

The justification for an emergency application for Benevia against *Drosophila suzukii* in straw berries and against cabbage flies, onion flies and thrips in cabbages and onions is confirmed by the Authorisation board after consultation of the Regions.

Taking into account the following considerations:

- Lack of alternatives for controlling these pests
- Limited surface
- In all crops except leek, the existing MRLs covers the uses applied for. For leek the present MRL will not cover the use. France applied for an higher MRL that has been voted already. Since the emergency authorisation only starts at August 15, the harvested leek will comply to the “new” MRL that will be applicable at that time.
- The Authorisation board decides to enforce the most severe risk mitigation measures to protect aquatic organisms: 20m and 99% of drift reduction

The authorisation board decides to grant this authorisation for Benevia

Dossier Summary for the Board of Authorisations:

Produit	Benevia		
Substance active	100 g/l cyantraniliprole		
Statut de la substance active	Approuvée (>>14/09/2026)		
Culture(s) concernée(s)	Fraises, choux, navets, chou-navets, oignons, oignons de printemps, poireaux		
Ennemi(s)	Drosophila suzukii, mouche du chou, mouche de l'oignon et Thrips		
contexte	Drosophila suzukii est une espèce invasive récente dont la progression évolue et provoquant d'importants dégâts dans les cultures concernées. Les autres ennemis sont également fortement présents avec notamment un niveau élevé en thrips en 2017 demandant un contrôle renforcé.		
Importance du problème	Strawberries:	1.976 ha (2017)	45.000 ton (2016)
	Swedes/turnips	575 ha (2017)	20.775 ton (2016)
	Cauliflower:	5.595 ha (2017)	109.435 ton (2016)
	Broccoli:	225 ha (2017)	2.662 ton (2016)
	Brussels sprouts:	2.550 ha (2017)	37.680 ton (2016)
	Head cabbage:	1.140 ha (2017)	54.675 ton (2016)
	Kohlrabi:	125 ha (2017)	12.760 ton (2016)
	Onions:	3.760 ha (2017)	130.775 ton (2016)
	Spring onions:	small acreage (no detailed statistics available)	

	Leek 3.825 ha (2016) 4.150 ha (2017) 99.650 ton (2016)
Alternative ?	<p>Fraises : Des produits à base de lambda-cyhalothrine et spinosad sont autorisés mais ne permettraient pas un contrôle suffisant de l'ennemi.</p> <p>Mouche du chou : sa autorisées dans certaines cultures spinosad, lambda-cyhalothrine, pyrèthrine, chlorpyrifos (pour certains choux).</p> <p>Mouche de l'oignon : pas de produit autorisé.</p> <p>Thrips : methiocarb, spinosad, pyrethrins et abamectine</p> <p>Mais dans l'ensemble les alternatives ne seraient pas suffisantes et un contrôle plus important serait nécessaire.</p>
Agréation classique	La procédure d'autorisation zonale du produit est en cours (zRMS=UK). Nous sommes cMS (dossier reçu le 17/08/2015).
Confirmation du besoin effectif de la pratique par les régions	Les régions ont confirmé l'intérêt de discuter de cette demande.
Conclusion des experts	<p>Analyse:/</p> <p>Toxicologie : classification</p> <p>Résidus : Positive for strawberries, broccoli, cauliflower, Brussels sprouts, head cabbage, kohlrabi, swedes, turnips, onions and spring onion. To be discussed for leek</p> <p>Comportement dans l'environnement : positif</p> <p>Ecotoxicologie : négatif</p> <p>Biologie:/</p>

DUPONT™ BENEVIA®**Type of product**

Insecticide

Formulation type

OD : oil dispersion

Active substance(s) and content

100 g/l cyantraniliprole

Formulation code

(development code)

Application for authorization for 120 days (Art. 53 – Emergency situations in plant protection products – Regulation 1107/2009)**Requested application period** 120-days: from **15/06/2018 till 15/10/2018****Destination** Professional use**Status of active substance** Cyantraniliprole is on annex I, [Reg. \(EU\) 2016/1414](#), [Reg. \(EU\) No 540/2011](#), expiration of approval 14/09/2026**Problem description** (all sections below should be completed by the applicant):

Cyantraniliprole is an active substance with good efficacy against *Drosophila suzukii*, cabbage fly, onion fly and thrips. For the requested product, Benevia is an evaluation procedure ongoing, but this will not result in an authorization for season 2018.

This request for a 120-days regulation is needed in cabbages to control cabbage fly, during production time in combination with the earlier authorized product Verimark 20 SC, which is used at the start of production (tray application).

Benevia is needed in strawberries to control *Drosophila suzukii* and Benevia is needed in onions and spring onions against onion fly.

For control of thrips in leek and spring onions is Benevia also needed.

In attachment: (available on: G:\DG4\DIVISION1\Phyto\11 Agrégations nationales\1119 Emergency Authorisations (120days)\DOSSIERS\cyantraniliprole\2018\Benevia)

- Zonal dossier is ongoing, with UK as zRMS and Belgium as concerned MS – dossier number: N29321 – sent by DUPONT (now FMC) and available on CIRCA.
- 120 days authorisation in France
- Emergency use in NL, 2017 - <https://zoek.officielebekendmakingen.nl/stcrt-2017-33059.pdf>
- Overview of trials
- Trial at PSKW, 2015: Control of cabbage fly in turnips, late cultivation – reference: rp15drmi
- EFSA Journal 2018;16(1):5124: Reasoned opinion Setting of a maximum residue level for cyantraniliprole in leeks - <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5124/epdf>

<p>Danger (<i>pest name EPPO, English and scientific</i>) <i>Group names only acceptable in case of approved substances</i>)</p>	<p>On strawberries: <i>Drosophila suzukii</i> - DROSSU</p> <p>On cabbages as broccoli, cauliflower, Brussels sprouts, head cabbages, kohlrabi, swedes and turnips <i>Delia radicum</i> - cabbage fly – HYLERA</p> <p>On Onions: <i>Delia antiqua</i> – onion fly – HYLEAN On Spring onions: <i>Delia antiqua</i> (onion fly – HYLEAN) and thrips – (<i>Thysanoptera</i> - 1THYSO)</p> <p>On Leek: Thrips – <i>Thysanoptera</i> - 1THYSO</p>
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<p>Crop, plants or situation (<i>crop or plant name EPPO, English; no group names</i>)</p>	<p>0152000 - Strawberries (<i>Fragaria ananassa</i>) - FRAAN</p> <p>0213100 Swedes (<i>Brassica napus var. Napobrassica</i>) - BRSNA 0213110 Turnips (stoppelraap, meiraap) (<i>Brassica rapa subsp. rapa</i>) - BRSRR</p> <p>0241010 – Broccoli (<i>Brassica oleracea var. italic</i>) - BRSOK 0241020 – Cauliflower (<i>Brassica oleracea var. botrytis</i>) - BRSOB 0242010 - Brussels sprouts (<i>Brassica oleracea var. gemmifera</i>) - BRSOF 0242020 - Head cabbage (<i>Brassica oleracea var. capitata</i>) – BRSOL 0244000 – Kohlrabi (<i>Brassica oleracea var. gongylodes</i>) - BRSOG</p> <p>0220020 - Onions (<i>Allium cepa</i>) – ALLCE 0220040 – Spring onions (<i>Allium fistulosum/ A. cepa</i>) – ALLFI</p> <p>0270060 – Leek (<i>Allium porrum</i>) - ALLPO</p>
<p>Minor or major use (<i>Indicate if the use is considered to be minor</i>)</p>	<p>Minor use for the requested crops</p>
<p>Further limitations (<i>e. g. amount of product, restriction to certain regions or individual sites, conditions to be checked by regional plant protection service</i>)</p>	<p>/</p>
<p>MRL: Reference to product code number in Annex I of regulation (EC) No 396/2005</p>	<p>0152000 - Strawberries</p> <p>0213100 – Swedes 0213110 - Turnips</p> <p>0241010 – Broccoli 0241020 – Cauliflower 0242010 - Brussels sprouts 0242020 - Head cabbage 0244000 – Kohlrabi</p> <p>0220020 – Onions 0220040 – Spring onions</p>

