HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. BESLUIT

Op 13 februari 2018 is van

ISK Biosciences Europe N.V.
De Kleetlaan 12B bus 9
1831 DIEGEM
Belgium

een aanvraag tot wijziging van gewasbeschermingsmiddeltoelating met Nederland als zonaal rapporteur ontvangen als bedoeld in artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

TEPPEKI

op basis van de werkzame stof flonicamid.

HET COLLEGE BESLUIT tot toelating van bovenstaand middel.

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

1.1 Samenstelling, vorm en verpakking

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

1.2 Gebruik

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

1.3 Classificatie en etikettering

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

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

- De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II en in hoofdstuk 2 van deel A van het registratierapport.

1.4 Aflever- en opgebruiktermijn (respijtperiode)
Niet van toepassing.

2. WETTELIJKE GRONDSLAG

Besluit	artikel 28 Verordening (EG) Nr. 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Conform Bgb en Rgb d.d. 16 december 2011 en Evaluation Manual Zonaal 2.0

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

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

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

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

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

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

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

Ede, 3 augustus 2018

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraaginformatie

Aanvraagnummer:	20180482 ZWTG
Type aanvraag:	Aanvraag tot wijziging van gewasbeschermingsmiddeltoelating met Nederland als zonaal rapporteur
Middelnaam:	TEPPEKI
Verzenddatum aanvraag:	13 februari 2018
*Formele registratiedatum: **	19 maart 2018
Datum in behandeling name:	26 maart 2018

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

2.2 Stofinformatie

Werkzame stof	Gehalte
flonicamid	50 %

- De stof is per 1 september 2010 geplaatst op Annex I van Richtlijn 91/414/EEG (Dir 2001/29/EC d.d. 27 april 2010) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 31 augustus 2023.

2.3 Toelatingsinformatie

Toelatingsnummer:	12757 N
Expiratiedatum:	1 mei 2024
Afgeleide parallel of origineel:	Wijziging Middel
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewas
Gebruikers:	Professioneel

W-coderingen en aflever- en opgebruiktermijnen:

- *W-codering professioneel gebruik: 8*
- *Vorige w-codering professioneel gebruik: 7*
- *Aflevertermijn professioneel gebruik: nvt*
- *Opgebruiktermijn professioneel gebruik: nvt*

2.4 Verpakkingsinformatie

Aard van het preparaat:
Water dispergeerbaar granulaat

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BIJLAGE II Etikettering van het middel TEPPEKI

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

Pictogram	GHS07	
Signaalwoord	Waarschuwing	
Gevarenaanduidingen	H319	Veroorzaakt ernstige oogirritatie.
Voorzorgsmaatregelen	SP 1	Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
	P280C	Beschermende handschoenen en beschermende kleding dragen.
Aanvullende etiketelementen	EUH401	Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht		Nee
Voelbare gevaarsaanduiding verplicht		Nee

REGISTRATION REPORT
Part A

Risk Management

Product code: Teppeki (IKI-220 50% WG)

Active Substance: 500 g Flonicamid/kg

COUNTRY: Netherlands

All Zones

Zonal Rapporteur Member State: NL

NATIONAL ASSESSMENT

Applicant: **ISK Biosciences Europe**

Date: **July 2018**

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PART A – Risk Management

This document describes the acceptable use condition required for the extension of use (sweet pepper) of Teppeki (IKI-220 50 % WG) containing Flonicamid in the Netherlands. There are no other CMS.
The risk assessment conclusions are based on the information, data and assessments provided in Registration Report. For this application only an amended Part B7 (efficacy) has been provided. For the other aspects, we refer to the RR of the original authorisation (number of authorisation 12757 N).

This document describes the specific conditions of use and labelling required for the Netherlands for the re-registration of Teppeki.

Appendix 1 of this document provides a copy of the registration certificates for Teppeki in Netherlands.
Appendix 2 of this document is a copy of the current commercial label in use in Netherlands.

No letter of access to the Annex II data is required since the applicant is also the notifier of Flonicamid for Annex I inclusion. All the data presented is the exclusive property of ISK and no protected data belonging to a third party is referred to in order to conclude on the risk assessment of Teppeki.

1 Details of the application

1.1 Application background

The first application was prepared by ISK Biosciences Europe on 19 December 2013 and revised on 24 September 2014.

Teppeki is a WG formulation containing 500 g/kg Flonicamid for use as an insecticide. It is currently approved for use two to three times per season with a maximum application rate of 0.08 kg a.s./ha Flonicamid (range 0.05 to 0.08 kg a.s./ha). It is approved for use against aphids on a range of crops.

