and technical knowledge using guidance documents available at the time of application the active substance is not expected to meet the approval criteria provided for in Article 4 of the Regulation.

No critical areas of concern were identified.

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		**Tomatoes** (glasshouse)
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Bystander risk	Risk identified	
	Assessment not finalised	
Consumer risk	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	

Representative use		**Tomatoes** (glasshouse)
Groundwater exposure metabolites	Legal parametric value breached[(a)]	
	Parametric value of 10µg/L[(b)] breached	
	Assessment not finalised	
Comments/Remarks		

The superscript numbers in this table relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2 to 6 for further information.

(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.

(b): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003.

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APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Chapter 1 (identity, biological properties, details of uses, further information and proposed classification and labelling)

Identity, Biological properties, Details of uses, Further information, and Proposed Classification and Labelling

Active microorganism:	*Pepino mosaic* virus strain CH2 isolate 1906
Function (e.g. control of fungi):	Virus inoculation for cross protection

Rapporteur Member State	Belgium
Co-rapporteur Member State (if relevant)	-

Identity of the Microbial Pest control Agent / Active substance (OECD data point IIM 1)

Name of the organism:	*Pepino mosaic virus* strain CH2 isolate 1906
Taxonomy:	Family: Alphaflexiviridae Genus: potexvirus
Species, subspecies, strain:	*Pepino mosaic* virus strain CH2 isolate 1906
Identification / detection:	Sequencing of complete genome: genome composed of a 6410 nucleotide long, sinlge stranded RNA with 5 Open Reading Frames (ORF): ORF1 encodes a 164-k Da RNA dependent polymerase ORF2-4 form the PepMV triple (gene block TGB) ORF5 codes for a 25-k Da coat protein (CP) Best method for detection, identification and differentiation of genotypes is TaqMan real-time quantitative reverse transcription PCR (RT-qPCR). To unambiguously identify the mild CH2 isolate 1906, the sequence of part of TGB and CP regions has to be determined.
Culture collection:	The strain is deposited in GenBank, under accession number JN835466
Minimum and maximum concentration of the MPCA used for manufacturing of the formulated product (viable granules; g/kg):	PMV-01 formulation contains: $>5\times10^5$ genome copies /µL product
Identity and content of relevant impurities, additives, contaminating organisms in the technical grade of MPCA:	Data gap for the pathogenicity assessment of the coliforms potentially present in the production batches.
Is the MCPA genetically modified; if so provide type of modification	*Pepino mosaic* virus strain CH2, isolate 1906 is a natural wild-type.

Biological properties of the microorganism (OECD data point IIM 2)

Origin and natural occurrence, Background level:	*Pepino mosaic* virus strain CH2 isolate 1906 was isolated from a commercial tomato crop in Belgium and further screened for its properties of providing protection through the mechanism of cross protection against all other isolates of *Pepino mosaic* virus (PepMV) on tomatoes in green house.
Target organism(s):	All other isolates of PepMV on tomatoes
Mode of action:	Cross protection
Host specificity:	Restricted to *Solanaceae* species
Life cycle:	It starts by penetration of the virion into the cytoplams of plant cell through wounds caused by mechanical damage to the cuticle and cell wall, or through the stomata. The next phase is the partial or complete removal of the coat protein shell of the virion in the cytoplasm. Next the cell mediates expression of the viral genome by providing a translation apparatus producing viral proteins that are required for completion of the virus life cycle. The next step in the virus reproduction cycle is movement of the virus into neighboring cells. Virions are transported into neighboring cells through small channels called plasmodesmata that form connections between cells. The time between initial infection of one or a few cells and systemic infection of the plant varies from a few days to a few weeks depending on the virus, host plant, and environmental conditions. Transmission of the virus from one plant to another completes the virus life cycle.
Infectivity, dispersal and colonisation ability:	Not applicable: the isolate 1906 prevents other isolates from entering into the crop.
Relationships to known plant, animal or human pathogens:	PepMV is closely related to *Narcissus mosaic virus* (NMV), *Scallion virus X* (SVX), *Cymbidium mosaic virus* (CymMV) and *Potato aucuba mosaic virus* (PAMV). The highest overall nucleotide identities are with NMV and CymMV. No relationship with human or animal pathogens due to the lack of specific receptors for recognition and entry into host cells.
Genetic stability:	The mild isolate 1906 has a high genetic stability and a narrow quasi species cloud. Genetic stability was confirmed in a new study.
Information on the production of relevant metabolites (especially toxins):	Viruses have no metabolism of their own and are therefore not able to produce secondary metabolites. The complete viral genome sequence is known and the five encoded typical Potexvirus proteins are well understood. None of these proteins show any homology to known human or animal toxins. It can therefore be stated with certainty that PepMV does not produce toxins, not even after infecting the plant host cell.
Resistance/ sensitivity to antibiotics / anti-microbial agents used in human or veterinary medicine:	Not applicable to viruses: viruses are not metabolically active and cannot produce antimicrobial substances; they are not sensitive to antibiotics and therefore cannot become resistant to these substances or spread resistance.