	0270060 – Leek
Compliance with MRL set in Regulation (EC) No 396/2005 (<i>yes/no; if no, complete attached GAP table and provide proposal for tMRL and consumer risk assessment</i>)	<p>YES</p> <p>Remark for leeks:</p> <p>EFSA Journal 2018;16(1):5124: Reasoned opinion Setting of a maximum residue level for cyantraniliprole in leeks - http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5124/epdf</p>
Value of tMRL if needed , including information on the measures taken in order to confine the commodities resulting from the treated crop to the territory of the notifying MS pending the setting of a tMRL on the EU level. (PRIMO EFSA model to be attached)	/
Validated analytical method for monitoring of residues in plants and plant products.	<p>Source: EFSA: Peer review of the pesticide risk assessment of the active substance cyantraniliprole</p> <p>EFSA Journal 2014;12(9):3814: http://www.efsa.europa.eu/en/efsajournal/pub/3814.htm</p> <p><i>1. Identity, physical/chemical/technical properties and methods of analysis</i> <i>The following guidance documents were followed during the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000), Sanco/10597/2003 – rev. 10.1 (European Commission, 2012), SANCO/825/00 rev. 8.1 (European Commission, 2010).</i> <i>The minimum purity of the active substance as manufactured is 940 g/kg. Impurities IN-Q6S09, IN-RYA13, methanesulfonic acid, acetonitrile, heptane and 3-picoline were considered relevant with no toxicological concern at the levels present in the technical material (see section 2). The levels should be considered provisional as a data gap has been identified for a revised technical specification.</i> <i>The main data regarding the identity of cyantraniliprole and its physical and chemical properties are given in Appendix A.</i> <i>The formulations were fully supported and no data gaps were identified.</i> <i>The residue definition for all matrices is cyantraniliprole only. LC-MS/MS methods are available for products of animal and plant origin, soil, water and air. A method of analysis for body fluids and tissues is not required as the active substance is not proposed for classification as toxic or very toxic.</i></p>
Function of the product (<i>E.g. systemic long acting insecticide; foliar fungicide, used for</i>	<p>Insecticide to control:</p> <p>- <i>Drosophila suzukii</i> in strawberries</p>

<p><i>regular control, elimination scenario etc)</i></p>	<ul style="list-style-type: none"> - <i>Delia radicum</i> (cabbage fly) in swedes, turnips, cauliflower, broccoli, Brussels sprouts, head cabbages and kohlrabi - <i>Delia antiqua</i> (onion fly) in onions and spring onions - <i>Thrips</i> in spring onions and leek
<p>Type of danger to plant production or ecosystem. <i>(Provide reasoning for what category the 120 day authorisation is given: quarantine pest; emergent pest, either invading non-native, or native; emerging resistance in a pest, etc. Whereas reference to the EU quarantine legislation may suffice for quarantine pests elaborate reasoning should be provided for the category 'any harmful pest')</i></p>	<p><u><i>Drosophila suzukii</i> in strawberries:</u></p> <p><i>Since 2011, <i>Drosophila suzukii</i> is present in Belgium and is a very invasive pest. <i>D. suzukii</i> is one of the very few <i>Drosophila</i> species which are able to feed on healthy ripening fruit while they are still attached to the plant. Damage is caused by larvae feeding on fruit pulp inside the fruit and berries. Very rapidly, infested fruit begin to collapse around the feeding site. Thereafter, secondary fungal or bacterial infections may contribute to further fruit deterioration (i.e. rotting). Reproduction in <i>Drosophila</i> species is particularly rapid with a short life cycle of 1 to 2 weeks depending of the climatic conditions, therefore a single pair of flies can produce hundreds of offspring within a couple of weeks.</i></p> <p>2017: in the context of the IWT-project (IWT/LATR/135079) was the monitoring ongoing. Winter 2016-2017 was not really cold. A lot of <i>Suzukii</i> fruit flies could overwinter, which resulted already at the beginning of 2017 in high numbers of monitored fruit flies. The numbers counted in cherry orchards were 5 to 10 times higher in comparison with the same time a year before.</p> <p>Each year is noticed that more female flies than male flies are caught just after winter time. About 3 to 20 times more female flies. Further in the season, in July the number of monitored male flies is again increasing. It's assumed that especially female flies overwinter. With the high temperatures of springtime in 2017, the first ripened eggs were observed at the end of March. Which is almost one month earlier than in 2016.</p> <p>From the results of the monitoring in 2017: the first eggs of <i>Drosophila suzukii</i> were seen in March 2017 and about 7 generations of <i>Drosophila</i> were detected. One generation more than in 2016, because of the extreme early development of the <i>suzukii</i> fly in spring 2017.</p> <p><i>D. suzukii</i> is a threat for stone fruits and all small fruits, including strawberries.</p> <p>Remark: Data for cyantraniliprole, formulation Exirel are available for cherries and berries, but data for strawberries are only available for the formulation Benevia. Cfr request of a 120-days regulations for Exirel in cherries, plums, grapes, kiwiberries, berries, raspberries and blackberries.</p> <p><u>Cabbage fly in cabbages:</u></p>

Since many years is cabbage fly in cauliflower, broccoli, Brussels sprouts, head cabbages and kohlrabi a very serious problem. On 29th of November 2017, at het annual meeting for minor uses of outdoor vegetables, cabbage flies were again of a very high priority. Also at the European meetings is finding a solution against cabbage a priority.

The larvae of cabbage fly feed on the roots and on the buttons of Brussels sprouts, with yield reduction as result. More severe infestations cause stunting, bluish or purple/red discoloration of the leaves, plants may wilt and die. Infested buttons will rot.

Life cycle:

Each year, there are 2 or 3 generations, starting from emergence and egg laying in April and extending, with some overlapping into September.

Eggs are laid at the feet of the plant, where larvae tunnel into the roots. This cause growth retardation and infested plants become more sensitive to dryness. With the development of the cabbage the plant falls down.

But in Brussels sprouts may eggs also be laid on the lower buttons and larvae tunnel into the sprouts.

Early damage to the sprouts is not visible from the outside, but as the larvae mature they tunnel out and drop into the soil to pupate. At this stage is damage noticeable. Brussels sprouts maturing from August to the end of October are most at risk. Specially this late cabbage fly is very difficult to control. A tray application at the beginning of the growing season isn't enough to control cabbage fly till the end of the season.

In Belgium, the control of cabbage fly is based on the monitoring of adult cabbage flies and eggs at different fields in the most important production regions of Flanders. At each observation field, 3 traps are placed on a row, above the crop with an interlace of 25 meter. When the damage threshold of 15 flies/trap is exceeded, a control treatment is necessary.

This work is done by the research station Inagro, PSKW and PCG. During a growing season monitoring is performed at a frequency of 3 counts in 2 weeks and afterwards a warnings message is sent to producers.



