12757 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. BESLUIT

Op 23 december 2013 is van

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

een aanvraag tot wijziging van een 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 bovenstaande aanvraag. De aanvraag betreft een uitbreiding van het middel in de teelt van suikerbieten en winterkoolzaad.

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. Het betreft een uitbreiding van een bestaande toelating.

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, 29 december 2017

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:	20131146 ZWTG
Type aanvraag:	Aanvraag tot wijziging van gewasbeschermingsmiddeltoelating met Nederland als zonaal rapporteur
Middelnaam:	TEPPEKI
Verzenddatum aanvraag:	16 augustus 2013
*Formele registratiedatum: **	25 februari 2014

* 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
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel

W-coderingen en aflever- en opgebruiktermijnen:

- *W-codering professioneel gebruik: 7*
- *Vorige w-codering professioneel gebruik: 6*
- *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: **December 2017**

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PART A – Risk Management

This document describes the acceptable use conditions required for the extension of use (new crops) of Teppeki (IKI-220 50 % WG) containing Flonicamid in the EU Central Zone.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C and where appropriate the relevant national addendum. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration/registration by the EU review. It also includes assessment of data and information relating to Teppeki where that data has not been considered in the EU review. Otherwise assessments for the safe use of Teppeki have been made using endpoints agreed in the EU review of Flonicamid.

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

This 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 0.09 kg a.s./ha Flonicamid (range 0.07 to 0.09 kg a.s./ha). It is approved for use against aphids on a range of crops. This dossier is intended to support a new use on sweet pepper grown under protected conditions and to support new uses on sugar beet, oilseed rape, peach and plum.

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 and is submitted in order to support the registration of Teppeki for new uses on sugar beet and oilseed rape 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:	-	-	
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 uses

Applicant	ISK Biosciences Europe NV
Active substance	Flonicamid 500 g/L
Toelatingsnummer	12757N

Note:
As this concerns the national addendum for the Netherlands, only uses relevant to the Netherlands are included below.
Only acceptable uses have been included. For a full overview of requested and evaluated uses, please refer to the core dossier (part B section 1, appendix II of both the field and interzonal dossier)

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. g safener/synergist per ha**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**kg, L product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
1	NL	Sugar beet	F	Aphids (*Myzus persicae, Aphis fabae*)	Foliar application	BBCH 16* till PHI (May-June)	1	0.140kg/ha	70 g/ha	200-500	60	*most often as correction on seed treatments with neonicotinoids (clothianidin/thiamethoxam)
6	NL,	Winter Oil Seed Rape	F	Aphids (*Myzus persicae, ~~Brevicoryne brassicae~~*)	foliar application	BBCH 12-16- (Sept-Nov).	1	0.100 kg/ha	50 g/ha	200-300	BBCH 16/18	*recommended window for application autumn at GS BBCH 12/13 till 15/16; >6 months before anticipated harvest

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)

Teppeki was the representative formulation in the EU dossier for Flonicamid inclusion. The acute toxicity studies for the Teppeki were evaluated and considered adequate.

Teppeki 50% WG containing 500 g/kg flonicamid has low acute oral, dermal and inhalation toxicity. It is not a skin irritant, but it does induce eye irritation. It does not possess skin sensitising potential according to the results of the LLNA and Bühler tests.

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

Teppeki was evaluated as part of the EU review of flonicamid for wheat, potatoes and apples. However, the use in protected crops and hand-held application were not evaluated as part of the EU review. Moreover, the EU evaluation does not reflect the Dutch specific requirements for operator exposure assessment. In addition, different values for dermal absorption, according to the 2012 EFSA guidance document on dermal absorption applicable to this application were used for the risk assessment of Teppeki: 7% was used for the concentrate and 15% for the spray dilution.

For **tractor boom sprayer application outdoors to low crops**, the estimated levels of exposure using the NL model (mixing & loading) and EUROPOEM (application) are less than the AOEL for flonicamid when no PPE is worn.

For **tractor mounted/ trailed broadcast air-assisted sprayer application outdoors to high crops** using the NL model (mixing & loading) and EUROPOEM (application) are less than the AOEL for flonicamid when gloves and coverall are worn during application.

For **hand-held knapsack sprayer application outdoors to high crops**, the estimated levels of exposure using the NL model (mixing & loading) and German model 90th percentile (application) are less than the AOEL for flonicamid when gloves and coverall are worn during application.

For **greenhouse hand-held knapsack sprayer application**, the estimated levels of exposure using the Dutch greenhouse model are less than the AOEL for flonicamid when no PPE is worn.

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

The total systemic exposure of a (professional) bystander positioned near to a field being sprayed is estimated to be maximally 8% (based on EUROPOEM II) of the AOEL for flonicamid. For the outdoor use, the total systemic exposure of bystanders/residents is estimated to be 2-33% of the AOEL for flonicamid.
During spraying operations there should be no bystanders present in the greenhouse. No exposure to bystanders is therefore expected. For residents living near greenhouses, the exposure is estimated using the lee side turbulence model; based on worst case assumptions, the exposure is not exceeding the reference value.

The risk to bystanders and residents following the application of Teppeki is considered to be acceptable.

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

Worker exposure was estimated using the approach recommended by EUROPOEM II (Report of the re-entry working group, December 2002)[1].

For the **outdoor use**, the AOEL is exceeded (121% of the AOEL) without the use of PPE. Using PPE (gloves), the AOEL is not exceeded (24% of the AOEL).

For the **indoor use**, harvesting of peaches and peppers was presented in the core. It was concluded that worker exposure during harvesting of peaches and peppers was safe when gloves were worn. In that calculation, it was assumed that only part of the 2 applications would dissipate. In the Netherlands, we usually calculate worker exposure based on 1 time the application rate. In that case, the use is safe without gloves.

As a standard rule, treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

[1] van Hemmen et al. (2002). Post-application exposure of workers to pesticides in agriculture. Report of the re-entry working group, EUROPOEM II project: FAIR3-CT96-. Policy paper on agricultural transfer coefficients

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

This dossier is presented to support the product Teppeki (IKI-220 50 % WG) for the use on protected peaches and peppers and on outdoor plums, oilseed rape, peach, pumpkin for seed oil production and sugar beet in the Netherlands.

For the active substance flonicamid, the main information and data are available in the Draft Assessment Report on Flonicamid of July 2005, the EFSA Conclusion (EFSA Journal 2010; 8(5): 1445) and in the EFSA MRL Opinions (EFSA Journal 2014;12(6):3740, EFSA Journal 2015;13(5):4103).

A new storage stability study in oilseed rape and dry beans was submitted. Stability of Flonicamid and its metabolites TFNG and TFNA is given for at least 12 months in oily (rape seed) and dry/protein rich (dry bean) crops.

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

MRLs flonicamid are published in Regulation (EC) No 2016/1902 amending Annex III to Regulation (EC) No 396/2005.

The use of Teppeki on indoor and outdoor peaches was proposed in the Netherlands. Four new trials in northern Europe compliant with the intended outdoor GAP for peach have been submitted. Sufficient trials have been provided to support the use on outdoor peaches, which is a minor crop in northern Europe. The outdoor use is covered by the current MRL in peach. Since no residue data on indoor peaches are available, the applicant decided to withdraw the indoor use on peaches in the Netherlands.

Eight GAP-compliant trials conducted on peppers under greenhouse conditions in 2012 were submitted. The proposed PHI is 1 day. Trials on protected crops from one growing season are acceptable (EC, 1997b). All trials were designed as decline up to PHI 3 or 7 days. The data are sufficient to derive an MRL of 0.3 mg/kg. This is confirmed by EFSA, based on the same trials (EFSA Journal 2015;13(5):4103). The current MRL of 0.3 mg/kg covers the intended indoor use on peppers.

Eight new trials in northern Europe compliant with the intended outdoor GAP of plum have been submitted. Sufficient trials for a major crop northern EU have been provided. The use is covered by the current MRL.

A total of four trials have been conducted on oilseed rape in northern and southern Europe following the proposed GAP for Teppeki. The number of trials conducted in northern Europe does not meet the data requirements. However, when the residues of an active substance are foreseen to be below the limit of quantification (limit of determination) and at least two residue trials confirm this, then no further trials are normally necessary (SANCO 7525/VI/95 Rev. 10.3, 13 June 2017). In oilseed rape the last application is allowed in autumn at GS BBCH 16-18; >6 months before anticipated harvest. Due to the early application timing, residues of flonicamid, TFNA and TFNG in rape seed are foreseen to be below <0.01 mg/kg. The 2 residue trials in northern Europe and 2 residue trials in southern Europe confirm that residues of flonicamid, TFNA and TFNG in rape seed at harvest are all <0.01 mg/kg. Residues are therefore considered to be non-relevant and it is considered appropriate to deviate from the data requirements in the present case. The presented residue trials provide sufficient evidence that MRL at the LOQ of 0.06 mg/kg

for flonicamid (sum of flonicamid, TFNA and TFNG expressed as flonicamid) in oilseed rape published in Regulation (EC) No 2016/1902 will not be exceeded.

Four residue trials performed in northern Europe showed a zero residue situation in pumpkin seeds. Sufficient trials were submitted to prove a zero residue situation. Residue levels are covered by the MRL for pumpkin seed.

Eight residue trials with sugar beet in northern Europe were submitted. Residues are determined in root (relevant for sugar production) and tops (relevant for livestock feeding). Sufficient trials are submitted for an authorisation on sugar beet in northern Europe. Residue levels in sugar beet roots are covered by the MRL.