In December 2017 The Netherlands as ZRMS granted an authorisation for several uses. The use on sweet pepper was not authorised because efficacy was not proven. For all other aspects safe use was proven. Therefore in February 2018 the applicant submitted a new zonal extension for the use on sweet pepper under protected conditions.

1.2 Annex I inclusion

Flonicamid was included in Annex I of Directive 91/414/EEC on 01 September 2010 under Inclusion Directive 2010/29/EU.

The Annex I Inclusion Directive for Flonicamid (2010/29/EU**)** provides specific provisions under Part B which need to be considered by the applicant when preparing a submission and by Member States prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Flonicamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010, shall be taken into account. In this overall assessment,

Member States must pay particular attention to the:

- risk to operators and re-entry workers,
- risk to bees.

These concerns have been addressed within the current submission in the respective sections.

1.3 Regulatory approach

To obtain registration, Teppeki must meet the conditions of Annex I inclusion and be supported by data satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application is submitted in order to support the registration of Teppeki for a new use on protected peppers in Netherlands in accordance with the above

1.4 Data protection claims

ISK Biosciences Europe N.V., representative of Ishihara Sangyo Kaisha Ltd, hereby specifically requests data protection in Netherlands for all the information contained in this document on the basis of the provisions of Article 59 of Regulation 1107/2009/EU and of Council Directive 90/313/EEC of 7 June 1990 or Article 63 of the new Regulation on the freedom of access to information.

Confidential information presented in Part C is proprietary information belonging to ISK and may not be published or otherwise be made available to any third party without the written permission of ISK or its representative.

Data protection and confidentiality are claimed on the basis of commercial value, industrial secret, and including intellectual property.

1.5 Letters of Access

No letter of access to the Annex II data is required since the applicant is also the notifier of Flonicamid for Annex I inclusion. All the data presented is the exclusive property of ISK and no protected data belonging to a third party is referred to in order to conclude on the risk assessment of Teppeki.

2 Details of the authorisation

2.1 Product identity

Product Name	Teppeki
Authorization Number (for re-registration)	12757N
Function	Insecticide
Applicant	ISK Biosciences Europe
Composition	500 g/kg Flonicamid
Formulation type	Water dispersible granule formulation [Code: WG]
Packaging	Packed in bottles made of high-density polyethylene (HDPE) opaque to sunlight: 0.5 kg in 1 L, 2.0 kg in 3 L and 100/140 g in 275 cc (mL) bottles.

2.2 Classification and labelling

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

The current classification and labelling of the formulation can be maintained.

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
-			
Pictogram:	GHS07	Signal word:	Warning
H-statements:	H319	Causes serious eye irritation.	
P-statements:	P280c	Wear protective gloves and protective clothing.	
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.	
	SP1	Do not contaminate water with the product or its container.	
Child-resistant fastening obligatory?			not applicable
Tactile warning of danger obligatory?			not applicable

Explanation:	
Pictogram:	-
H-statements:	H319 should be assigned as the results of the eye irritation study with the formulation triggers classification with H319 according to the CLP criteria.
P-statements:	-
Other:	-

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

2.2.2 Other phrases:

-

2.3.1 Intended new use

		GAP rev. 0, date: 2018-02-08
PPP (product name/code): Teppeki / IKI-220 500WG **active substance: flonicamid**		**Formulation type: WG** **Conc. of as: 500 g/kg**
Applicant: ISK Biosciences Europe N.V. **Zone(s): interzonal**		**professional use** ☒ **non professional use** ☐
Verified by MS: N		
Field of use: insecticide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		e.g. g safener/synergist per ha (f)
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
1	NL	Pepper (Paprika)	G	~~Aphids~~ (~~*Aphis gossypii, Myzus persicae, Macrosiphum euphorbiae, Aulacorthum solani*~~)(MYZUPE)	Foliar application	BBCH 11* till BBCH 90 (January-December*)	a) 2 b) 2 per 12 months	7	a) 0.120 kg/ha b) 0.240 kg/ha	a) 60 g/ha b) 120 g/ha	Crop height: 0 to 99 cm: 200-1000 100 to 200 cm: 400-2000 > 200 cm: 600-3000	1	**at first arrival of aphids The maximum concentration is 0.06% (= 6 g product/100 l)

**In previous EU-GAP, application from april-october was assessed, resulting in restriction for use in the dark period

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and 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
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Risk management

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

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary: The product Teppeki is a WG formulation. All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. The appearance of the product is that of free flowing cylindrical brown granules, with a slight odour of ammonia. It is not explosive and has no oxidising properties. Flonicamid is not flammable and the formulation contains no flammable components. In aqueous solution, it has a pH value around 8.33. The stability data indicate a shelf life of at least 3 years at ambient temperature. Its technical characteristics are acceptable for a WG formulation.