Summary of uses supported by available data

Crop and/or situation (a)	Zone	Product code or name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage &season (j)	number min-max (k)	interval between applica-tions	kg as/hL min-max	Water L/ha min-max	kg as/ha min-max	
Tomatoes	Northern Central Southern	PMV-01	G	*Pepino mosaic virus CH2 strain*	SC	>5x10^{5} viral genome copies per µL	Low volume Spraying	Seedlings, as soon as possible after planting, at the latest before the first tomato cluster flourishes, from Dec to Feb	1	NA	6.7x10^{11} in case of 4L product and 300L/Ha to 25x10^{11} in case of 8L product and 160L water/ha viral genome copies/hL	160-300 L/ha	>2x10^{12} viral genome copies/ha	NA

(a) For crops, the EU and codex classifications (both) should be used; where relevant, the situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emusifiable concentrate (EC), granule (GR)
(e) GCPF codes - Crop Life Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
(i) viable granules = colony forming units and g/kg or g/L
(j) Growth stage at last treatment (BBCH Monograph, growth stages of Plants, 1997, Blackwell ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Classification and proposed labelling (Symbol, Indication of danger, Risk phrases, Safety phrases)

with regard to physical/chemical data:	none
with regard to toxicological data:	Microorganisms may have the potential to provoke sensitising reactions
with regard to fate and behaviour:	none
with regard to ecotoxicological data:	none

Chapter 2: Methods of analysis

Analytical methods for the microorganism (OECD data point IIM 4.2, 4.3 and IIIM 5.3)

Manufactured microorganism (principal of method):	A scientifically validated and published TaqMan RT-qPCR assay is used to quantify the active ingredient PepMV, CH2 strain (isolate 1906). The test results in C_T values, from which an estimated number of genome copies per µL product can be calculated.
Impurities and contaminating microorganisms in manufactured material (principal of method):	The virus does not produce secondary metabolites and during the production process the quality control procedure includes tests to exclude the presence of contaminants that could be harmful to tomato production. It should be required to add the analysis of the microbial contaminants in the quality control phase (step 2); batches exceeding the threshold limits fixed for microbials cannot be used and must be discarded.
Microbial Pest control product (principle of method):	A scientifically validated and published TaqMan RT-qPCR assay is used to quantify the active ingredient PepMV, CH2 strain (isolate 1906) in the formulation. The test results in C_T values, from which an estimated number of genome copies per µL product can be calculated.

Analytical methods for residues (viable and non-viable) in exposed compartments and organisms (OECD data point IIM 4.5)

Of the active microorganism (principle of method):	methods are not required
Of relevant metabolites (principle of method):	methods are not required

Chapter 3: Impact on Human and animal Health

Impact on Human and Animal Health

Medical data: (including medical surveillance on manufacturing plant personnel) (OECD data point IIM 5.1, 5.2)	Routine exposure of personnel, laboratory researchers, as well as consumers of tomatoes affected with the ubiquitous CH2 strain of *Pepino mosaic* virus, has not resulted in any known adverse effects of toxicological significance.
Sensitisation: (OECD data point IIM 5.3.1 & IIIM 7.1.6)	Sensitiser (no studies available, classification based on general assumptions for microorganisms)
Acute oral infectivity, toxicity and pathogenicity (OECD data point IIM 5.3.2 & IIIM 7.1.1)	LD_{50} oral rat > 2000 mg/kg bw = 10×10^8 viral particles/kg bw; No evidence of adverse effects.
Acute intra-tracheal/ inhalation toxicity, pathogenicity and infectivity: (OECD data point IIM 5.3.3 & IIIM 7.1.3)	LC_{50} (4h) >20 mg/L = 9.99×10^6 viral particles /L; no evidence of adverse effects.
Acute intravenous/intraperitonial infectivity: (OECD data point IIM 5.3.4 & IIIM 7.1.2)	No study provided.
Genotoxicity: (OECD data point IIM 5.3.5)	Negative *in vitro* results using the Ames test.
Cell culture study: (OECD data point IIM 5.3.6)	Cell culture tests could provide information on the ability of viral pest control agents to infect, replicate in, transform or cause toxicity in mammalian cell lines. Infectivity and replication of the isolate 1906 was tested in human epithelial cell line A549. PepMV did not multiply and was unable to enter into the cells in culture.
Information on short-term toxicity and pathogenicity: (OECD data point IIM 5.3.7)	No data – not required. Plant viruses do not infect mammals, since they do not possess receptors that bind to human cells. Thus the pathogenicity potential of PepMV, CH2 strain can be considered irrelevant, as the virus has no ability to infect humans.
Dermal toxicity: (OECD data point IIIA 7.1.2)	LD_{50} dermal > 2000 mg/kg = 9.99×10^8 viral particles/kg bw No evidence of adverse effects.
Specific-toxicity, pathogenicity and infectivity:(OECD data point IIM 5.5)	No data – not required
Genotoxicity – *in vivo* studies in germ cells: (OECD data point IIM 5.5.3)	No data – not required

Exposure (operator, workers, bystander, consumer): (OECD data point IIM 6.1, IIIM 7.2, 7.3 and 8.0)	Not available; not required

Chapter 4: Residues (normally not required)

Not required

Pepino mosaic virus strain CH2 isolate 1906 is a candidate for inclusion in Annex IV of Regulation (EC) No 396/2005 (providing that it could be guaranteed that the active substance can be produced free of potential microbial contaminants that could be pathogenic for humans).