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

In the framework of the review of the existing MRLs for flonicamid according to Article 12 of Regulation (EC) No 396/2005 a comprehensive long-term exposure assessment was performed taking into account the existing uses at the EU level (EFSA, 2014). In its most recent Reasoned opinion on the modification of the existing MRLs for flonicamid in several crops (EFSA Journal 2015;13(5):4103), EFSA updated this risk assessment with the STMRs derived from the residue trials for the crops under consideration. Those food commodities, for which no uses were reported in the framework of the Article 12 review, were excluded from the exposure calculation, assuming that there is no use of flonicamid on these crops. Calculations were performed taking into account all the crops in/on which Teppeki may be applied.

EFSA calculated maximal 17% of the ADI will be used (Danish children). All other consumer groups use less of the ADI. No chronic risk has to be expected for European consumers. Calculations have been performed using total residues of flonicamid, TFNA and TFNG (expressed as mg flonicamid equivalents/kg), in accordance with the current residue definition.

For flonicamid, the results of the NESTI calculations demonstrate that the ARfD is not exceeded for any of the crops/commodities by adults/general population or by children. Thus, the acute risk to the consumer based on the short-term intake of residues of Flonicamid and its metabolites TFNG and TFNA, is considered to be acceptable.

Based on the different calculations made to estimate the risk for consumer through diet it can be concluded that the use of product Teppeki does not lead to an unacceptable risk for consumers when applied according to the recommendations.

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

No new studies are presented; all data were reviewed in the EU evaluation of the active substance Flonicamid. Appropriate EU agreed endpoints (EFSA Journal 2010; 8(5): 1445) were used to calculate PEC values for Flonicamid and its metabolites in soil, surface water, ground water and air for the intended use patterns. This Addendum contains specific environmental exposure assessments for protected crops.

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

The PEC of Flonicamid and its metabolites, TFNA, TFNA-OH, TFNA-AM, TFNG and TFNG-AM, in soil has been assessed with the FOCUS model, the FOCUS groundwater interception values (FOCUS (2012)) and EU agreed endpoints (EFSA Journal 2010; 8(5): 1445).
The maximum initial predicted environmental concentration in soil (PECs) of flonicamid will be 0.075 mg/kg.
For the metabolites TFNA, TFNA-OH, TFNA-AM, TFNG and TFNG-AM, the proposed use pattern will lead to maximum initial PECs of 0.023 mg/kg, 0.015 mg/kg, 0.005 mg/kg, 0.003 mg/kg and 0.008 mg/kg, respectively, which is acceptable according to the uniform principles.

The results for PEC soil for the active substance and its metabolites were used for the eco-toxicological risk assessment.

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

Groundwater modelling of Flonicamid and its metabolites, TFNA, TFNA-OH, TFNA-AM, TFNG and TFNG-AM has been undertaken in the Core dossier using the relevant FOCUS groundwater scenarios, including the for NL relevant Kremsmünster scenario, using the FOCUS PEARL 4.4.4 model. As a worst case, the standard FOCUS scenarios for outdoor uses were used as a surrogate for protected uses.

PECgw for flonicamid and all its metabolites was < 0.001 µg/l in the Kremsmünster scenario for all crops.

Monitoring data groundwater
There are no data available regarding the presence of the substance flonicamid in groundwater.

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

The PEC of Flonicamid and its metabolites in surface water has been assessed in accordance with the standard Dutch TOXSWA model. Application of flonicamid to sugar beets and plums (worst case uses applied for) was simulated according to the proposed GAP, using a drift value of 1 % (sugar beets) and 8.6 % (plums, full leave stage, after May 1st). The maximum initial PEC values, corresponding to multiple application in plums were 5.222 µg/l for flonicamid, and 0.5758 µg/l for TFNA-OH.

The results for PEC surface water for the active substance and its metabolite were used for the eco-toxicological risk assessment.

Monitoring data surface water
The Pesticide Atlas on internet (www.pesticidesatlas.nl, www.bestrijdingsmiddelenatlas.nl) is used to evaluate measured concentrations of pesticides in Dutch surface water, and to assess whether the observed concentrations exceed threshold values.

The active substance flonicamid was observed in the surface water (most recent data from 2013). In the Pesticide Atlas, surface water concentrations are compared to the authorisation threshold value of 310 µg/L (consisting of higher tier acute ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case 0.01 * LC50 fish) and to the indicative Maximum Permissible Concentration (MPC) of 120 µg/L as presented in the Pesticide Atlas.

The currently available MPC value is reported here for information purposes when no EQS values are available.

As there are no exceedance of thresholds, the monitoring data have no consequences for the proposed uses of the product.

Drinking water criterion
Substances are categorized as new substances on the Dutch market (less than 3 years authorisation) or existing substances on the Dutch market (authorised for more than 3 years).

- For new substances, a pre-registration calculation is performed.
- For existing substances, the assessment is based on monitoring data of VEWIN (drinking water board).
    - If for an existing substance based on monitoring data no problems are expected by VEWIN, Ctgb follows this VEWIN assessment.
    - If for an existing substance based on monitoring data a potential problem is identified by VEWIN, Ctgb assesses whether the 90th percentile of the monitoring data meet the drinking water criterion at each individual drinking water abstraction point.

Flonicamid has been on the Dutch market for > 3 years (authorised since 16-12-2005). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

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

The DT50 of flonicamid in air is 13.7 days derived from the Atkinson model. Due to the low volatility [vapour pressure of 9.43 x 10-7 Pa (20 °C) and Henry's Constant Law of 4.2 x 10-8 Pa m3 mol-1] the occurrence of Flonicamid in air is very unlikely.

Implications for labelling resulting from environmental fate assessment: R53

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)

Birds and mammals
The risk to birds and mammals was assessed in line with the EFSA Guidance Document (2009). An initial worst-case dietary screening assessment demonstrated an acceptable acute and long-term risk to birds and acute risk to mammals for flonicamid from the proposed uses of Teppeki (IKI-220 50% WG).

The risk to birds and mammals from drinking contaminated water (puddle scenario) was assessed and showed an acceptable risk.

The log K_{OW} value of flonicamid is -0.24, which is below the trigger value of 3. It was therefore not necessary to further consider the risk from secondary poisoning. Based on the low log K_{OW} value the risk from bioaccumulation of flonicamid via terrestrial food chain is negligible for terrestrial vertebrates.

This information is considered irrelevant for protected uses.

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

Protected uses
The risk to aquatic organisms was assessed in line with the Aquatic Guidance Document (SANCO/3268/2001) and using the standard Dutch glasshouse model (for more information please refer to dRR Protected crop addendum, Section 5, IIIA 9.7).

An acceptable acute and long-term risk to fish, aquatic invertebrates, algae and aquatic plants was demonstrated for flonicamid and its surface water metabolites from the proposed uses of Teppeki (IKI-220 50% WG) with no requirement of risk mitigation measures.

Field usese

The risk to aquatic organisms was assessed in line with the Aquatic Guidance Document (SANCO/3268/2001). Predicted concentrations in surface water (PECsw) have been calculated according to Dutch National Requirements and using the TOXSWA GUI model (Version 1.0) (refer to Section 5 “Environmental Fate”, IIIA 9.7 and 9.8 for further details).

An acceptable acute and long-term risk to fish, aquatic invertebrates, algae and aquatic plants was demonstrated for flonicamid and its surface water metabolites from the proposed uses of Teppeki (IKI-220 50% WG) with no requirement of risk mitigation measures.

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

Field uses

Bees
The risk to honeybees from exposure to Teppeki (IKI-220 50% WG) was assessed in line with the Terrestrial Guidance document, SANCO/10329/2002). All hazard quotients for honey bees are considerably lower than 50, indicating that the active substances pose a low risk to bees. Therefore, a low risk to bees is expected from the application of IKI-220 50 % WG. Adverse effects on bees were observed in some of the additionally submitted tunnel tests when bees were present during spraying. However, under realistic outdoor field conditions no significant adverse effects on honey bees were observed when

Teppeki (IKI-220 50 % WG) is applied in the evening, after bee flight. Therefore, Teppeki (IKI-220 50 % WG) can be applied during flowering, in the evening, when bees are not active.
In line with Dutch national requirements, the following risk management phrase will appear on the label:

> *Dangerous for bees. To protect bees and other pollinators, this product may not be used on blooming crops, or crops that are not blooming but where bees are actively foraging. Apply only between sunset and sunrise.*

Non-target arthropods
The risk to non-target arthropods was assessed in line with ESCORT 2 (Candolfi, *et al* 2001) but also following Dutch national requirements. The Tier 1 risk assessment indicates a potential high risk to *Typhlodromus pyri*. The Tier 2 risk assessment was performed with extended laboratory studies with *T. pyri* and three additional species, the green lacewing *Chrysoperla carnea*, the ladybird beetle *Coccinella septempunctata* and the hover fly *Episyrphus balteatus* representing further leaf-dwelling arthropod species, according to the current guidance document ESCORT 2.

Considering the rapid foliar dissipation of flonicamid, the worst case field and drift rates are lower than all LR_{50} and ER_{50} values, indicating that the in-field and off-field risk for non-target arthropods is acceptable when Teppeki (IKI-220 50 % WG) is applied according to GAP. A warning sentence should appear on the label/instructions for use regarding IPM uses in orchards, due to reproductive effects > 25% in extended laboratory studies with the hover fly:

> *Warning. This product is dangerous for natural enemy arthropods used in integrated pest management (IPM). Consult your supplier of arthropods for IPM regarding the use of this product in concert with IPM.*

Protected uses
Use of Teppeki (IKI-220 50% WG) at the proposed label rates to glasshouse fruiting vegetables, according to good agricultural practice, poses low risk non-target arthropod species. The potential risk to bees used as pollinators within glasshouses should be mitigated by the inclusion of label phrases to prevent exposure as follows (see IIIA 10.4.1):

Application to flowering plants in greenhouses is allowed when no bees are actively foraging.