Implications for labelling:
There is no implication for labelling based on the physical-chemical properties of the product Teppeki.

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

Compatibility of mixtures: A complete report regarding physical and chemical compatibility of the tank mixes with Novodor FC 20 % SC (a.s.: *Bacillus thuringiensis*), Score 25 % EC (a.s.: Difenoconazole), Dithane DG 75 % WG (a.s.: Mancozeb), Decis 2.5 % EC (a.s.: Deltamethrin), Karate 5 % EC (a.s.: lambda-Cyhalothrin), Shirlan 50 % SC (a.s.: Fluazinam), Benomyl 52.4 % WP (a.s.: Benomyl), Stroby DF 50 % WG (a.s.: Kresoxim-methyl), Kumulus DF 80 % WG (a.s.: Sulfur), Phytocap Ultra 80 % WG (a.s.: Captan), Juwel Top SE (a.s.: Epoxiconazole 125 g/L, Kresoxim-methyl 125 g/L, Fenpropimorph 150 g/L), Ranman (IBE 3878) 40 % SC (a.s.: Cyazofamid) and Wetter (IBE 3869) is submitted which has demonstrated compatibility. Tank mixes with these products can therefore be recommended on the product label for Teppeki**.**

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

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

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

All data on analytical methods, the analytical method for the formulation as well as for the residues were provided for the EU evaluation of Flonicamid and were considered adequate.

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

Teppeki was the representative formulation in the EU evaluation dossier of Flonicamid. Analytical methods for determination of Flonicamid in Teppeki and relevance of CIPAC methods are considered adequate.

An analytical method for the determination of Toluene in the formulation was provided in this submission.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

The residue analytical methods included in the EU dossier did not include a method for crops with a high fat/oil content. Therefore, an adequate method, including an ILV, was provided, validated for all four crop groups. The remaining methods were covered as part of the EU evaluation of flonicamid.

The Dutch national requirement for a LOQ of 0.1µg/L for surface water is met. A LC-MS/MS method with a LOQ of 0.05 µg/L in surface water is available.

3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)

3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)

3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil) (Part B, Section 5, Points 9.4 and 9.5)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PECgw) (Part B, Section 5, Point 9.6)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.5.3 Predicted Environmental Concentration in Surface Water (PECsw) (Part B, Section 5, Points 9.7 and 9.8)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.6.4 Effects on Earthworms and Other Soil Macro/Micro-organisms (Part B, Section 6, Point 10.6, 10.7)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

We refer to the already authorised Teppeki. No new data were submitted.

3.1.7 Efficacy (Part B, Section 7, Point 8)

This application concerns the label extension of TEPPEKI for use in the control of aphids in greenhouse cultivation of sweet pepper. Greenhouse use: TEPPEKI is applied in 1-2 applications at dose rates of 0.12 kg/ha in sweet pepper.

Greenhouse use:

Minimum effective dose

Sweet pepper (Solanaceae)
Only one greenhouse trial from the South-East climate zone in sweet pepper and one supportive greenhouse trial from the Mediterranean climate zone in watermelon (Cucurbitaceae) were provided. This number of trials is too low to evaluate dose justification. In addition, the trial in watermelon did not employ a dose range and both greenhouse trials did not include the proposed dose rate of 0.12 kg/ha.
As supportive data to the greenhouse trials 11 field trials in a range of Cucurbitaceous and Solanaceous crops were provided, all from the Mediterranean climate zone. The proposed dose rate of 0.12 kg/ha for sweet pepper was included only in a limited number of trials (3). Generally the field trials demonstrated that a higher dose was not necessarily better than a dose rate of 0.1 kg/ha. For field use it was concluded that a dose rate of 0.10 kg/ha was acceptable.
- *Maritime zone*
It is expected that there are significant differences in crop agronomy and pest severity between the field cultivation in the Mediterranean zone and protected cultivation in the Maritime zone, therefore extrapolation from field data from the Mediterranean zone to protected crop in the Maritime zone is not acceptable without a proportion of data on crops grown in both situations.
Thus, it cannot be concluded that the proposed dose rate of 0.12 kg/ha for control of Aphids in protected culture of sweet pepper is effective.
- *South-East and Mediterranean Zone*
For the South-East and Mediterranean zone the field use may represent more challenging conditions with regard to agronomy and pest severity compared to protected use. It is therefore left to the CMS to decide whether based on the provided field data, extrapolation possibilities and expert judgement a minimum effective dose rate of 0.10 kg/ha – as accepted for field use – is acceptable for greenhouse use in sweet pepper.