Foto 1



Foto 2



Foto 3

Foto 1: a trap in a field of Brussels sprouts

Foto 2: damage caused by cabbage flies

Foto 3: An infested button of Brussels sprouts

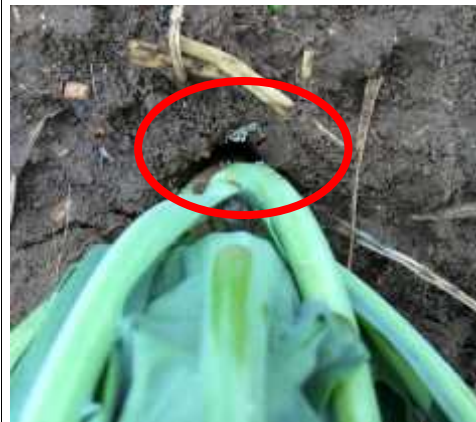


Foto 4: Eggs at the feet of the plant



Foto 5: Larvae at the feet of the plant

Observations of cabbage fly in Brussels sprouts in 2015:

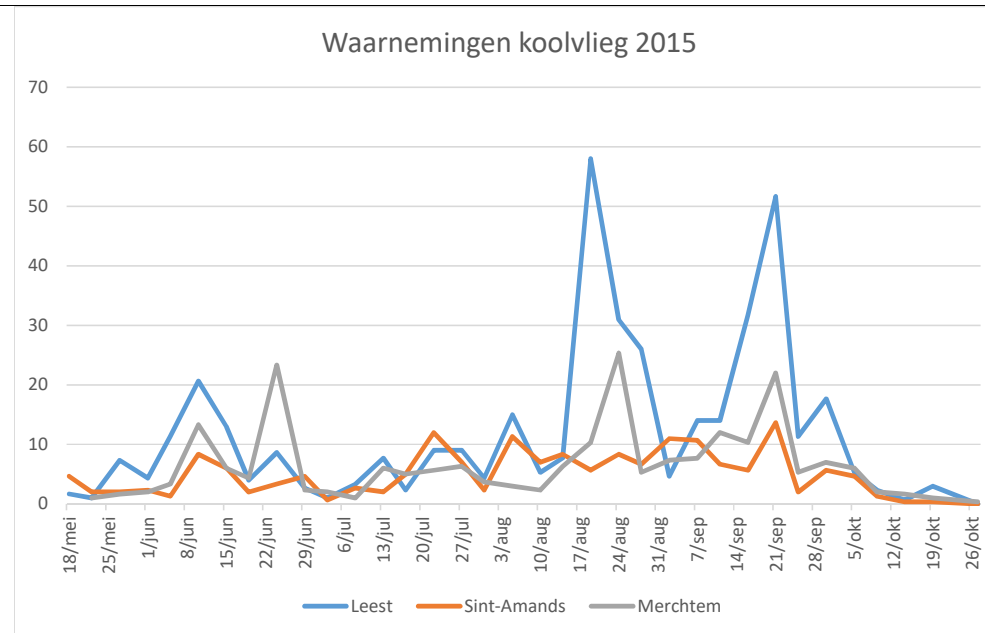


Figure 1: Monitoring results of cabbage fly in Brussels sprouts in 2015 at 3 different locations, PSKW 2015.

From the beginning till the end of the culture cabbage flies were detected.

The first peak was in June. The most important peaks were monitored after half of August. At that time, control of cabbage fly was necessary. And also in September was a peak of cabbage flies monitored at each of the 3 fields. Less flies were detected at the end of September.

Observations of cabbage fly in Brussels sprouts in 2016:

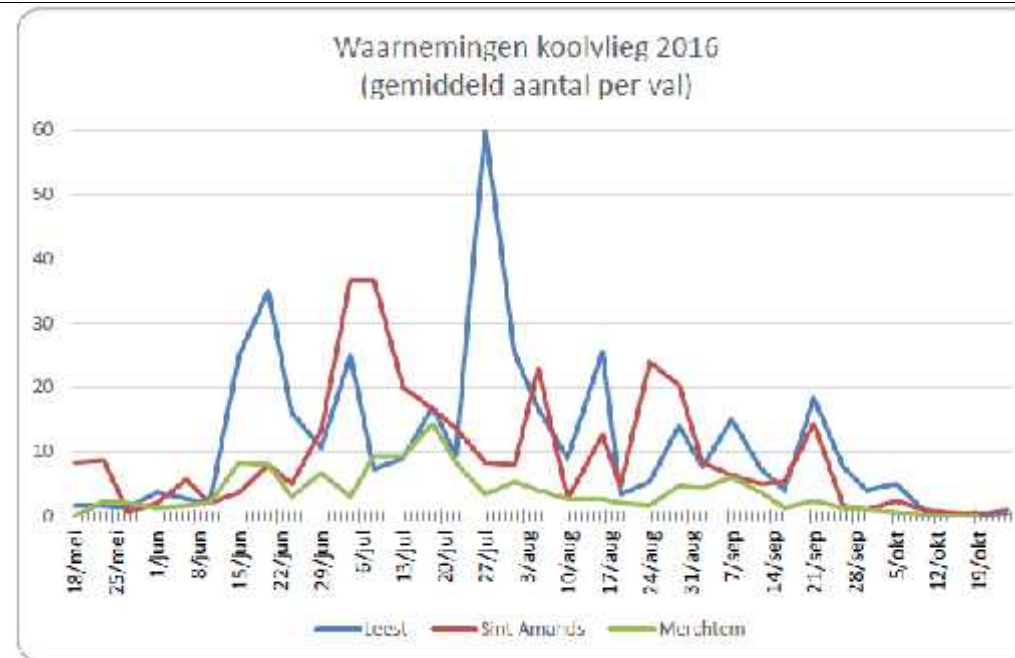


Figure 2: Monitoring results of cabbage fly in Brussels sprouts in 2016 at 3 different locations, PSKW 2016.

From planting time (18 may) till the end of the culture (end of October) cabbage flies were detected. The first peak was in June. The most important peaks were monitored in July and August. At that time, control of cabbage fly was necessary. And also in September was a peak of cabbage flies monitored at each of the 3 fields. Less flies were detected at the end of September.

Observations of cabbage fly in Brussels sprouts in 2017:

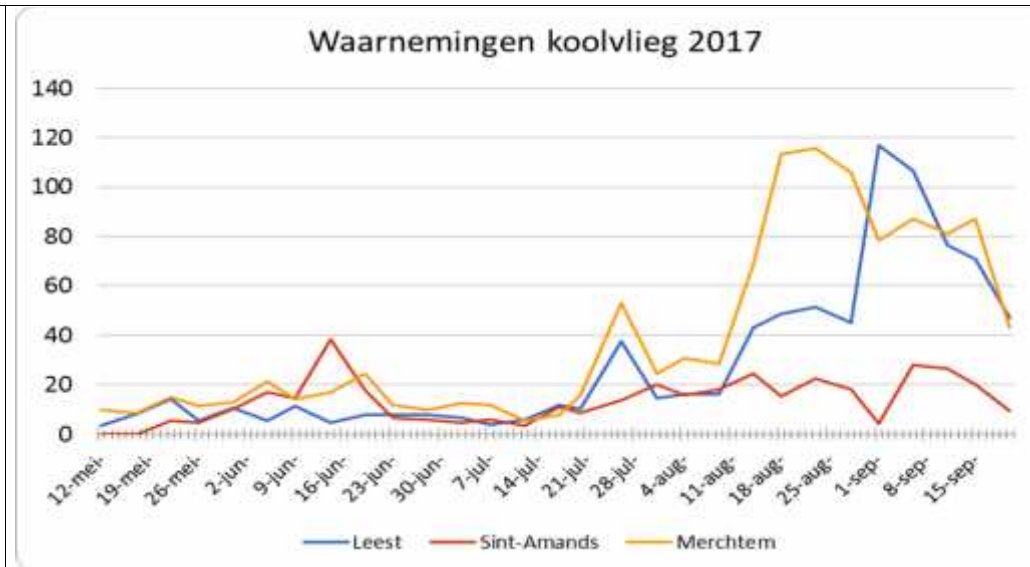


Figure 7: Monitoring results of cabbage fly in Brussels sprouts in 2017 at 3 different locations, PSKW 2016.