Remove or cover beehives during application and for 4 hours after treatment.

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

Field uses

The risk assessment for soil organisms was conducted in line with the Terrestrial Guidance Document (SANCO/10329/2002). A first tier risk assessment demonstrated an acceptable acute risk to earthworms from exposure to the active substance and its major soil metabolites from the proposed uses of Teppeki (IKI-220 50% WG).

No effects of >25% on soil respiration and nitrification were observed in tests with flonicamid at concentrations higher than the maximum calculated PEC_{soil} values.

It is concluded that when applied under the proposed uses, Teppeki (IKI-220 50% WG) poses no unacceptable risks to soil organisms.

Protected uses
This information is considered irrelevant for protected uses.

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

Field uses

Non-Target Plants
A profiling study of the effects on pre- and post-emergence non-target higher plants was conducted and showed no effects on any of the minimum 11 species tested at rates up to 300 g a.s./ha. Less than 50 % effect on seedling emergence and vegetative vigour on minimum six species was observed at 300 g a.s./ha, a far higher rate than the full proposed label rate of 70 g a.s./ha. In addition, less than 50% effect on seedling emergence and vegetative vigour on minimum six species was observed at 300 g a.s./ha, a far higher rate than the estimated off-field exposure level of 3.29 g a.s./ha and even the full proposed label rate of 70 g a.s./ha. It can therefore be concluded that the proposed use of IKI-220 50 % WG poses no unacceptable risk to non-target plants.

IKI-220 50 % WG poses no unacceptable risk to terrestrial non-target plants in off-crop areas following the proposed uses.

Protected uses
This information is considered irrelevant for protected uses.

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

Referred is to the core assessment.

This application concerns the label extension of TEPPEKI for use in the control of aphids in sugar beet, peach (unprotected crop), plum, winter oilseed rape and greenhouse cultivation of sweet pepper.
Field use: TEPPEKI is applied in 1-2 applications at the proposed dose rate of 0.10 - 0.14 kg/ha, depending on the crop.
Greenhouse use: TEPPEKI is applied in 1-2 applications at dose rates of 0.12 kg/ha in sweet pepper.

Field uses:

Minimum effective dose

Trials were established as part of the efficacy trials, to determine the minimum effective dose for TEPPEKI in the control of aphids in sugar beet, plum, peach and winter oilseed rape.

Sugar beet

In a total of 13 trials, conducted in the Maritime EPPO Zone from 2008 to 2013, the effectiveness of different dose rates of TEPPEKI against black bean aphid (*Aphis fabae*) was tested. Two of these trials were excluded as the number of aphids per plant was too low to provide reliable results.
In a total of 4 trials, conducted in the Maritime EPPO Zone from 2010 to 2012, the effectiveness of different dose rates of TEPPEKI against green peach aphid (*Myzus persicae*) was tested. One trial was excluded as the number of aphids was very low.

The data demonstrate a dose related effect of TEPPEKI on sugar beet for the control of aphid species *Aphis fabae* and *Myzus persicae.* Though the differences between dose rates were slight, a higher and more consistent control was achieved at a dose rate of 0.14 kg/ha, compared to the lower dose rates of 0.10 and 0.07 kg/ha.
Based on the presented data the proposed dose rate of 0.14 kg/ha for the control of *Aphis fabae* and *Myzus persicae* in the Maritime EPPO Zone is concluded to be justified.

Stone fruit

In 26 trials in peach and 1 trial in plum, conducted in the Mediterranean EPPO Zone (France, Spain and Italy) from 1998 to 2003, TEPPEKI was applied against *Myzus persicae*.
TEPPEKI was applied at dose rates of 0.08, 0.10, 0.12, 0.14, 0.16 and 0.18 kg/ha.
Over all trials, the level of control achieved by TEPPEKI was high, with marginal differences between dose rates. Though generally comparable levels of control were observed between dose rates, a tendency towards higher control was observed for the proposed dose rate of 0.14 kg/ha shortly after application and at approximately 30 days after application, compared to the lower dose rates of 0.08, 0.10 and 0.12 kg/ha. Higher dose rates of TEPPEKI did not result in higher levels of control.

In 1 trial in peach conducted in the Mediterranean EPPO Zone (Italy) in 2002, TEPPEKI was applied against *Myzus varians*. TEPPEKI was applied at dose rates of 0.08 and 0.14 kg/ha. A slightly higher control was observed for TEPPEKI at the proposed dose rate of 0.14 kg/ha shortly after application, yet no differences in control were observed during later assessments.

In a total of 6 trials in plum, conducted in the South-East EPPO Zone (Slovakia) (1) and Mediterranean EPPO Zone (France, Spain and Italy) (5) from 2001 to 2005, TEPPEKI was applied against *Brachycaudus helichrysi*. TEPPEKI was applied at dose rates of 0.10 and 0.14 kg/ha in the trial conducted in the South-East EPPO Zone and at dose rates of 0.08 and 0.14 kg/ha in the trials conducted in the Mediterranean EPPO Zone.
In the trial conducted in the South-East EPPO Zone, the proposed dose rate of 0.14 kg/ha was more effective compared to the lower dose rate of 0.10 kg/ha. In the trials conducted in the Mediterranean EPPO Zone, with exception to a slightly higher control shortly after application for the proposed dose rate of 0.14 kg/ha, control levels between dose rates were comparable.
In 2 trials in plum, conducted in the North-East EPPO Zone (Poland) (1 trial) in 2003 and in the Mediterranean EPPO Zone (Italy) (1 trial) in 2002, TEPPEKI was applied against *Hyalopterus pruni*.
TEPPEKI was applied at dose rates of 0.06, 0.08, 0.1 and 0.14 kg/ha.
In the trial conducted in the North-East EPPO Zone, all dose rates achieved very high levels of control, though complete control was achieved at the proposed dose rate of 0.14 kg/ha.

In the trial conducted in the Mediterranean EPPO Zone control levels were more variable, yet a slightly higher control was observed for the proposed dose rate of 0.14 kg/ha compared to the lower dose rate of 0.08 kg/ha.

Overall, very marginal differences between dose rates were observed for the control of aphids in peach and plum. However, a tendency towards higher control was observed for the proposed dose rate of 0.14 kg/ha shortly after application combined with a longer duration of protection compared to lower dose rates.
The majority of trials were conducted in the Mediterranean EPPO Zone, in addition some data are also provided for the North-East and South-East EPPO Zone. No data are provided for the Maritime zone. According to the zRMS the provided dose justification is not acceptable for the Maritime EPPO zone as climatological circumstances differ too much.

Oilseed rape

In all 11 efficacy trials in oilseed rape conducted in the Maritime EPPO Zone (Northern-France) from 2007 to 2011, TEPPEKI was applied against *Myzus persicae*. TEPPEKI was applied at dose rates of 0.07, 0.1, 0.14 and 0.28 kg/ha.
Generally, a dose related effect on control was observed. The proposed dose rate of 0.1 kg/ha achieved a higher and more consistent control of *Myzus persicae* compared to the lower dose rate of 0.7 kg/ha. Higher dose rates (0.14 and 0.28 kg/ha) achieved even higher levels of control, yet sufficient control was achieved at the proposed dose rate of 0.1 kg/ha and a higher dose rate is not desirable for use in oilseed rape.

In 2 efficacy trials conducted in Maritime EPPO Zone (Northern-France) in 2008 and 2009 different dose rates of TEPPEKI were tested against cabbage aphid (*Brevicoryne brassicae*). However no reliable results were observed in either of the trials.

Based on the presented data the proposed dose rate of 0.10 kg/ha for the control of aphids in oilseed rape in the Maritime EPPO Zone is concluded to be justified.

Efficacy

In a total of 100 efficacy trials in sugar beet (15), peach (29), plum (19) and oilseed rape (11) conducted in the Maritime, Mediterranean, North-East and South-East EPPO Zone from 1998 to 2013, TEPPEKI was applied at its proposed dose rate and compared to treatment with reference products.

Sugar beet

Maritime EPPO zone
Over 11 trials in sugar beet in presence of *Aphis fabae* conducted in the Maritime EPPO Zone from 2008 to 2013, TEPPEKI at the proposed dose rate of 0.14 kg/ha was effective in the control of black bean aphids. TEPPEKI achieved, with exception of the time shortly after application, comparable high control of aphids per plant compared to the reference products containing pirimicarb and cyhalothrin + pirimicarb.
Over 3 trials in sugar beet in presence of *Myzus persicae* conducted in the Maritime EPPO Zone from 2010 to 2012, TEPPEKI at the proposed dose rate of 0.14 kg/ha was effective in the control of aphids. TEPPEKI achieved comparably to higher control of aphids compared to reference products containing pirimicarb and lambda-cyhalothrin + pirimicarb. Especially at the later assessments TEPPEKI was more effective than the reference product containing pirimicarb. Likewise TEPPEKI was comparably to more effective in the control of infestation on plants compared to both reference products.
The number of trials carried out with *Myzus persicae* is too low to draw a conclusion. Extrapolation from trials with *Aphis fabae* is not possible, as *M. persicae* is considered more difficult to control. However, to

the evaluators opinion the limited number of trials (3) could be acceptable in case already claims in other crops for control of *Myzus persicae* are authorized, considering the mode of action and the uniform results in the provided trials. It is left to the CMS to draw a conclusion regarding *Myzus persicae* in sugar beet. As in The Netherlands TEPPEKI is already authorized in other arable crops for control of *Myzus persicae* aphids, based on the provided trials and expert judgement the claim in sugar beet for control of *Myzus persicae* is acceptable.