Extrapolation possibilities:
- Sweet pepper (crop group Solanaceae):
According to the minor use EPPO extrapolation table for effectiveness of insecticides on pests of Solanaceae, for control of aphids in Solanaceae it is possible to extrapolate efficacy data for indicator species Aphis gossypii and Myzus persicae in indicator crop tomato to aphids in sweet pepper. In addition, data from – amongst others - Cucurbitaceae can be used as supportive data.

Efficacy

Sweet pepper

Only one greenhouse trial from the South-East climate zone in sweet pepper and one supportive greenhouse trial from the Mediterranean climate zone in watermelon (Cucurbitaceae) were provided. In the trial in sweet pepper the aphid species were not specified. The trial in watermelon only employed a dose rate of 0.05 kg/ha which is lower than the proposed dose rate of 0.12 kg/ha and lower than the dose rate accepted for the field use in sweet pepper (0.10 kg/ha). Thus, the results of both greenhouse trials have to be excluded.

For authorisation EPPO guidance states for a major pest in protected conditions typically 6 (4-8) supportive trials should be presented.
(NB. The zonal dossier was commented on by cMS from EU countries: for this use ES suggested 2 additional GEP trials on greenhouse pepper, against *Aphis gossypii, Myzus persicae and Macrosiphum euphorbiae* to support the use. AT: 1 trial is not acceptable, UK agreed with zRMS conclusions).

In addition, supportive data are provided from 25 field trials conducted in a range of Cucurbitaceous and Solanaceous crops at a dose rate of 0.10 kg/ha. All trials are conducted in the Mediterranean zone. The trials were carried out against *Aphis gossypii*, *Myzus persicae* and *Macrosiphum euphorbia.*
TEPPEKI demonstrated in all tested crops and against all aphid species sufficient effectiveness at the dose rate of 0.10 kg/ha. In case of re-infestation a second application may be required.

Extrapolation possibilities:
According to the minor use EPPO extrapolation table for effectiveness of insecticides on pests of Solanaceae, for control of aphids in Solanaceae it is possible to extrapolate efficacy data for indicator species *Aphis gossypii* and *Myzus persicae* in indicator crop tomato to aphids in sweet pepper. In addition, data from – amongst others - Cucurbitaceae can be used as supportive data.
With regard to extrapolation from unprotected crop to protected crop: extrapolation from field data to protected crop is generally not acceptable without a proportion of data on crops grown in both situations. E.g. in the maritime zone cotton aphids are generally a more severe pest in protected culture than unprotected culture as they only appear in the unprotected culture of crops under particular circumstances. For other aphid species this may differ.

Maritime EPPO Zone
No greenhouse or field trials are provided for the Maritime EPPO Zone. As significant differences in crop agronomy and pest severity are expected between the field cultivation in the Mediterranean zone and protected cultivation in the Maritime zone, extrapolation from field data from the Mediterranean zone to protected crop in the Maritime zone is not acceptable without a proportion of data on crops grown in both situations.
Therefore, for the Maritime EPPO Zone it is concluded in the core assessment that the claim for the control of Aphids in the protected cultivation of sweet pepper cannot be accepted

Specifically for The Netherlands the applicant provided an advice prepared by the Dutch NVWA to substantiate that the use in sweet pepper can be accepted through extrapolation from the already authorized use in ornamental crops.
In The Netherlands, TEPPEKI is currently authorized for use against aphids in a number of field crops at a dose rate of 0.14 – 0.16 kg/ha (depending on the crop). TEPPEKI is also authorized for use against aphids in ornamentals (both protected and unprotected) at a dose rate is 0.14 kg/ha. The use in ornamentals was evaluated in 2008. In the Dutch evaluation regarding the dose justification for ornamentals it was concluded that “not always a clear dose response was observed. In some trials there was a trend that 8 and 12 g/100 L was less effective when compared to 14 g/100 L”. In the current application for extension, the claimed dose rate for control of aphids in sweet pepper is 12 g/100 L. This

dose rate is lower than the currently authorised use in ornamentals, thus based on the prior evaluation cannot be accepted for sweet pepper through extrapolation. In addition, sweet pepper is a high growing crop for which extrapolation from low growing crops without additional data is not acceptable.
Conclusion: As the applicant did not provide any data for sweet pepper (G) with the dose rate of 0.12 kg/ha and extrapolation from ornamental crops to sweet pepper (high growing crop) is not possible, for The Netherlands the use in protected crop of sweet pepper cannot be accepted.