Chapter 5: Fate and behaviour in the environment

Fate and Behaviour in the Environment (OECD IIM 7 & IIIM 9)

Persistence and multiplication in soil, water and air:	*Pepino mosaic* virus, CH2 strain is endemic in tomato culture in most European countries. Plant virus does not replicate outside the plant cell. The virus does not have a cellular structure and does not produce metabolites. In the laboratory experiment at 4 °C and 20 °C the virus remained present up to a period of 31 d (at 20 °C) and up to 52 d (at 4 °C). In any case, it was demonstrated that phosphate buffer suspension from the soils stored at 4 °C (during 3d, 7d and 14 d) were unable to infect tomato plants. Samples from a greenhouse treated with the formulation PMV-01 revealed that no viral particles are detectable 8 months after application. Worst case PEC soil has been calcuated as >$2.67x10^6$ viral genome copies / kg soil. After application of the virus to distilled water and maintained at 4 °C and 20 °C the *Pepino mosaic* virus strain CH2, isolate 1906 was present for a period of 31 d (at 20 °C) and 90 d (at 4 °C). Samples stored at 20 °C for 3 d or more and samples stored at 4 °C for 90 d or more were not able to infect tomato plants. Worst case PEC SW has been calculated as >$1.33x10^3$ viral genome copies / l for the case of application in tomatoes grown in soil in permanent greenhoses assuming an emission of 0.2 %. *Pepino mosaic virus* is not an air borne virus and infection occurs by surface contact with contaminated surfaces to damaged surfaces in the plant.
Mobility	Given the high natural infection pressure of PepMV, large part of the tomato crops in important production areas are infected with the CH2 strain of PepMV, regardless of vaccination treatment. Infection of plant occurs by contact to contaminated surfaces with damaged surfaces in the plant. Infestation by the mild isolate *Pepino mosaic* virus, strain CH2, isolate 1906 is intended to vaccinate the plants to prevent the infestation by wilder and commercially damaging varieties.

Chapter 6: Effects on non-target organisms

Effects on terrestrial vertebrates (OECD IIM 8.1 & IIIM 10.1, IIIM 10.3)

No data on infectiveness or pathogenicity are available. The exposure of birds and mammals was considered negligible.

Effects on aquatic organisms (OECD IIM 8.2, 8.3, 8.4 & IIIM 10.2)

No data on infectiveness or pathogenicity are available. Data gap for a risk assessment for algae and aquatic plants.

Effects on terrestrial plants (OECD IIM 8.5 & IIIM 10.2)

No data on infectiveness or pathogenicity are available. The exposure of terrestrial plants outside the greenhouses was considered negligible.

Effects on bees (OECD IIM 8.7 & IIIM 10.4)

No negative effects of PepMV on bumble bees in contact with PepMV infected plants were observed. No data on infectiveness or pathogenicity to honey bees are available. The exposure of honey bees is considered negligible.

Effects on terrestrial arthropods other than bees (OECD IIM 8.8 & IIIM 10.4)

No data on infectiveness or pathogenicity are available. The exposure of arthropods other than bees is considered negligible.

Effects on earthworms and other soil non-target macroorganisms (OECD IIM 8.9, 8.9.1 , 8.9.2 & IIIM 10.5)

No data on infectiveness or pathogenicity are available. The risk to earthworms and other soil non-target macroorganisms is considered as low.

Effects on non-target soil microorganisms (OECD IIM 8.10 & IIIM 10.6)

No data on infectiveness or pathogenicity are available. The risk to non-target soil microorganisms is considered as low.

Effects on other taxa (OECD IIM 8.11 & IIIM 10.7)

Not relevant, not necessary.

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
CP	coat protein
CymMV	Cymbidium mosaic virus
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DDD	daily dietary dose
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemicals Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FIR	Food intake rate

FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre (also used for mean measured concentrations)
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake

ng	nanogram
NMV	*Narcissus mosaic* virus
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen phosphorous detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
ORF	open reading frames
Pa	pascal
PAMV	*Potato aucuba mosaic* virus
PCR	polymerase chain reaction
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PepMV	*Pepino mosaic* virus
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RNA	ribonucleic acid
RPE	respiratory protective equipment
RT-qPCR	real-time quantitative reverse transcription polymerase chain reaction
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SSD	species sensitivity distribution
STMR	supervised trials median residue
SVX	*Scallion* virus X
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TGB	triple gene block
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue

TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organization
wk	week
yr	year