Overall it can be concluded that 1 application of TEPPEKI at a dose rate of 0.14 kg/ha is effective in the control of *Aphis fabae* and *Myzus persicae* in sugar beet in the Maritime EPPO Zone.

Stone fruit (peach, plum)

Maritime EPPO zone
No efficacy trials in stone fruits are presented for the maritime EPPO zone. Therefore, it cannot be concluded that TEPPEKI is effective for control of Aphid spp. in peach and plum in the Maritime EPPO zone.

Oilseed rape

Maritime EPPO zone
Over 11 trials in oilseed rape in presence of *Myzus persicae* conducted in the Maritime EPPO Zone from 2007 to 2011, TEPPEKI at the proposed dose rate of 0.10 kg/ha was effective in the control of aphids. Though rather than having an immediate high knock-down effect, high control starts after a few days. TEPPEKI was more effective than reference products containing pirimicarb and pirimicarb + lambda-cyhalothrin.
Over 2 trials in oilseed rape in presence of *Brevicoryne brassicae* conducted in the Maritime EPPO Zone in 2008 and 2009 no reliable results were obtained. Therefore it cannot be concluded that TEPPEKI is effective for the control of *Brevicoryne brassicae*.

Overall, TEPPEKI in single application at a dose rate of 0.10 kg/ha is concluded to be effective against *Myzus persicae* in oilseed rape in the Maritime EPPO Zone. It cannot be concluded that the use against *Brevicoryne brassicae* in oil seed rape is effective, therefore this use has to be removed from the claim.

Quality
In 1 efficacy trial in sugar beet conducted in the Maritime EPPO Zone in 2008 and in 11 selectivity trials in peach (1), nectarine (2), plum (3), melon (1), zucchini (1) and tomato (3) conducted in the Mediterranean EPPO Zone from 2001 to 2004, the effect of treatment with TEPPEKI on quality was assessed. No negative effects on quality were observed.
Considering the above and the lack of phytotoxic symptoms after treatment with TEPPEKI, negative effects on quality are considered unlikely.

Effects on the processing procedure
As no symptoms of phytotoxicity were observed in the trials, and generally no effect on the processing procedure of peach, plum and tomato were observed, negative effects on the processing procedure after treatment with TEPPEKI are considered unlikely.

Yield
In 1 efficacy trial in sugar beet conducted in the Maritime EPPO Zone in 2008 and in 16 selectivity trials in peach (2), nectarine (7), plum (3), cucumber (1), melon (1), pumpkin (1), zucchini (1) and tomato (4) conducted in the Mediterranean EPPO Zone from 1999 to 2004, the effect of treatment with TEPPEKI on yield was assessed. No negative effects on yield were observed in any of the trials.
Considering the above and the lack of phytotoxic symptoms after treatment with TEPPEKI, negative effects on yield are considered unlikely.

Crop safety
As a general principle, insecticides are be expected to have low to no herbicidal activity with limited adverse effects on the target plant.
In a total of 109 efficacy trials and 20 selectivity trials conducted in the Maritime, Mediterranean, North-East and South-East EPPO Zone from 1998 to 2013 in sugar beet, oilseed rape, peach, plum, nectarine, cherry, cucumber, melon, pumpkin, zucchini and tomato, no symptoms of phytotoxicity were observed.

Based on the presented data and extrapolation, for the EPPO zones in which sufficient trials are provided it is concluded that TEPPEKI, when applied according to the label, is safe to sugar beet, oilseed rape, peaches and plum. As no symptoms of phytotoxicity were observed in the efficacy and selectivity trials in tomato and no phytotoxicity was observed in the efficacy trial in sweet pepper, negative effects to sweet pepper are considered unlikely. No symptoms of phytotoxicity were observed in pumpkin.

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

Resistance
TEPPEKI is an insecticide of wettable granule (WG) formulation containing 500 g/kg flonicamid. Flonicamid acts as a rapid feeding depressant and has a unique mode of action which is as yet not fully determined. According to the Arthropod Pesticide Resistance Database there are no recorded incidences of flonicamid resistance in any insect pests.
At this moment the general recommendation is to reduce the selection pressure on aphids for this compound; a maximum of two consecutive treatments, depending on the crop, will be recommended. If aphid problem persists, then at least one treatment with a product from another mode of action category should be made in order to reduce the selection pressure for this compound/substance.
It is advised to include a warning sentence to this extent on the label.
A resistance management sentence is already stated on the currently authorized Dutch label (WG) and is sufficient. The sentence only has been adapted to match the currently updated IRAC code for group classification (group 29 instead of 9):

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.*

Overall conclusion and expert judgement – Field use
Maritime zone
Based on the presented data it can be concluded that TEPPEKI is expected to be effective and crop safe
- in the control of *Myzus persicae* and *Aphis fabae* in sugar beet;
- in the control of *Myzus persicae* in winter oilseed rape

Based on the presented data it cannot be concluded that TEPPEKI is expected to be effective and crop safe
- in the control of *Brevicoryne brassicae* in winter oilseed rape
- in the control of Aphid spp. in plum and peach

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.

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.

Mediterranean EPPO Zone
One greenhouse trial in watermelon was provided. The proposed dose rate was not included, only a low dose of 0.05 kg/ha was tested, thus this trial is further excluded.
As supportive trials, the effectiveness of TEPPEKI against cotton aphid (*Aphis gossypii*) was tested in a total of 18 field trials conducted in the Mediterranean EPPO Zone (Italy and Spain) from 1999 to 2004 in cucumber (2), melon (5 field), pumpkin (4) and tomato (6).

In all tested crops TEPPEKI demonstrated sufficient effectiveness at a dose rate of 0.1 kg/ha . In case of re-infestation a second application may be required.
In addition to the trials with *A. gosypii* 7 field trials in tomato at a dose rate of 0.10 kg/ha against *Myzus persicae* (4 trials) and *Macrosiphum euphorbiae* (3 trials) demonstrated sufficient efficacy, comparable to the reference products. In case of re-infestation a second application may be required.
For the Mediterranean 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.

Quality
In a total of 5 crop safety trials conducted in the Mediterranean EPPO Zone (Italy and Spain) in 2003 and 2004, the effect of treatment with TEPPEKI on quality of fruits was assessed. The trials were conducted in melon (1), zucchini (1) and tomato (3). No negative effects were observed on the quality of tomato, melon or zucchini.
Considering the above and the lack of phytotoxic symptoms after treatment with TEPPEKI, negative effects on quality are considered unlikely.

Effects on the processing procedure
No negative effects on the processing procedure of Cucurbitaceae and Solanaceae are expected. The lack of phytotoxic symptoms in efficacy and crop safety trials suggest that negative effects on the processing procedure after treatment with TEPPEKI are unlikely. No negative effects of TEPPEKI were observed on the processing procedures of peach.

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' .

Overall conclusion and expert judgement
Maritime zone
Based on the presented data it cannot be concluded that TEPPEKI is expected to be effective and crop safe
- in the control of *Aphis gossypii, Myzus persicae* and *Macrosiphum euphorbiae* in the protected cultivation of sweet pepper.

3.2 Conclusions

Based on the presented data it can be concluded that TEPPEKI is expected to be effective and crop safe
- in the control of *Myzus persicae* and *Aphis fabae* in sugar beet;
- in the control of *Myzus persicae* in winter oilseed rape

Based on the presented data it cannot be concluded that TEPPEKI is expected to be effective and crop safe
- in the control of *Brevicoryne brassicae* in winter oilseed rape
- in the control of Aphid spp. in plum and peach
- in the control of *Aphis gossypii, Myzus persicae* and *Macrosiphum euphorbiae* in the protected cultivation of sweet pepper

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

Will be inserted after finalisation of the RR

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

Toepassings-gebied	Te bestrijden organisme	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	2 per teeltcyclus	21	14
Suikerbieten	bladluis[2]	0,14 kg/ha	1 per teeltcyclus		60
Wintertarwe	bladluis	0,14 kg/ha	2 per teeltcyclus	21	28
Triticale	bladluis	0,14 kg/ha	2 per teeltcyclus	21	28
Spelt	bladluis	0,14 kg/ha	2 per teeltcyclus	21	28
Zomertarwe	bladluis	0,14 kg/ha	2 per teeltcyclus	21	28
Winterkoolzaad	bladluis[3]	0,10 kg/ha	1 per 12 maanden		BBCH 16-18 (6e tot 8ste bladstadium)
Pitvruchten	bladluis	0,14 kg/ha	3 per 12 maanden	21	21
Bloembol- en bloemknolgewassen	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Bloemisterijgewassen	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Boomkwekerijgewassen	Bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Vaste plantenteelt	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Bloemenzaadteelt	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Veredelingsteelt en basiszaadproductie van akkerbouw- en groentegewassen	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Openbaar groen	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Vruchtbomen en struiken van pitvruchten	bladluis	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.