South East EPPO Zone
One greenhouse trial in sweet pepper against Aphid spp. is provided for the South East EPPO Zone, as the aphid species are not specified this trial is further excluded.
In addition, there are no supportive field trials from this zone.
For the South-East zone the field use in sweet pepper may represent more challenging conditions with regard to agronomy and pest severity compared to protected use. It is therefore left to the CMS to decide whether based on the provided field data, extrapolation possibilities and expert judgement a limited dose rate of 0.10 kg/ha (concluded to be the effective dose for field use) against aphids in the protected cultivation of sweet pepper is acceptable.

Yield
Sweet pepper
In a total of 8 crop safety trials conducted in the Mediterranean EPPO Zone (Italy and Spain) in 2003 and 2004, the effect of TEPPEKI on yield was determined. The trials were carried out in cucumber (1), melon (1), pumpkin (1), zucchini (1) and tomato (4). No significant effect of treatment with TEPPEKI on marketable or unmarketable yield was observed in relation to the untreated objects.
Based on the presented data, negative effects on yield after treatment with TEPPEKI are considered unlikely.

Crop safety

Sweet pepper:
In a total of 28 efficacy trials and 8 selectivity trials conducted in the Mediterranean EPPO Zone from 1999 to 2004 in cucumber, melon, pumpkin, zucchini and tomato, no symptoms of phytotoxicity were observed.
As a general principle, insecticides are expected to have low to no herbicidal activity and are thus expected to have low phytotoxic activity with limited adverse effects on the treated crop. However, with the exception of 1 efficacy trial in water melon and 1 selectivity trial in tomato which were conducted in greenhouses, all trials were conducted in the field. Protected cultivated crops are expected to be more sensitive to phytotoxicity, especially when grown under low light conditions.
According to the GAP the use in sweet pepper in low light conditions is excluded as the application period is limited to the period April - October. If authorized a restriction sentence to this extent should be included on the label. In Dutch:

De toepassing in paprika is uitsluitend toegestaan van 1 april tot 1 november.

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Adverse effects
Adverse effects to beneficial organisms, succeeding and adjacent crops of TEPPEKI are, when applied according to the label, considered unlikely.

Resistance
Referred is to the resistance paragraph under ‘field uses’ .
Zonal Extension: Sweet Pepper (April 2018)

One (1) additional greenhouse trial was provided. In this trial different doses were tested (dose rate 10-12-14 g/hectoliter, and application methods (Silwet or spray-drip application) in the control of green peach aphid (Myzus persicae) in a susceptible cultivar (Keessie). Concluding from this trial: all treatments gave good control of M.persicae, similar to the reference product. Adding Silwet to the spray accelerates control of the pest and drip application is slower to reach acceptable efficacy levels. No phytotoxicity was observed in this trial.

Also a statement from a plant protection technical expert was provided stating that Teppeki is very effective in ornamental crops and controls all sorts of aphids in ornamentals. From a pilot experiment initiated by branche organization LTO on control of aphid species (Aulacorthum solani) in sweet pepper, by Teppeki a graph was provided showing that Teppeki is just as effective as Pirimor.

Based on expert judgement and provided data from the GEP certified trial, zRMS NL agrees that control of Myzus persicae at the proposed dose is very likely. On the Dutch label, control of Myzus persicae in protected culture of sweet pepper will be added. The more general claim for control of aphids in sweet pepper at the proposed dose is still not justified. The requested dose is lower for pepper than the dose authorised in other crops and efficacy against Aphis gossypii was not tested.

3.2 Conclusions

In the application Teppeki 20131146 ZWTG it was concluded that the application in sweet pepper (indoor) poses no unacceptable risk for human and environment. However based on the efficacy evaluation an authorisation could not be granted for the extension in sweet pepper.
In underlying application 20180482 ZWTG new efficacy data has been submitted for indoor the use on sweet pepper. For the other aspects the applicant refers to the assessment of Teppeki 20131146 ZWTG (number of authorisation 12757N).
Based on expert judgement and provided data from the GEP certified trial, Teppeki is expected to be effective and crop safe in the control of *Myzus persicae*. An authorization has been granted.