This are the counts of adult cabbage flies during a whole season. Mid June, there is a first peak. Afterwards is the infestation lower till the end of July. The whole summer were cabbage flies monitored at high amounts (above the damage threshold of 15 flies/trap). A third peak is at the end of August and begin of September.

It's necessary to control as good as possible the first peak of cabbage fly, to avoid damage and to avoid building up a population of cabbage fly. The first peak can be controlled with a tray application, but each year is also a second and a third peak monitored.

Depending on the year, these 2 peaks are noticed in July and August and sometimes in September. So the tray application isn't sufficient to control cabbage fly, afterwards an application with lambda-cyhalothrin or cyantraniliprole is needed.

REMARK: For **kohlrabi** is only the tray application with spinosad available. So, without an authorisation of Benevia, is no treatment possible against the second and third peak.

Swedes and turnips



Foto 6: Damage of cabbage fly in swedes., foto CTIFL

Cabbage fly is not only a problem in cabbages also in swedes and turnips. The control of cabbage fly is very difficult in swedes and turnips. No tray application is possible, so only spray application with a pyrethroïd and spray application with spinosad, which is less efficacy than a tray application.

Onion fly

Damage of onion fly is caused by larvae boring into the base plate and roots followed by secondary breakdown of tissues either in the field or during storage.

Each year, there are 2 or 3 generations. Late-generation pupae overwinter in the soil. The first flies are monitored at the end of April or begin of Mai. The eggs are laid in the ground, near young plants or between the shoots of bulbs. The larvae are white and cylindrical and hatch in 3 to 8 days. The larvae create large cavities in bulbs and roots. The first generation of larvae is the most harmful, because it occurs when the plants are small. Seedlings of onions/spring onions can be severely affected. The leaves start to turn yellow and the bulbs rot quickly or will be malformed.

Thrips in leek and spring onions

In Flanders, the control of thrips is based on a monitoring system with advice. The system is based on a prediction model with temperature sums and based on counts on sticky plates on 16 locations of leek fields. For 2017 were 12 advices of treatment given in West-Flanders and in East-Flanders and Antwerp were 10 advices of treatment given.

The pressure of thrips was extremely high in 2017: mean counts of 100 to 350 thrips a week on a sticky plate. Specifically in West-Flanders were peaks counted of 600 thrips on a sticky plate.

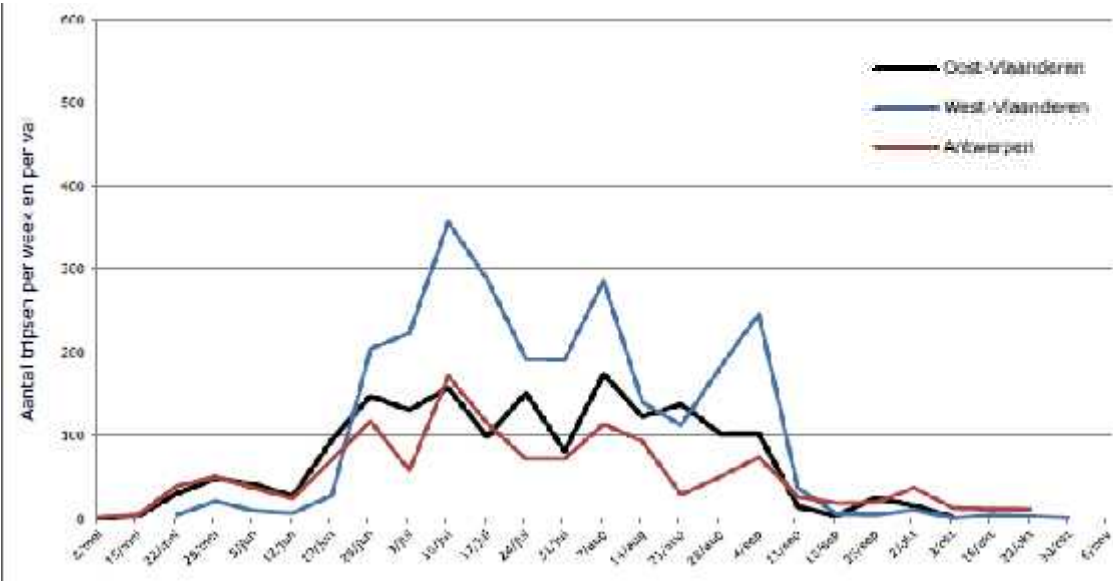


Figure 8: Monitoring results of thrips in leek in 2017, mean counts for West-Flanders, East-Flanders and Antwerp, PCG.

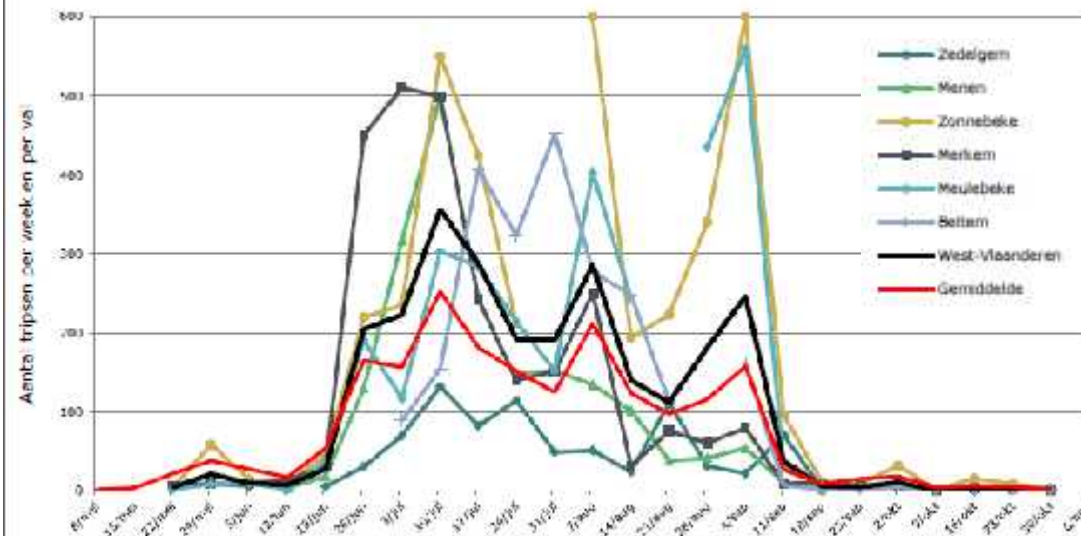


Figure 9: Monitoring results of thrips in leek in 2017, counts in West-Flanders at different locations, PCG.

Because of the high pressure of thrips it is necessary to treat on a sowing bed and afterwards on the production fields.

Size and effect of danger (Describe shortly the area affected, the development over time of the infestation, and the agronomic and economic effects it has)

Strawberries:	1.900 ha (2016)	1.976 ha (2017)	45.000 ton (2016)
Swedes/turnips	565 ha (2016)	575 ha (2017)	20.775 ton (2016)
Cauliflower:	5.265 ha (2016)	5.595 ha (2017)	109.435 ton (2016)
Broccoli:	242 ha (2016)	225 ha (2017)	2.662 ton (2016)
Brussels sprouts:	2.130 ha (2016)	2.550 ha (2017)	37.680 ton (2016)
Head cabbage:	1.055ha (2016)	1.140 ha (2017)	54.675 ton (2016)
Kohlrabi:	116 ha (2016)	125 ha (2017)	12.760 ton (2016)
Onions:	2.955 ha (2016)	3.760 ha (2017)	130.775 ton (2016)
Spring onions:	small acreage (no detailed statistics available)		
Leek	3.825 ha (2016)	4.150 ha (2017)	99.650 ton (2016)
VBT-data, annual statistics – production data of 2016 are not yet available			

For damage in strawberries, there is a zero tolerance. If strawberries are infected with *Drosophila suzukii*, the production is completely lost. It's not possible to bring any kind of soft fruit with a *Drosophila suzukii* infestation on the market, even not on a lower quality class. The damage is estimated on 20-80 % of the whole production of soft fruits in Belgium.