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. 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

Fysical and chemical proporties

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Relied on Y/N	Owner

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Relied on Y/N	Owner
IIIA1 5.2.4/01	2011	Validation of Analytical Method for Determination of Flonicamid and the Relevant Impurity Toluene in the Formulation Flonicamid 500 g/kg (WG Formulation) Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road, Ongar, Essex, CM5 0GZ, United Kingdom Report no. PL/11/001 GLP, unpublished	Y	Y	Y	ISK
IIIA 5.3.1/01	2012a	Determination of Residues of Flonicamid and its Metabolites TFNG and TFNA in Peach after Application of IKI-220 500 WG Insecticide National Food Chain Safety Office, Directorate of Plant Protection, Soil Conservation and Agri-environment, Pesticide Residue Analytical Laboratory, Miskolc, Hungary Report No.: 11 ISK AA 05 03 GLP, unpublished	Y	Y	Y	ISK
IIIA 5.3.1/02	2012b	Decline Study of Active Ingredient (Flonicamid) of Insecticide IKI-220 500 WG in Peach National Food Chain Safety Office, Directorate of Plant Protection, Soil Conservation and Agri-environment, Pesticide Residue Analytical Laboratory, Miskolc, Hungary Report No.: 11 ISK AA 05 04 GLP, unpublished	Y	Y	Y	ISK
IIIA 5.3.1/03	2011a	Decline Curve Analysis of the Active Ingredient Flonicamid of IBE 3894/Teppeki Insecticide in pepper According to GLP Quality Control System Agricultural Office, Directorate of Plant Protection, Soil Conservation and Agri-environment, Pesticide Analytical Laboratory, Velence, Hungary Report No.: 11 ISK AA 0701 GLP, unpublished	Y	Y	Y	ISK

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Relied on Y/N	Owner
IIIA 5.3.1/04	2011b	Residue Analysis of the Active Ingredient Flonicamid of IBE 3894/Teppeki Insecticide in pepper According to GLP Quality Control System Agricultural Office, Directorate of Plant Protection, Soil Conservation and Agri-environment, Pesticide Analytical Laboratory, Velence, Hungary Report No.: 11 ISK AA 0702 GLP, unpublished	Y	Y	Y	ISK
IIIA 5.3.1/05	2012	Residue Analysis of the Active Ingredient Flonicamid and its metabolites (TFNA and FTNG) of IBE 3894/Teppeki (Teppeki 50% Flonicamid WG) Insecticide in Pepper According to GLP Quality Control System National Food Chain Safety Office (NFCSO), Pesticide Analytical Laboratory, Velence, Hungary Report No.: 12 ISK AA 0702 GLP, unpublished	Y	Y	Y	ISK
IIIA 5.3.1/06	2008	IKI-220 and its major metabolites. Validation of an LC-MS/MS analytical method for the active substance IKI-220 and its 3 major metabolites (TFNA-AM, TFNA and TFNG) in lemon, potato, oil-seed rape and wheat grain, plum and prune. ADME Bioanalyses, 75, Chemin de Sommières, 30310 Vergèze, France Report No.: ISK/IKI/06001 GLP, unpublished	Y	Y	Y	ISK
IIIA 5.3.1/07	2010	Independent Laboratory Validation of an LC-MS/MS Analytical Method for the Active Substance IKI-220 and its 3 Major Metabolites (TFNA-AM, TFNA and TFNG) in Lemon, Potato, Oilseed rape, Wheat (grain) and Plum Eurofins Dr. Specht GLP GmbH, Germany Report No.: ISK-0901V GLP, unpublished	Y	Y	Y	ISK

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Relied on Y/N	Owner
IIIA 5.3.1/08	2013	Residue Analysis of the Active Ingredient Flonicamid and its metabolites (TFNA and TFNG) of IBE 3894/Teppeki (Teppeki 50% Flonicamid WG) Insecticide in Pumpkin According to GLP Quality Control System National Food Chain Safety Office (NFCSO), Pesticide Analytical Laboratory, Velence, Hungary Report No.: 12 ISK AA 0701 GLP, unpublished	Y	Y	Y	ISK
IIIA 5.3.1/11	2015a	Determination of Residues of Flonicamid and its Metabolites TFNG and TFNA in Peach after Application of IKI-220 500 WG Insecticide National Food Chain Safety Office, Directorate of Plant Protection, Soil Conservation and Agri-environment, Pesticide Residue Analytical Laboratory, Miskolc, Hungary Report No.: 11 ISK AA 05 03 – Amendment 1 GLP, unpublished	Y	Y	Y	ISK
IIIA 5.3.1/12	2015b	Decline Study of Active Ingredient (Flonicamid) of Insecticide IKI-220 500 WG in Peach National Food Chain Safety Office, Directorate of Plant Protection, Soil Conservation and Agri-environment, Pesticide Residue Analytical Laboratory, Miskolc, Hungary Report No.: 11 ISK AA 05 04 – Amendment 1 GLP, unpublished	Y	Y	Y	ISK

Metabolism and residues

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Study relied on Y/N	Data protection granted Y/N
IIIA	2013	IKI-220 – 12 month frozen	Y	ISK	Y	Y

8.1.1/01		storage stability study in crop matrices Eurofins Agroscience Services Chem SAS, 75, Chemin de Sommières, 30310 Vergèze, France Report No.: S12-04427 GLP, unpublished				
IIIA 8.3.1/01	2012a	Determination of Residues of Flonicamid and its Metabolites TFNG and TFNA in Peach after Application of IKI-220 500 WG Insecticide National Food Chain Safety Office, Directorate of Plant Protection, Soil Conservation and Agri-environment, Pesticide Residue Analytical Laboratory, Miskolc, Hungary Report No.: 11 ISK AA 05 03 GLP, unpublished	Y	ISK	Y	Y
IIIA 8.3.1/02	2012b	Decline Study of Active Ingredient (Flonicamid) of Insecticide IKI-220 500 WG in Peach National Food Chain Safety Office, Directorate of Plant Protection, Soil Conservation and Agri-environment, Pesticide Residue Analytical Laboratory, Miskolc, Hungary Report No.: 11 ISK AA 05 04 GLP, unpublished	Y	ISK	Y	Y
IIIA 8.3.2/06	2004c	Decline of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in plum trees after two treatments of IKI-220 50 % WG (IBE 3894) (Germany – Season 2003) Battelle, Carouge/Geneva, Switzerland Report No.: FA-22-03-08 GLP, unpublished	Y	ISK	Y	Y
IIIA 8.3.2/07	2004d	Decline of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in plum trees after two treatments of IKI-220 50 % WG (IBE 3894) (France – Season 2003) Battelle, Carouge/Geneva, Switzerland Report No.: FA-22-03-07 GLP, unpublished	Y	ISK	Y	Y
IIIA	2006b	Decline of residues of IKI-220	Y	ISK	Y	Y

8.3.2/08		and its metabolites TFNG, TFNA and TFNA-AM in plums after two applications of IKI-220 50 % WG (IBE 3894) (Northern France and Germany – Season 2005) Battelle, Carouge/Geneva, Switzerland Report No.: FA-22-05-04 GLP, unpublished				
IIIA 8.3.3/01	2013a	Residue study in protected Pepper after two foliar applications of IBE 3894 in Greece, Italy and Spain in 2012 Eurofins Agroscience Services Chem SAS, 75, Chemin de Sommières, 30310 Vergèze, France Report No.: S12-01918 GLP, unpublished	Y	ISK	Y	Y
IIIA 8.3.4/01	2011a	Decline Curve Analysis of the Active Ingredient Flonicamid of IBE 3894/Teppeki Insecticide in pepper According to GLP Quality Control System Agricultural Office, Directorate of Plant Protection, Soil Conservation and Agri-environment, Pesticide Analytical Laboratory, Velence, Hungary Report No.: 11 ISK AA 0701 GLP, unpublished	Y	ISK	Y	Y
IIIA 8.3.4/02	2011b	Residue Analysis of the Active Ingredient Flonicamid of IBE 3894/Teppeki Insecticide in pepper According to GLP Quality Control System Agricultural Office, Directorate of Plant Protection, Soil Conservation and Agri-environment, Pesticide Analytical Laboratory, Velence, Hungary Report No.: 11 ISK AA 0702 GLP, unpublished	Y	ISK	Y	Y
IIIA 8.3.4/03	2012	Residue Analysis of the Active Ingredient Flonicamid and its metabolites (TFNA and TFNG) of IBE 3894/Teppeki (Teppeki 50% Flonicamid WG) Insecticide in Pepper According to GLP Quality	Y	ISK	Y	Y

		Control System National Food Chain Safety Office (NFCSO), Pesticide Analytical Laboratory, Velence, Hungary Report No.: 12 ISK AA 0702 GLP, unpublished				
IIIA 8.3.4/04	2016	Determination of residues of Flonicamid and its metabolites TFNA and TFNG in pepper at intervals and at harvest under open field conditions following two applications of IBE 3894 in Northern Europe in 2015.	Y	ISK	Y	Y
IIIA 8.3.5/01	2011	IKI-220 (IBE 3894): Residue study on Oil Seed Rape in France in 2010 Eurofins|ADME Bioanalyses, 75, Chemin de Sommières, 30310 Vergèze, France Report No.: S10-02867 GLP, unpublished	Y	ISK	Y	Y
IIIA 8.3.5/02	2013b	IKI-220 (IBE 3894): Residue study on Oil Seed Rape in France in 2011 Eurofins|ADME Bioanalyses, 75, Chemin de Sommières, 30310 Vergèze, France Report No.: S11-03751 GLP, unpublished	Y	ISK	Y	Y
IIIA 8.3.6/01	2013	Residue Analysis of the Active Ingredient Flonicamid and its metabolites (TFNA and TFNG) of IBE 3894/Teppeki (Teppeki 50% Flonicamid WG) Insecticide in Pumpkin According to GLP Quality Control System National Food Chain Safety Office (NFCSO), Pesticide Analytical Laboratory, Velence, Hungary Report No.: 12 ISK AA 0701 GLP, unpublished	Y	ISK	Y	Y
IIIA 8.3.7/01	2012	IKI-220 500 WG - Residue study on Sugar Beet in France in 2010 Eurofins|ADME Bioanalyses, 75, Chemin de Sommières, 30310 Vergèze, France Report No.: S10-02994 GLP, unpublished	Y	ISK	Y	Y
IIIA 8.3.7/02	2012	Residues of Flonicamid in Sugar Beet in Open Field	Y	ISK	Y	Y

		Conditions at Intervals Following One Foliar Application of IBE 3894. Belgium and Northern France, Season 2011 Redebel SA, Rue de Chassart, 4, B-6221 Saint-Amand, Belgium Report No.: ISK-G901TO904-11 GLP, unpublished				

Fate and behaviour

For fate and behaviour, no relevant studies have been submitted.

