

**DE CEUSTER** n.v.  
*grond-veredeling*®  
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ontv. dd. <b>16 NOV. 2015</b>			
no. CTB			
ter behandeling		aangewend d.	
ago.	td	1-2-3-4	5-6
opdr. van		1-2-3-4	5-6

Sint-Katelijne-Waver  
13 November 2015

### Contactpersoon

Uw bericht van

**Telefoon**

Uw kenmerk

## GSM

Ons kenmerk

10.2.e

Dear Madam, Dear Sir,

Re : Application for approval of PMV-01 containing the approved active substance *Pepino mosaic virus*, strain CH2, isolate 1906

In July 2012, De Ceuster N.V. submitted an Annex II dossier for approval and inclusion in the Annex I list under Regulation (EC) 1107/2009, for the new active substance *Pepino mosaic virus*, strain CH2, isolate 1906. The dossier was submitted to Belgium acting as zonal Rapporteur Member State.

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments for the active substance *Pepino mosaic virus* strain CH2 isolate 1906 were carried out by the competent authority of the rapporteur Member State Belgium. The assessment of the application to include *Pepino mosaic virus*, strain CH2, isolate 1906 in Annex IV of Regulation (EC) No 396/2005, has been 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 on the Pesticide Peer Review 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, have been presented.



The EFSA Conclusions on the Pesticide Peer Review of the active substance *Pepino mosaic virus*, strain CH2, isolate 1906 were published on the EFSA website and in the EFSA Journal 2015;13(1):3977 on January 9, 2015.

The approval of the active substance *Pepino mosaic virus* strain CH2 isolate 1906, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council have been published in Regulation (EU) 2015/1176 of July 17, 2015.

Since *Pepino mosaic virus*, strain CH2, isolate 1906 is a vaccine acting as an elicitor, used for cross protection of tomatoes in greenhouses to protect them against damage caused by other isolates of *Pepino mosaic virus*, one zonal Rapporteur Member State is sufficient for evaluation of the dRR for the end use product PMV-01 for both the Northern, Central and Southern zone. Belgium is evaluating the dossier as zRMS for the three European zones.

We would be pleased if the Netherlands could evaluate the dossier as concerned Member State. For your information, the end use product PMV-01 was also the representative formulation in the Annex II dossier for the active substance *Pepino mosaic virus* strain CH2, isolate 1906.

As per your e-mail of April 14, 2015, please find attached to this application the following documents:

- CD-ROM
  - Annex III dossier in dRR format
  - Application form
    - Form G – CMS
    - Annex I – WG-format 2.0
    - Annex VI – Report Pre Submission Meeting Anti-Mos; July 16, 2015
    - SDS PMV-01
- Hard copy
  - Application form (see above)

In case part B or parts of it would be made public, thanks to first blacken everything that is now highlighted in yellow in this document. It concerns among others :

- The name of the CRO, the name of their contact person and if needed the study code of all studies that has been conducted in vertebrates



- The name of the institutes/companies and the name of their contact person that provided us with a Letter of support, since giving info on the personal network of the applicant and his link or relationship with the author of the Letter.

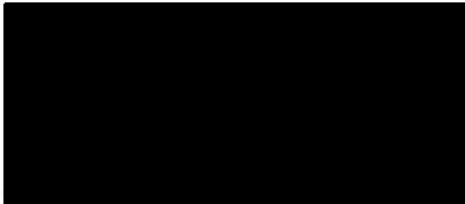
The above request for treating these data confidential is based on Article 63 of Regulation 1107/2009.

Finally, thanks for sending us the application number of our dossier so that we can pay the application fee.

Hoping to have provided you with all data needed in support of the application for approval of PMV-01,

Best Regards

For De Ceuster N.V.



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