For damage of cabbage fly or onion fly, there is a zero tolerance. If buttons of Brussels sprouts or cabbages are infested with cabbage fly, the buttons/cabbage can't be sold on the market, even not in a lower quality class. Also for onions: onions with a noticeable infection of onion fly can't be sold and infected onions in storage are also lost, because they will rot.

Thrips damage in leek and spring onions, becomes visible as silver-white stripes and in circumstances with a high pressure it looks like white spots.



Foto 7: Thrips damage in leek



Foto 8: Sticky plate in leek

Absence of any other reasonable means
(Describe the alternative control measures (chemical, non-chemical and cultural) and indicate why they do not (in combination) suffice. Describe which, if any, authorisations for the pest to be controlled

From **small fruit growers** there is an urgent call for the authorization of another active substance to control the invasive pest of *Drosophila suzukii* in **strawberries**.

Strawberries:

Spinosad [IRAC, 5] and lambda-cyhalothrin [IRAC, 3A] are authorized.

<p><i>exist in other Member States.</i></p>	<p>Because of the very short life cycle of <i>Drosophila suzukii</i>, it's very important to have another active substance available with good efficacy and different modes of action, to avoid resistance. Cyantraniliprole belongs to resistance group [28], so will be a good active substance to alternate.</p> <p>On 29th November 2017, at the annual meeting for minor uses on outdoor vegetables there was an urgent call for the authorization of another active substance to control cabbage fly in cauliflower, broccoli, Brussels sprouts, head cabbages, kohlrabi, swedes and turnips and onion fly in onions, spring onions and thrips in spring onions and leeks.</p> <p>Since 10/02/2017, the withdrawal of chlorpyrifos and since 14/3/2017 the withdrawal of dimethoate, a lot of growers are worried about the control of cabbage fly in season 2017.</p> <p><u>Brussels sprouts, head cabbages, cauliflower and broccoli:</u> Authorized active substances to control cabbage fly:</p> <p>Chlorpyrifos: withdrawal in 2017 Dimethoate: redrawn in 2017 Spinosad [IRAC, 5]: an application before planting (tray application) or 1 application after planting is authorised Lambda-cyhalothrin [IRAC, 3A]: authorized in Brussels sprouts, head cabbages and cauliflower – not in broccoli, phi of 7 days, but with a negative effect on beneficials.</p> <p><u>Kohlrabi:</u> <u>Chlorpyrifos</u>: withdrawal in 2017 Spinosad [IRAC, 5]: as tray application before planting</p> <p>The withdrawal of chlorpyrifos and dimethoate means that only spinosad (not in kohlrabi) and a pyrethroid are available in cabbages. But these active substances are not enough to control the cabbage fly in different cabbages. In one season are 3 peaks of cabbage fly monitored, so an active substance as cyantraniliprole with another mode of action [IRAC, 28] is needed to control cabbage fly during a growing season.</p> <p>It's very important to have an active substance available with good efficacy and different modes of action, to avoid resistance.</p> <p><u>Swedes and turnips</u></p>
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Chlorpyrifos: withdrawal in 2017
 Lambda-cyhalothrin [IRAC, 3A]:
 Spinosad [IRAC, 5], but only as spray application, not authorized as a tray application which is more efficient, cfr cabbages.

Just before the first peak of cabbage fly can a cover with nets help to avoid infestation by cabbage fly. But this is a lot of work and is maybe only realistic for smaller fields. Another difference is a change of climate under the nets and more risk for fungi infections. Next to the positive results with the nets is also an active substance needed for the last period of cultivation.

Onions:

Authorized active substances to control onion fly:
 Fipronil : as seed treatment (Mundial), but end date of use was 1/06/2017.
 Dimethoate: withdrawal 2017
 Actually are no active substances authorized against onion fly.

Spring onions and leek:

Authorized active substances to control thrips in leek and spring onions:
 Methiocarb, spinosad, pyrethrins and abamectine are authorized, but with a limited number of treatments.
 Which is a problem in a season with a very high pressure of thrips and leek is growing during a long period of the year.

For producers it's extremely important to have access to effective control measures until new authorizations for new active substances are obtained, dependent upon registration timelines.

Efficacy trials of cyantraniliprole in different vegetables, onions and strawberries were sent by DUPONT, in the context of the zonal procedure, with Belgium as concerned MS. [dossier number: N29321]

Situation in other member states:

- UK: a 120-days regulation for Benevia was authorized in 2017
- France: 120-dagys regulation for Benevia was authorized in 2017 for onions, spring onions, garlic, shallots, leek, strawberries, turnips, radish (in attachment) and an emergency use is submitted for 2018
- Germany: an emergency use was granted in 2017 for broccoli, savoy cabbage, onions, radish and is submitted for 2018
- NL: an emergency use is granted in 2017: <https://zoek.officielebekendmakingen.nl/stcrt-2017-33059.pdf>

	<p>And is submitted in 2018.</p> <p>During the growing season of cabbages, swedes, turnips, onions, spring onions and leek is more than one application needed against cabbage fly, onion fly and thrips. Also in strawberries are different applications needed against <i>Drosophila suzukii</i>. It's in terms of anti-resistance necessary to alternate products with a different mode of action.</p>
<p>Rationale (<i>Reason the risk management decision based on the findings of 15 to 18, containing especially a description of measures taken to ensure consumer protection</i>).</p>	/
<p>Mitigation measures (<i>Describe what mitigation measures are taken if needed for minimising risk to humans, animals, and the environment, attach summary risk assessment. Describe what measures are taken to limit and control use</i>)</p>	<p>This request is for use in strawberries, swedes and turnips, cauliflower, broccoli, Brussels sprouts, head cabbages, kohlrabi, leek and onions, spring onions.</p>
<p>Applications in progress (<i>The use notified may have been applied for already, or a suitable alternative PPP may be in the process of authorisation. Describe such applications, including a possible date of authorisation</i>)</p>	<p>Cabbage fly is part of an observation and warning system in Flanders. The different Research stations are responsible for an observation and warning system in cabbages.</p> <p><i>Drosophila suzukii</i> is monitored by PCF and warnings are sent to strawberry growers.</p> <p>Also for thrips in leek is an advice system available to inform growers for a correct timing of their treatments against thrips.</p> <p>A zonal dossier for Benevia, cyantraniliprole in different crops: strawberries, swedes and turnips, cauliflower, broccoli, Brussels sprouts, head cabbages, kohlrabi, onions, spring onions and leek is submitted and part of a dossier with more crops. The evaluation is ongoing by the RMS, UK and with Belgium as cMS.</p> <p>An MRL is published for strawberries, swedes and turnips, cauliflower, broccoli, Brussels sprouts, head cabbages, kohlrabi, onions, spring onions, Regulation 2017/626. For leeks: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5124/epdf</p>
	<p>Remarque du secrétariat: dossier comme cMS reçu le 17/08/2015</p>