Ecotoxicology

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Study relied on? Y/N	Data Protection Granted? Y/N
KIIIA1 10.4.5/01	2008	Toxicity Testing of Teppeki (IKI-220 50 % WG) on Honey Bees (*Apis mellifera* L.) in the Field IBACON GmbH, Rossdorf, Germany Report No.: 36061040 GLP, unpublished	Y	ISK	Y	Y
KIIIA1 10.4.5/02	2008	Teppeki (IKI-220 50 % WG) A field study to evaluate side effects on Honeybees (*Apis mellifera* L.) following application on Phacelia tanacetifolia after daily bee-flight in Germany RCC Ltd, Ittingen, Switzerland Report No.: B47520 GLP, unpublished	Y	ISK	Y	Y
KIIIA1 10.5.2/01	2007	Effects of Teppeki (IKI-220 50 % WG) on the predatory mite *Typhlodromus pyri* under Extended Laboratory Conditions IBACON GmbH, Rossdorf, Germany Report No.: 36063062 GLP, unpublished	Y	ISK	Y	Y

EFFICACY

Cucurbitaceae/Solanaceae

Annex point	Author	Year	**Title** **Source Company, Report No.** GEP status, (un)published	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA1 6.0	Versmissen, C	2014	Biological Assessment Dossier for TEPPEKI in Cucurbitaceae and Solanaceae ISK Biosciences Europe N.V -, unpublished	Y	ISK Biosciences	Y	Y

Annex point	Author	Year	**Title** **Source Company, Report No.** GEP status, (un)published	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA 6.1.3-01	Pozzi, T Terranegra, A	2004	Efficacy of IBE 3894 for aphid control on cucumber Agricola 2000 GCUO4-EF12-IT01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-02	Pozzi, T Terranegra, A	2004	Efficacy of IBE 3894 for aphid control on cucumber Agricola 2000 GCUO4-EF12-IT02 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-03	Bucchi, R. Berti, S.	1999	Determine effective rate, knockdown effect and persistence of treatments with IBE 3880 for Aphis Gossypii control in melon Agri2000 99-007-I-I-02 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-04	Avinent, L.	2001	Efficacy of IBE 3894 for aphids control on melon Recerca Agricola, 01-006-I-E-05 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-05	Avinent, L.	2002	Efficacy of IBE 3894 for aphids control on melons in Spain Recerca Agricola GME02-EF01-ES02 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-06	Folini, T.	2002	Efficacy of IBE 3894 for aphids control on melons Agri 2000 GME02-EF01-IT01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-07	Bucchi, R Folini, T.	2003	Efficacy of IBE 3894 for aphid control on crops of the cucurbit family Agri 2000 GME03-EF01-IT01 GEP, unpublished	Y	ISK Biosciences	Y	Y

Annex point	Author	Year	**Title** **Source Company, Report No.** GEP status, (un)published	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA 6.1.3-08	Avinent, L.	2003	Efficacy of IBE 3894 for Aphys gossypii control on a cucurbit family crop in Spain Recerca Agricola GME03-EF01-ES01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-09	Soler, J.	1999	Efficacy of IBE 3894 for Aphis gossypii control AgroSoler 99-008-I-E-01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-10	Torres, J.I.	2002	Define efficacy and selectivity of IBE 3894 for aphids control on melons (or any other cucurbit crop) AgroSoler GME02-EF01-ES01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-11	Ramos, D.	2003	Define efficacy of IBE 3894 for aphid control on crops of the cucurbit family AgroSoler GME03-EF01-ES02 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-12	Fernandez, E.	2004	Efficacy of IBE 3894 on Aphys gossypii on cucurbit in Spain Promo-Vert GPU04-EF11-ES01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-13	Leocata, S.	2001	Experimental field evaluation of efficacy of IBE 3894 for aphids control on zucchini in Italy ARA 01-006-I-I-01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-14	Pozzi, T., M. Lega	2002	Efficacy of IBE 3894 for aphid control on courgette Agri 2000 GME02-EF01-IT02 GEP, unpublished	Y	ISK Biosciences	Y	Y

Annex point	Author	Year	**Title** **Source Company, Report No.** GEP status, (un)published	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA 6.1.3-15	Bucchi, R Folini, T.	2003	Experimental field evaluation of the efficacy of IBE 3894 for aphids control on zucchini in Italy ARA GME03-EF01-IT02 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-16	Vargas, M.A.	2004	Define efficacy of IBE 3894 for aphid control on cucumber AgroSoler GCU04-EF11-ES02 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-17	Bucchi, R Folini, T.	2003	Efficacy of IBE 3894 for aphid control on tomatoes Agri 2000 GTO03-EF01-IT01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-18	Bucchi, R Folini, T.	2003	Efficacy of IBE 3894 for aphid control on tomatoes Agri 2000 GTO03-EF01-IT02 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-19	Pozzi, T.	2003	Efficacy of IBE 3894 for aphid control on tomatoes Agricola 2000 GTO03-EF01-IT03 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-20	Bucchi, R Folini, T.	2003	Experimental field evaluation of the efficacy of IBE 3894 for aphids control on tomatoes in Italy ARA GTO03-EF01-IT04 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-21	Bucchi, R Folini, T.	2004	Efficacy of IBE 3894 for aphid control on tomatoes Agri 2000 GTO04-EF12-IT01 GEP, unpublished	Y	ISK Biosciences	Y	Y

Annex point	Author	Year	**Title** **Source Company, Report No.** GEP status, (un)published	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA 6.1.3-22	Bucchi, R Folini, T.	2004	Efficacy of IBE 3894 for aphid control on tomatoes Agri 2000 GTO04-EF12-IT02 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-23	Koutná, V	2005	Report on the results of experiments with substances for the protection of plants UKSUP I/93/05-11/I/BA-05 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-24	Folini, T.	2002	Efficacy of IBE 3894 for aphid control on tomatoes Agri 2000 GTO02-EF01-IT01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-25	Folini, T.	2002	Efficacy of IBE 3894 for aphid control on tomatoes S.P.F. GAB GTO02-EF01-IT02 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-26	Fernandez, E.	2003	Efficacy of IBE 3894 for aphid control on tomatoes Promo-Vert GTO03-EF01-ES04 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-27	Avinent, L.	2003	Efficacy of IBE 3894 for aphids, Myzus persicae, control on tomatoes Recerca Agricola GTO03-EF01-ES06 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-28	Ramos, D.	2003	Define efficacy of IBE 3894 for aphid control on tomatoes AgroSoler GTO03-EF01-ES02 GEP, unpublished	Y	ISK Biosciences	Y	Y

Annex point	Author	Year	**Title** **Source Company, Report No.** GEP status, (un)published	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA 6.1.3-29	Ramos, D.	2003	Define efficacy of IBE 3894 for aphid control on tomatoes AgroSoler GTO03-EF01-ES05 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.3-30	Prevotat, M.	2003	Field study IBE 3894 Efficacy on aphids Tomatoes (open field) Pestagro GTO03-EF01-FR51 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.1.4-01	Gingzburg, N.	2003	Processing study for determination of IKI-220 ad its metabolites TFNG, TFNA and TFNA-AM on tomatoes after two treatments of IKI-220 50% WG (IBE 3894) Battelle P-22-03-14 GLP- Unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.2.1-01	Avinent, L.	2003	Crop safety of IBE 3894 on cucumbers S.P.F. GAB GCU03-SE01-ES01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.2.1-02	Rossi, E.	2003	Selectivity IBE 3894 in melon crop following proposed GAP for aphid control S.P.F. GAB GME03-SE01-IT01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.2.1-03	Avinent, L.	2004	Crop safety of IBE 3894 on pumpkin crop in Spain Recerca Agricola GPU04-SE11-ES01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.2.1-04	Rossi, E.	2004	Selectivity IBE 3894 in zucchini crop following proposed GAP for aphid control S.P.F. GAB GSQ04-SE11-IT01 GEP, unpublished	Y	ISK Biosciences	Y	Y

Annex point	Author	Year	**Title** **Source Company, Report No.** GEP status, (un)published	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA 6.2.1-05	Avinent, L.	2003	Crop safety of IBE 3894 for tomato crop in Spain Recerca Agricola GTO03-SE01-ES01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.2.1-06	Vargas, M.A.	2003	Determine selectivity of IBE 3894 when used at proposed maximum and double rate under spray program for aphid control in tomato crop Agrosoler GTO03-SE01-ES02 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.2.1-07	Bucchi, R Folini, T.	2003	Selectivity of IBE 3894 in tomato crop following proposed GAP for aphid control Agri 2000 GTO03-SE01-IT01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.2.1-08	Rossi, E.	2003	Selectivity of IBE 3894 in tomato crop following proposed GAP for aphid control S.P.F. GAB GTO03-SE01-IT02 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.2.4-09	Leblanc, F.	1999	Etude des effets non intenntionnels d'especialetes agropharmaceutiques sur Typhlodromus pyri INRA 99-009-I-F-01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.2.6/7-01	Morita, M. Iwasa, M.	2002	Impact of IKI-220 50WG (IBE 3894) on adjacent crops and on succeeding crops Ishihara Sangyo Kaisha Ltd, Report no. AL0201-I-08 Non-GEP, unpublished	Y	ISK Biosciences	Y	Y