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

Not relevant

Appendix 1: Copy of the product authorisation

See cover letter

Appendix 2: Copy of the product label

Wettelijk Gebruiksvoorschrift
Toegestaan is uitsluitend het professionele gebruik als insectenbestrijdingsmiddel door middel van een gewasbehandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden

Toepassingsgebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximale dosering middel per toepassing	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen of uiterst gewasstadium waarop toegepast mag worden
Aardappelen	bladluis [1]	0,16 kg/ha	0,16 kg/ha	2 per teeltcyclus	21	14
Suikerbieten	bladluis [2]	0,14 kg/ha	0,14 kg/ha	1 per teeltcyclus	-	60
Wintertarwe	bladluis	0,14 kg/ha	0,14 kg/ha	2 per teeltcyclus	21	28
Triticale	bladluis	0,14 kg/ha	0,14 kg/ha	2 per teeltcyclus	21	28
Spelt	bladluis	0,14 kg/ha	0,14 kg/ha	2 per teeltcyclus	21	28
Zomertarwe	bladluis	0,14 kg/ha	0,14 kg/ha	2 per teeltcyclus	21	28
Winterkoolzaad	bladluis [3]	0,10 kg/ha	0,10 kg/ha	1 per 12 maanden	-	BBCH 16-18 (6e tot 8ste bladstadium)
Pitvruchten	bladluis	0,14 kg/ha	0,14 kg/ha	3 per 12 maanden	21	21
Paprika (bedekte teelt)	bladluis [3]	0,06% (6 g per 100 l water)	0,12 kg/ha	2 per 12 maanden	7	1
Bloembol- en bloemknolgewassen	bladluis	0,14 kg/ha	0,14 kg/ha	3 per 12 maanden	21	-
Bloemisterijgewassen	bladluis	0,14 kg/ha	0,14 kg/ha	3 per 12 maanden	21	-
Boomkwekerijgewassen	Bladluis	0,14 kg/ha	0,14 kg/ha	3 per 12 maanden	21	-
Vaste plantenteelt	bladluis	0,14 kg/ha	0,14 kg/ha	3 per 12 maanden	21	-
Bloemenzaadteelt	bladluis	0,14 kg/ha	0,14 kg/ha	3 per 12 maanden	21	-
Veredelingsteelten basiszaadproductie van akkerbouw- en	bladluis	0,14 kg/ha	0,14 kg/ha	3 per 12 maanden	21	-

Toepassingsgebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximale dosering middel per toepassing	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen of uiterst gewasstadium waarop toegepast mag worden
groentegewassen						
Openbaar groen	bladluis	0,14 kg/ha	0,14 kg/ha	3 per 12 maanden	21	-
Vruchtbomen en struiken van pitvruchten	bladluis	0,14 kg/ha	0,14 kg/ha	3 per 12 maanden	21	-

[1] wegedoornluis *(Aphis nasturtii),* groene perzikluis *(Myzus persicae),* aardappeltopluis *(Macrosiphum euphorbiae),*
vuilboomluis *(Aphis frangulae)*
[2] zwarte bonenluis *(Aphis fabae), groene perzikluis (Myzus persicae)*
[3] groene perzikluis *(Myzus persicae)*

Toepassingsvoorwaarden
Draag geschikte handschoenen bij werkzaamheden aan behandeld gewas.

De toepassing in paprika is uitsluitend toegestaan van 1 april tot 1 november.

Voor zaadteelten geldt dat aangeraden wordt om op kleine schaal te toetsen of het middel van invloed is op de kiemkracht van het gewas of ras.

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product op in bloei staande gewassen of op niet bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels alleen toepassen tussen zonsondergang en zonsopkomst.

Gebruik is wel toegestaan in de kas mits er geen bijen of hommels actief naar voedsel zoeken. Voorkom dat bijen en andere bestuivende insecten de kas binnenkomen door bijvoorbeeld alle openingen met insectengaas af te sluiten.

Let op: dit middel kan schadelijk zijn voor natuurlijke vijanden en bestuivers. Raadpleeg uw leverancier van natuurlijke vijanden over het gebruik van dit middel in combinatie met het gebruik van natuurlijke vijanden en/of bestuivers.

Resistentiemanagement:
Dit middel bevat de werkzame stof flonicamid. Flonicamid behoort tot de pyridinecarboxamiden. De Irac code is 29. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

Appendix 3: Letter of Access

Not applicable

Appendix 4: Reference list

Not applicable: No new studies are claimed for data