<p>Research activities (<i>Describe the research efforts undertaken and/or in progress, their aims, their funding, and their expected date of results. This is needed for all categories of dangers, except quarantine pests that can still be eliminated, or infrequent pests, for which no official application for a normal authorisation or extension of use of the plant protection product exists.</i> <i>In case of a repeated notification: indicate the state of works of the research projects.</i>)</p>	<p>Since many years is <i>Drosophila suzukii</i>, cabbage and onion fly an important item at the yearly meeting of minor uses in outdoor vegetables and soft fruits in Belgium and also at the European meeting of minor uses. The biggest problem was the unavailability of an active substance with efficacy against <i>Drosophila suzukii</i>, cabbage fly and onion fly.</p> <p>Thrips is since many years difficult to control in leek and spring onions. Last year, with the reregistration of abamectin, the number of treatments was lowered and also 1 application less with methiocarb is authorized in comparison with the situation in 2017. Because of the high pressure of thrips in 2017, growers are worried about the control of thrips for season 2018.</p> <p>In 2018, an emergency use was granted for leeks on sowing bed in the Netherlands.</p> <p><i>Drosophila suzukii</i>: IWT-project/LATR/135079: ‘Knowledge based practical solutions to protect the Flemish cultures of fruit against <i>Drosophila suzukii</i>’), coordinated by PCF.</p> <p><i>Cabbage fly</i>: Since many years is research done at the Belgian trial stations to find a solution/strategy to control cabbage fly: A short overview of trials is described by the trial stations, document is attached.</p> <p>In different trials were different types of applications and combinations tested. Trials were done with a seed coating of fipronil, tray applications with spinosad and cyantraniliprole, spray application of cyantraniliprole and an application of a granulate with chlorpyrifos.</p> <p>Conclusion is that the granulate treatment with chlorpyrifos had a clear added value to control cabbage fly. It’s clear that the withdrawal of the granulate application has consequences for the growers. In different trials is the efficacy of a tray application demonstrated, both active substances, spinosad and cyantraniliprole give a sufficient efficacy to control cabbage fly in the first weeks of the growing season. [cfr. 120-days request for Verimark]</p> <p>BUT, a tray application with cyantraniliprole is only possible for cauliflower, broccoli, Brussels sprouts and head cabbages. Because no data are available for other crops sensitive to cabbage fly.</p> <p>For the other crops, sensitive to cabbage fly: kohlrabi, swedes and turnips is a spray application with cyantraniliprole an alternative to dimethoate and/or chlorpyrifos. But even for cauliflower, broccoli, Brussels</p>
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sprouts and head cabbages with the possibility to use a tray application is also a spray application with cyantraniliprole useful and needed against the second and third peak of cabbage fly.

In 2015, PSKW demonstrate in a trial with turnips the efficacy of a spray application with cyantraniliprole. **Trial report with reference rp15drmi is attached.**

Turnips are very sensitive to infestations of cabbage fly. In practice some growers use nets, but because of the bigger surface of fields it's not always possible to use a net. So active substances are needed.

In this trial were the pyrethroids less efficient. Spinosad and cyantraniliprole, (proefmiddel 1) gave both a good result. So, cyantraniliprole is a good active substance, with another mode of action, [IRAC, 28] and can be used as alternative to spinosad, [IRAC: 5].

Onion fly

No alternatives available since the withdrawal of dimethoate.

Trials are done by Dupont.

Thrips

An advice system is available and the experience of each year can contribute to changes to the system.

For 2018: The temperature sum of another location will be the reference. Because the temperature is at the new location a little higher and this will result in an advice for Flanders a few days earlier.

Leek is in Flanders growing on about 4.000 ha, so it's important to have a correct control of thrips on the fields.

And in 2018 will a project start to collect more information about beneficials on leek fields.

Since many years is research done at the Belgian trial stations to find a solution/strategy to control cabbage fly:

In a context of an anti-resistance strategy it's necessary to have next to lambda-cyhalothrin [IRAC: 3A] and spinosad, [IRAC: 5] an active substance with another mode of action. In this case is cyantraniliprole, [IRAC: 28] a good active substance to alternate.

In Belgium are almost 8.800 ha of cabbages grown, in some regions of Flanders are all kind of cabbages growing at a small surface, so the pressure of cabbage fly is very high. And therefore, it's important to have another product available to control cabbage fly.

A zonal dossier [number: N29321] with UK as zRMS and with Belgium as concerned MS is already submitted by the company Dupont (now FMC), but the evaluation is still ongoing. Nevertheless, MRL's for cauliflower,

broccoli, Brussels sprouts, head cabbages, kohlrabi, swedes, turnips, strawberries, onions, spring onions are published.
For leeks: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5124/epdf>

1. PHYSICAL/CHEMICAL PROPERTIES AND METHODS OF ANALYSIS

Advice of the expert concerning physical-chemical analysis and analysis methods:

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2. TOXICOLOGY

Applicant proposal for labelling:

Classified as: toxic, harmful, ... flammable, ,...
Hazard symbol: Xi, N, ...
Risk phrases: R38, R43, R50/53
Safety phrases: S2, S13, S20/21, S23, S24, S37, S35, S61

CLP proposal for labelling:

Proposed Classification:

Classification:			
Symbol(s):	GSH07	GSH09	
Pictograms			
Signal words:	WARNING		
H-statement(s):	H317, H410		
P-statement(s):	P280, P302+P352, P333+P313, P391		
Other mentions:	EUH401, SP1, SPe2, SPe3, SPe8		

Advice of the expert concerning toxicology :**Classification and labelling under Dir. 99/45/EC:**

Xi, R37-43, S2-13-20/21-24-37-46

Classification and labelling under CLP Regulation (EC) No. 1272/2008:

GHS07

Signal Word: Warning

Skin sens. Cat.1B H317: May cause an allergic skin reaction

STOT SE Cat. 3: H335: May cause respiratory irritation

EUH401

P261

P280: Wear protective gloves, protective clothing

P302 + P352

P333 + P313

P304 + P312

3. EFFICACYRequested usage

GAP rev. , date: 2017-03-13

PPP (product name/code) **DUPONT™ BENEVIA®** Formulation: Type: SE type
 active substance 1 cyantraniliprole Conc. of as 1: 100 g/l

safener: /
 synergist: /

Conc. of safener: n.a.
 Conc. Of synergist: n.a.

Applicant: **KDT**company: **DuPont de Nemours (now FMC)**

1	2	3	4	5	6	7	8	9	10	11	12
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Use- No.	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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
				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	Strawberries	F	<i>Drosophila suzukii</i>	Spray application	BBCH 12-89	2 applications Interval: 7 days	0,75 l/ha	75 g as/ha	300-1000	1 day	
2	Cauliflower	F	<i>Delia radicum</i>	Spray application	BBCH 12-49	2 applications Interval: 7 days	0,75 l/ha	75 g as/ha	300-800	7 days	
3	Broccoli	F	<i>Delia radicum</i>	Spray application	BBCH 12-49	2 applications Interval: 7 days	0,75 l/ha	75 g as/ha	300-800	7 days	
4	Head cabbage	F	<i>Delia radicum</i>	Spray application	BBCH 12-49	2 applications Interval: 7 days	0,75 l/ha	75 g as/ha	300-800	7 days	
5	Brussels sprouts	F	<i>Delia radicum</i>	Spray application	BBCH 12-49	2 applications Interval: 7 days	0,75 l/ha	75 g as/ha	300-800	7 days	
6	Kohlrabi	F	<i>Delia radicum</i>	Spray application	BBCH 11-89	2 applications Interval: 7 days	0,75 l/ha	75 g as/ha	300-800	7 days	
7	Swedes	F	<i>Delia radicum</i>	Spray application	BBCH 11-89	2 applications Interval: 10 days	0,6 l/ha	60 g as/ha	300-800	14 days	
8	Turnips	f	<i>Delia radicum</i>	Spray application	BBCH 11-89	2 applications Interval: 10 days	0,6 l/ha	60 g as/ha	300-800	14 days	
9	Onions	F	<i>Delia antiqua</i>	Spray application	BBCH 12-80	2 applications Interval: 7 days	0,75 l/ha	75 g as/ha	200-800	14 days	
10	Spring onions	F	<i>Delia antiqua, Thrips</i>	Spray application	BBCH 12-80	2 applications Interval: 7 days	0,75 l/ha	75 g as/ha	200-800	14 days	
11	Leek (production field)	F	<i>Thrips</i>	Spray application	BBCH 12-80	2 applications Interval: 7 days	0,75 l/ha	75 g as/ha	200-800	14 days	
12	Leek (sowing bed)	F	<i>Thrips</i>	Spray application	BBCH 12-80	2 applications Interval: 7 days	0,75 l/ha	75 g as/ha	200-800	14 days	