Annex point	Author	Year	**Title** **Source Company, Report No.** GEP status, (un)published	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA 6.4.4-01	Anonymous	1998	Sensibilite de diverses souches de poucerons, au nouvel aphicide IKI-220 de la societe ISK Biosciences INRA 98-005-I-F-01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.4.4-02	Poullot, D.	2001	Efficacité de la preparation d'essai IBE 3894 sur 3 souches de Dysaphis plantaginea Enigma 01-008-I-F-03 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.4.4-03	Poullot, D.	2002	Efficacité de la preparation d'essai IBE 3894 sur 3 souches de Myzus persicae Enigma GLB02-RS01-FR01 GEP, unpublished	Y	ISK Biosciences	Y	Y
IIIA 6.4.4-04	Poullot, D.	2004	Efficacité de la preparation d'essai IBE 3894 sur 2 souches de Myzus cerasi Enigma GCH04-RS11-FR01 GEP, unpublished	Y	ISK Biosciences	Y	Y

Stone fruit

Annex point	Author	Year	**Title** **Source Company,** **Report No.** **GEP status, (un)published**	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA1 6.0	Versmissen, C	2014	Biological Assessment Dossier for TEPPEKI in stone fruits ISK Biosciences Europe N.V -, unpublished	Y	ISK	Y	Y
IIIA 6.1.3-01	Prevotat, M.	1998	Field biological evaluation IBE 3880 aphids on peach trees Pestagro, Report no. 98-001-I-F-51 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-02	Prevotat, M.	1998	Field biological evaluation IBE 3880 aphids on peach trees Pestagro, Report no. 98-001-I-F-52 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-03	Prevotat, M.	1998	Field biological evaluation IBE 3880 aphids on peach trees Pestagro, Report no. 98-001-I-F-53 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-04	Roussel, C.H.	1998	Efficacy against aphids on peach tree Stage, Report no. 98-001-I-F-54 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-05	Touche, C.	1998	Evaluate efficacy of insecticides against aphids on peach tree Staphyt, Report no. 98-001-I-F-55 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-06	Touche, C.	1998	Evaluate efficacy of insecticides against aphids on peach tree Staphyt, Report no. 98-001-I-F-56 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-07	Touche, C.	1998	Evaluate efficacy of insecticides against aphids on peach tree Staphyt, Report no. 98-001-I-F-57 GEP / Unpublished	Y	ISK	Y	Y

Annex point	Author	Year	**Title** **Source Company,** **Report No.** **GEP status, (un)published**	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA 6.1.3-08	Chianella, M.	1998	Evaluation of efficacy of different doses of IBE-3880 for control of Myzus persicae on peach S.P.F. GAB, Report no. 98-017-I-I-01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-09	Prevotat, M.	1999	Field study IBE 3880 Peach trees Myzus persicae Pestagro, Report no. 99-001-I-F-02 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-10	Prevotat, M.	1999	Field study IBE 3880 Peach trees Myzus persicae Pestagro, Report no. 99-001-I-F-51 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-11	Touche, C.	1999	Evaluate efficacy of insecticides against aphids on peach trees Staphyt, Report no. 99-001-I-F-54 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-12	Prevotat, M.	1999	Field study IBE 3880 aphids on peach trees Pestagro, Report no. 99-002-I-F-51 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-13	Picault, F.	1999	Insecticide efficacy against aphids on peach tree Stage, Report no. 99-002-I-F-55 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-14	Bucchi, R. Manzoli, P. Berti, S.	1999	Determination of effective rate, knockdown effect and persistence of treatments with IBE 3880 for Myzus persicae (and Brachycaudus schwarzi) control on peach Agri2000, Report no. 99-009-I-I-01 GEP / Unpublished	Y	ISK	Y	Y

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IIIA 6.1.3-15	Chianella, M.	1999	Determination of effective rate, knockdown effect and persistence of treatments with IBE 3880 for control of Myzus persicae on peach Agri2000, Report no. 99-009-I-I-02 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-16	Camps, E.	1999	Define efficacy, effective rate, knockdown effect and persistence of IBE 3880 in different rates for Myzus persicae control. AgroSoler, Report no. 99-013-I-E-01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-17	Avinent, L.	1999	Define efficacy, effective rate, knockdown effect and persistence of IBE 3880 in different rates for Myzus persicae control on peach trees Recerca Agrícola, Report no. 99-013-I-E-03 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-18	Camps, E.	1999	Define efficacy, effective rate, knockdown effect and persistence of IBE 3880 in different rates for Myzus persicae control. AgroSoler, Report no. 99-013-I-E-04 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-19	Soler, J.	2000	Comparative efficacy of IBE 3894 and IBE 3880 for aphid control on peach trees AgroSoler, Report no. 00-017-I-E-01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-20	Old, J. Anderson, I.	2000	To determine the efficacy of TEPPEKI formulations for aphid control on peach trees Inveresk, Report no. 00-017-I-E-02 GEP / Unpublished	Y	ISK	Y	Y

Annex point	Author	Year	**Title** **Source Company,** **Report No.** **GEP status, (un)published**	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA 6.1.3-21	Bucchi, R. Manzoli, P.	2000	Efficacy of TEPPEKI formulations for aphid control on peach trees Agri2000, Report no. 00-017-I-I-03 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-22	Rossi, E.	2000	IBE 3894 WG Efficacy for aphid control on peach trees S.P.F. GAB, Report no. 00-018-I-I-04 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-23	Rossi, E.	2000	IBE 3894 WG Efficacy for aphid control on peach trees S.P.F. GAB, Report no. 00-018-I-I-05 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-24	Bucchi, R. Manzoli, P.	2000	Efficacy of IBE 3894 WG formulation for aphid control on peach trees Agri 2000, Report no. 00-018-I-I-06 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-25	Manzoli, P.	2000	IBE 3894 Efficacy for aphid control on peach trees Agri 2000, Report no. 01-028-I-I-01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-26	Rossi, E.	2000	IBE 3894 Efficacy for aphid control on peach trees S.P.F. GAB, Report no. 01-028-I-I-03 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-27	Folini, T.	2002	Efficacy of IBE 3894 for aphid control on peach trees Agri 2000, Report no. GPE02-EF02-IT01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-28	Rossi, E.	2002	Efficacy of IBE 3894 for aphids different than Myzus persicae on peach trees S.P.F. GAB, Report no. GPE02-EF02-IT02 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-29	Pozzi, T. Perricone, M.	2002	Efficacy of IBE 3894 for aphid control on peach trees Agricola 2000, Report no. GPE02-EF02-IT03 GEP / Unpublished	Y	ISK	Y	Y

Annex point	Author	Year	**Title** **Source Company,** **Report No.** **GEP status, (un)published**	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA 6.1.3-30	Folini, T.	2003	Efficacy of IBE 3894 for aphid control on peach trees in early spray Agri 2000, Report no. GPE03-EF02-IT01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-31	Folini, T.	2003	Efficacy of IBE 3894 for aphid control on peach trees in early sprays Agri 2000, Report no. GPE03-EF02-IT02 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-32	Rossi, E.	2000	Efficacy of IBE 3894 for aphid control on peach trees in early spray S.P.F. GAB, Report no. GPE03-EF02-IT03 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-33	Wojciech	2006	The assessment of biological efficacy of IBE-220 in the control of aphids (Aphididae) on plum tree Research Institute of Horticulture, Report no. OR/11/2006/1a/I GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-34	Wojciech	2006	The assessment of biological efficacy of IBE-220 in the control of aphids (Aphididae) on plum tree Research Institute of Horticulture, Report no. OR/11/2006/1a/II GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-35	Wojciech	2006	The assessment of biological efficacy of IBE-220 in the control of aphids (Aphididae) on plum tree Research Institute of Horticulture, Report no. OR/11/2006/1a/III GEP / Unpublished	Y	ISK	Y	Y

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IIIA 6.1.3-36	Wojciech	2006	The assessment of biological efficacy of IBE-220 in the control of aphids (Aphididae) on plum tree Research Institute of Horticulture, Report no. OR/11/2006/1a/IV GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-37	Maciesiak, A	2007	The assessment of biological efficacy of IBE-3894 500 WG in the control of aphids (Aphididae) on plum tree Research Institute of Pomology and Floriculture, Report no. OR/10/2007/1/II GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-38	Maciesiak, A	2007	The assessment of biological efficacy of IBE-3894 500 WG in the control of aphids (Aphididae) on plum tree Research Institute of Pomology and Floriculture, Report no. OR/10/2007/1/I GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-39	Wojcieh	2013	The control of aphids on plum trees (IBE 3894 WG I Ibe 4084 100 OD) Research Institute of Horticulture, Report no. OR/23/2013/1/I GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-40	Jozefiak, D	2005	Report on results of plant protection product tests UKSUP, Report no. I/93/05-161/KE-05 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-41	Touche, C.	2001	Efficacy evaluation of insecticide products against aphids in plum trees orchard Staphyt, Report no. 01-004-I-F-51 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-42	Prevotat, M.	2001	Field study IBE 3880 aphids on plum trees Pestagro, Report no. 01-004-I-F-52 GEP / Unpublished	Y	ISK	Y	Y