Te behandelen	Aardbeien (<i>Fragaria ananassa</i>) – FRAAN (openlucht)	A traiter	Fraisiers (<i>Fragaria ananassa</i>) – FRAAN (plein air)	To be treated	Strawberries (<i>Fragaria ananassa</i>) – FRAAN (outdoor)
Stadium	BBCH 12-89	Stade	BBCH 12-89	Stage	BBCH 12-89
Wachttijd	1 dag	Délais	1 jour	Waiting period	1 day
Vijand	<i>Drosophila suzukii</i> - DROSSU	Ennemis	<i>Drosophila suzukii</i> - DROSSU	Enemy	<i>Drosophila suzukii</i> - DROSSU
Dosis	0,75 l/ha	Dose	0,75 l/ha	Rate	0,75 l/ha
Aantal toepassingen	1-2 toepassingen met een interval van 7 dagen	Nombre de traitements	1-2 applications à l'intervalle de 7 jours	Number of applications	1-2 applications with an interval of 7 days

Te behandelen	Bloemkool (<i>Brassica oleracea</i> var. <i>botrytis</i> subvar. <i>cauliflora</i>) - BRSOB (openlucht)	A traiter	Chou-fleur (<i>Brassica oleracea</i> var. <i>botrytis</i> subvar. <i>cauliflora</i>) – BRSOB (plein air)	To be treated	Cauliflower (<i>Brassica oleracea</i> var. <i>botrytis</i> subvar. <i>cauliflora</i>) – BRSOB (outdoor)
Stadium	BBCH 12-49	Stade	BBCH 12-49	Stage	BBCH 12-49
Wachttijd	7 dagen	Délais	7 jours	Waiting period	7 days
Vijand	Koolvlieg - <i>Delia radicum</i> - HYLERA	Ennemis	Mouche du chou – <i>Delia radicum</i> - HYLERA	Enemy	<i>Delia radicum</i> - cabbage fly – HYLERA
Dosis	0,75 l/ha	Dose	0,75 l/ha	Rate	0,75 l/ha
Aantal toepassingen	1-2 toepassingen met een interval van 7 dagen	Nombre de traitements	1-2 applications à l'intervalle de 7 jours	Number of applications	1-2 applications with an interval of 7 days

Te behandelen	Broccoli (<i>Brassica oleracea</i> var. <i>botrytis</i> subvar. <i>cymosa</i>) - BRSOK (openlucht)	A traiter	Chou brocoli (<i>Brassica oleracea</i> var. <i>botrytis</i> subvar. <i>cymosa</i>) – BRSOK (plein air)	To be treated	Broccoli (<i>Brassica oleracea</i> var. <i>botrytis</i> subvar. <i>cymosa</i>) – BRSOK (outdoor)
Stadium	BBCH 12-49	Stade	BBCH 12-49	Stage	BBCH 12-49
Wachttijd	7 dagen	Délais	7 jours	Waiting period	7 days
Vijand	Koolvlieg - <i>Delia radicum</i> - HYLERA	Ennemis	Mouche du chou – <i>Delia radicum</i> - HYLERA	Enemy	<i>Delia radicum</i> - cabbage fly – HYLERA
Dosis	0,75 l/ha	Dose	0,75 l/ha	Rate	0,75 l/ha
Aantal toepassingen	1-2 toepassingen met een interval van 7 dagen	Nombre de traitements	1-2 applications à l'intervalle de 7 jours	Number of applications	1-2 applications with an interval of 7 days

Te behandelen	Sluitkolen (kabuskool, witte, rode, savooi- en spitskool) (<i>Brassica oleracea var. capitata</i>) - BRSOL (openlucht)	A traiter	Choux pommés (blanc, rouge, chou cabus et chou de savoie) (<i>Brassica oleracea var. capitata</i>) - BRSOL (plein air)	To be treated	Head cabbage (<i>Brassica oleracea var. capitata</i>) - BRSOL (outdoor)
Stadium	BBCH 12-49	Stade	BBCH 12-49	Stage	BBCH 12-49
Wachttijd	7 dagen	Délais	7 jours	Waiting period	7 days
Vijand	Koolvlieg - <i>Delia radicum</i> - HYLERA	Ennemis	Mouche du chou – <i>Delia radicum</i> - HYLERA	Enemy	<i>Delia radicum</i> - cabbage fly – HYLERA
Dosis	0,75 l/ha	Dose	0,75 l/ha	Rate	0,75 l/ha
Aantal toepassingen	1-2 toepassingen met een interval van 7 dagen	Nombre de traitements	1-2 applications à l'intervalle de 7 jours	Number of applications	1-2 applications with an interval of 7 days

Te behandelen	Spruitkool (<i>Brassica oleracea var. gemmifera</i>) – BRSOF (openlucht)	A traiter	Chou de Bruxelles (<i>Brassica oleracea var. gemmifera</i>) – BRSOF (plein air)	To be treated	Brussels sprouts (<i>Brassica oleracea var. gemmifera</i>) – BRSOF (outdoor)
Stadium	BBCH 12-49	Stade	BBCH 12-49	Stage	BBCH 12-49
Wachttijd	7 dagen	Délais	7 jours	Waiting period	7 days
Vijand	Koolvlieg - <i>Delia radicum</i> - HYLERA	Ennemis	Mouche du chou – <i>Delia radicum</i> - HYLERA	Enemy	<i>Delia radicum</i> - cabbage fly – HYLERA
Dosis	0,75 l/ha	Dose	0,75 l/ha	Rate	0,75 l/ha
Aantal toepassingen	1-2 toepassingen met een interval van 7 dagen	Nombre de traitements	1-2 applications à l'intervalle de 7 jours	Number of applications	1-2 applications with an interval of 7 days

Te behandelen	Koolrabi (koolraap-boven-de-grond) (<i>Brassica oleracea var. gongylodes</i>) (openlucht) - BRSOG	A traiter	Chou rave (koolraap-boven-de-grond) (<i>Brassica oleracea var. gongylodes</i>) - BRSOG	To be treated	Kohlrabi (koolraap-boven-de-grond) (<i>Brassica oleracea var. gongylodes</i>) - BRSOG
Stadium	BBCH 12-49	Stade	BBCH 12-49	Stage	BBCH 12-49
Wachttijd	7 dagen	Délais	7 jours	Waiting period	7 days
Vijand	Koolvlieg - <i>Delia radicum</i> - HYLERA	Ennemis	Mouche du chou – <i>Delia radicum</i> - HYLERA	Enemy	<i>Delia radicum</i> - cabbage fly – HYLERA
Dosis	0,75 l/ha	Dose	0,75 l/ha	Rate	0,75 l/ha

Aantal toepassingen	1-2 toepassingen met een interval van 7 dagen	Nombre de traitements	1-2 applications à l'intervalle de 7 jours	Number of applications	1-2 applications with an interval of 7 days
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Te behandelen	Raap (stoppelraap, meiraap) (<i>Brassica rapa subsp. rapa</i>) (openlucht) - BRSRR	A traiter	Navet (<i>Brassica rapa subsp. rapa</i>) (plein air) - BRSRR	To be treated	Turnip (<i>Brassica rapa subsp. rapa</i>) (outdoor) - BRSRR
Stadium	BBCH 11-89	Stade	BBCH 11-89	Stage	BBCH 11-89
Wachttijd	14 dagen	Délais	14 jours	Waiting period	14 days
Vijand	Koolvlieg - <i>Delia radicum</i> - HYLERA	Ennemis	Mouche du chou – <i>Delia radicum</i> - HYLERA	Enemy	<i>Delia radicum</i> - cabbage fly – HYLERA
Dosis	0,6 l/ha	Dose	0,6 l/ha	Rate	0,6 l/ha
Aantal toepassingen	1-2 toepassingen met een interval van 10 dagen	Nombre de traitements	1-2 applications à l'intervalle de 10 jours	Number of applications	1-2 applications with an interval of 10 days