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IIIA 6.1.3-43	Soler, J.	2001	Determine efficacy of IBE 3894 at different rates and compare to an official standard for aphid control on plum AgroSoler, Report no. 01-028-I-E-02 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-44	Serrano, C.	2001	To evaluate the efficacy of IBE 3894 for aphid control on plum trees TrialCamp, Report no. 01-028-I-E-03 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-45	Vargas, M.	2002	Efficacy of IBE 3894 for aphid control on plum trees AgroSoler, Report no. GPL02-EF01-ES01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-46	Serrano, C.	2002	Study the efficacy of IBE 3894 for aphid control on plum trees Trial Camp, Report no. GPL02-EF01-ES02 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-47	Touche, C.	2002	Determine efficacy of IBE 3894 at different rates and compare to an official standard for aphid control on plum-trees Staphyt, Report no. GPL02-EF01-FR51 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-48	Prevotat, M.	2002	Field study IBE 3894 aphids on plum trees Pestagro, Report no. GPL02-EF01-FR52 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-49	Folini, T	2002	Efficacy of IBE 3894 for aphids control on plum trees Agri 2000, Report no. GPL02-EF01-IT01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-50	Rossi, E.	2002	Efficacy of IBE 3894 for aphid control on plum trees S.P.F. GAB, Report no. GPL02-EF01-IT02 GEP / Unpublished	Y	ISK	Y	Y

Annex point	Author	Year	**Title** **Source Company,** **Report No.** **GEP status, (un)published**	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA 6.1.3-51	Avinent, L.	2003	Efficacy of IBE 3894 for the control of aphids on plum trees Recerca Agricola, Report no. GPL03-EF01-ES01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-52	Avinent, L.	2003	Efficacy of IBE 3894 for the control of aphids on plum trees Recerca Agricola, Study GPL03-EF01-ES02 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-53	Bucchi, R Folini, T.	2003	Efficacy of IBE 3894 for aphid control on plum trees Agri 2000, Report no. GPL03-EF01-IT01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-54	Vargas, M.	2003	Efficacy of IBE 3894 for aphid control on plum trees AgroSoler, Report no. GPL03-EF02-ES01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-55	Serrano, C.	2003	Efficacy of IBE 3894 for aphid control on plum trees in early sprays Trial Camp, Report no. GPL03-EF02-ES02 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-56	Vargas, M.	2003	Determine efficacy of IBE 3894 in early sprays (pre-bloom) for aphid control on plum trees AgroSoler, Report no. GPL03-EF02-ES03 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-57	Rossi, E.	2003	Efficacy of IBE 3894 for aphid control on plum trees in early sprays S.P.F. GAB, Report no. GPL03-EF02-IT02 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-58	Maciesiak, A	2007	The assessment of biological efficacy of IBE-3894 500 WG in the control of black cherry aphid (*Myzus cerasi*) on sweet cherry tree Research Institute of Pomology and Floriculture, Report no. OR/10/2007/2II GEP / Unpublished	Y	ISK	Y	Y

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IIIA 6.1.3-59	Maciesiak, A	2007	The assessment of biological efficacy of IBE-3894 500 WG in the control of black cherry aphid (*Myzus cerasi*) on sweet cherry tree Research Institute of Pomology and Floriculture, Report no. OR/10/2007/2IV GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-60	Maciesiak, A	2007	The assessment of biological efficacy of IBE-3894 500 WG in the control of black cherry aphid (*Myzus cerasi*) on sweet cherry tree Research Institute of Pomology and Floriculture, Report no. OR/10/2007/2I GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-61	Maciesiak, A	2007	The assessment of biological efficacy of IBE-3894 500 WG in the control of black cherry aphid (*Myzus cerasi*) on sour cherry tree Research Institute of Pomology and Floriculture, Report no. OR/10/2007/2III GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-62	Imbert, G.C.	2003	Efficacy of IBE 3894 at 0.008 and 0.014 Kg/Hl straight on Myzus cerasi /Cherry tree Agrolis Consulting, Report no. GCH03-EF01-FR51 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-63	Imbert, G.C.	2004	Efficacy of IBE 3894 at 0.008 and 0.014 Kg/Hl straight on Myzus cerasi /Cherry tree Agrolis Consulting, Report no. GCH04-EF01-FR51 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-64	Touche, C.	2004	Efficacy of IBE 3894 for aphid control on cherry trees Staphyt, Report no. GCH04-EF01-FR52 GEP / Unpublished	Y	ISK	Y	Y

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IIIA 6.1.3-65	Filleron, E.	2005	Essay d'efficacite de l'insecticide IBE 3894 contre le puceron noir du cerisier La Tapy, Report no. GCH05-EF01-FR51 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.3-66	Imbert, G.C.	2005	Efficacy of IBE 3894 at 0.008 and 0.014 Kg/Hl straight on Myzus cerasi /Cherry tree Agrolis Consulting, Report no. GCH05-EF01-FR52 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.4.2-01	Gingzburg, N.	2001	Processing study for determination of TEPPEKI ad its metabolites TFNG, TFNA and TFNA-AM on peaches after two treatments of TEPPEKI (IBE 3894) Battelle, Report no. P-22-01-02 GLP- Unpublished	Y	ISK	Y	Y
IIIA 6.1.4.2-02	Seck, C.	2005	Processing study for determination of TEPPEKI ad its metabolites TFNG, TFNA and TFNA-AM on peaches after two treatments of TEPPEKI (IBE 3894) (study no. P-22-05-13) Battelle, Report no. P-22-06-15 GLP / Unpublished	Y	ISK	Y	Y
IIIA 6.1.4.2-03	Seck, C.	2005	Determination of TEPPEKI ad its metabolites TFNG, TFNA and TFNA-AM in plums and in processed commodities Battelle, Report no. P-22-05-13 GLP- Unpublished	Y	ISK	Y	Y
IIIA 6.2.1-01	Bonnamour, O.	1999	Selectivity of insecticide on peach tree Stage, Report no. 99-003-I-F-51 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.2.1-02	Prevotat, M.	2000	Field Study IBE 3894 Peach trees Crop susceptibility Pestagro, Report no. 00-006-I-F-51 GEP / Unpublished	Y	ISK	Y	Y

Annex point	Author	Year	**Title** **Source Company,** **Report No.** **GEP status, (un)published**	Data protection claimed Y/N	Owner	Used	Data protection granted Y/N
IIIA 6.2.1-03	Schroth, E.	2001	Selectivity of the insecticide IBE 3894 after two applications at different doses in peach trees Agrología, Report no. 01-001-I-E-01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.2.1-04	Soler, J.	2001	Crop safety of IBE 3894 on nectarine AgroSoler, Report no. 01-001-I-E-02 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.2.1-05	Manzoli, P.	2001	Crop safety of IBE 3894 on peach tree Agri 2000, Report no. 01-001-I-I-01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.2.1-06	Pozzi, T., M.Tonni	2001	Crop safety of IBE 3894 on peach trees Agricola 2000, Report no. 01-001-I-I-02 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.2.1-07	Prevotat, M.	2001	Field Study IBE 3894 Peach trees Crop susceptibility Pestagro, Report no. 01-002-I-F-51 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.2.1-08	Avinent, L.	2001	Crop safety of IBE 3894 on nectarine trees: Fruit setting Recerca agricola, Report no. 01-003-I-E-01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.2.1-09	Chianella, M	2001	Crop safety of IBE-3894 WG for peach trees: fruit setting S.P.F. GAB, Report no. 01-003-I-I-01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.2.1-10	Bucchi, R. Folini, T.	2003	Crop safety of IBE 3894 on plum trees Agri2000, Report no. GPL03-SE01-IT01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.2.1-11	Avinent, L.	2003	Crop safety of IBE 3894 on plum trees Recerca Agricola, Report no. GPL03-SE01-ES01 GEP / Unpublished	Y	ISK	Y	Y

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IIIA 6.2.1-12	Vargas, M.A.	2003	Measure incidence on plum trees of IBE 3894 applications versus standard. Selectivity study where IBE 3894 is applied at maximum and double recommended rate with proposed munber of sprays AgroSoler, Report no. GPL03-SE01-ES02 GEP / Unpublished	Y	ISK	Y	Y
IIIA, 6.2.7	Morita, M. Iwasa, M.	2002	Impact of TEPPEKI 50WG (IBE 3894) on adjacent crops and on succeeding crops Ishihara Sangyo Kaisha Ltd, Report no. AL0201-I-08 Non-GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.4.4-01	Anonymous	1998	Sensibilite de diverses souches de poucerons, au nouvel aphicide TEPPEKI de la societe ISK Biosciences INRA, Report no. 98-005-I-F-01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.4.4-02	Poullot, D.	2001	Efficacité de la preparation d'essai IBE 3894 sur 3 souches de Dysaphis plantaginea Enigma, Report no. 01-008-I-F-03 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.4.4-03	Poullot, D.	2002	Efficacité de la preparation d'essai IBE 3894 sur 3 souches de Myzus persicae Enigma, Report no. GLB02-RS01-FR01 GEP / Unpublished	Y	ISK	Y	Y
IIIA 6.4.4-04	Poullot, D.	2004	Efficacité de la preparation d'essai IBE 3894 sur 2 souches de Myzus cerasi Enigma, Report no. GCH04-RS11-FR01 GEP / Unpublished	Y	ISK	Y	Y