Te behandelen	Koolraap (<i>Brassica napus var. Napobrassica</i>) (openlucht) - BRSNA	A traiter	Chou-navet, rutabaga (<i>Brassica napus var. Napobrassica</i>) – BRSNA (plein air)	To be treated	Swedes (<i>Brassica napus var. Napobrassica</i>) - BRSNA (outdoor)
Stadium	BBCH 11-89	Stade	BBCH 11-89	Stage	BBCH 11-89
Wachttijd	14 dagen	Délais	14 jours	Waiting period	14 days
Vijand	Koolvlieg - <i>Delia radicum</i> - HYLERA	Ennemis	Mouche du chou – <i>Delia radicum</i> - HYLERA	Enemy	<i>Delia radicum</i> - cabbage fly – HYLERA
Dosis	0,6 l/ha	Dose	0,6 l/ha	Rate	0,6 l/ha
Aantal toepassingen	1-2 toepassingen met een interval van 10 dagen	Nombre de traitements	1-2 applications à l'intervalle de 10 jours	Number of applications	1-2 applications with an interval of 10 days

Te behandelen	Uien (drooggeogst) (<i>Allium cepa</i>) – ALLCE (openlucht)	A traiter	Oignons (<i>Allium cepa</i>) – ALLCE (plein air)	To be treated	Onions (<i>Allium cepa</i>) – ALLCE (outdoor)
Stadium	BBCH 12-80	Stade	BBCH 12-80	Stage	BBCH 12-80
Wachttijd	14 dagen	Délais	14 jours	Waiting period	14 days

Vijand	Uievlieg - <i>Hylemyia antiqua</i> (<i>Delia antiqua</i>) - HYLEAN	Ennemis	Mouche de l'oignon (<i>Hylemyia antiqua</i> (<i>Delia antiqua</i>) - HYLEAN	Enemy	<i>Hylemyia antiqua</i> (<i>Delia antiqua</i>)- onion fly - HYLEAN
Dosis	0,75 l/ha	Dose	0,75 l/ha	Rate	0,75 l/ha
Aantal toepassingen	1-2 toepassingen met een interval van 7 dagen	Nombre de traitements	1-2 applications à l'intervalle de 7 jours	Number of applications	1-2 applications with an interval of 7 days

Te behandelen	Bosuien/lente-ui (<i>Allium fistulosum</i>/ <i>A. cepa</i>) – ALLFI/ALLCE (openlucht)	A traiter	Oignons de printemps (<i>Allium fistulosum</i>/ <i>A. cepa</i>) – ALLFI/ALLCE (plein air)	To be treated	Spring onions (<i>Allium fistulosum</i>/ <i>A. cepa</i>) – ALLFI/ALLCE (outdoor)
Stadium	BBCH 12-80	Stade	BBCH 12-80	Stage	BBCH 12-80
Wachttijd	14 dagen	Délais	14 jours	Waiting period	14 days
Vijand	Trips – Thysanoptera - 1THYSO Uievlieg - <i>Hylemyia antiqua</i> (<i>Delia antiqua</i>) - HYLEAN	Ennemis	Thrips – Thysanoptera - 1THYSO Mouche de l'oignon (<i>Hylemyia antiqua</i> (<i>Delia antiqua</i>) - HYLEAN	Enemy	Thrips – Thysanoptera - 1THYSO <i>Hylemyia antiqua</i> (<i>Delia antiqua</i>)- onion fly - HYLEAN
Dosis	0,75 l/ha	Dose	0,75 l/ha	Rate	0,75 l/ha
Aantal toepassingen	1-2 toepassingen met een interval van 7 dagen	Nombre de traitements	1-2 applications à l'intervalle de 7 jours	Number of applications	1-2 applications with an interval of 7 days

Te behandelen	Prei (productieveld) (<i>Allium porrum</i>) – ALLPO (openlucht)	A traiter	Poireau (champ de production) (<i>Allium porrum</i>) – ALLPO (plein air)	To be treated	Leek (production field) (<i>Allium porrum</i>) – ALLPO (outdoor)
Stadium	BBCH 12-80	Stade	BBCH 12-80	Stage	BBCH 12-80
Wachttijd	14 dagen	Délais	14 jours	Waiting period	14 days
Vijand	Trips – Thysanoptera - 1THYSO	Ennemis	Thrips – Thysanoptera - 1THYSO	Enemy	Thrips – Thysanoptera - 1THYSO
Dosis	0,75 l/ha	Dose	0,75 l/ha	Rate	0,75 l/ha
Aantal toepassingen	1-2 toepassingen met een interval van 7 dagen	Nombre de traitements	1-2 applications à l'intervalle de 7 jours	Number of applications	1-2 applications with an interval of 7 days

Te behandelen	Prei (zaaibed) (<i>Allium porrum</i>) – ALLPO (openlucht)	A traiter	Poireau (pépinière) (<i>Allium porrum</i>) – ALLPO (plein air)	To be treated	Leek (sowing bed) (<i>Allium porrum</i>) – ALLPO (outdoor)
Stadium	BBCH 12-80	Stade	BBCH 12-80	Stage	BBCH 12-80
Wachttijd	14 dagen	Délais	14 jours	Waiting period	14 days
Vijand	Trips – Thysanoptera - 1THYSO	Ennemis	Thrips – Thysanoptera - 1THYSO	Enemy	Thrips – Thysanoptera - 1THYSO
Dosis	0,75 l/ha	Dose	0,75 l/ha	Rate	0,75 l/ha
Aantal toepassingen	1-2 toepassingen met een interval van 7 dagen	Nombre de traitements	1-2 applications à l'intervalle de 7 jours	Number of applications	1-2 applications with an interval of 7 days

Advice of the expert concerning biology:

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4. RESIDUS

4.1. End points

Active substance	Cyantraniliprole (= Cyazypyr)
ADI (mg/kg bw/d) + source (Review report or JMPR*)	0,01 mg/kg bw per day - Reg. (EU) No 2016/1414
ARfD (mg/kg bw) + source (Review report or JMPR*)	Not applicable - Reg. (EU) No 2016/1414
Residue definition for products of plant origin + tested crop category	
Residue definition for products of animal origin + tested animals	

*see doc. 3010 at the following internet address: http://europa.eu.int/comm/food/plant/protection/evaluation/index_en.htm

4.2. MRL's setting

Products of plant origin						
Crop	Existing EU MRL (mg/kg) + Directive EC	Existing Belgian MRL (mg/kg)	Proposed MRL (mg/kg)	Proposed critical GAP (application rate s.a. kg/ha, application number, PHI or crop growth stage)	Residue trials complying with the critical GAP (number, north/south/indoor) or extrapolation (guideline reference)	Argumentation or study reference (tile, author, year, ref n° applicant, ref n° lab). GLP: Y/N
Strawberries	0,5 mg/kg			0,075 kg as /ha,	Gap is supported by the MRL	Sent by Dupont

015200				2 applications, PHI: 1 day BBCH 12-89		Zonal dossier number: N29321
Broccoli 0241010	2 mg/kg			0,075 kg as /ha, 2 applications, PHI: 7 days BBCH 12-49	Gap is supported by the MRL	Sent by Dupont Zonal dossier number: N29321
Cauliflower 021020	2 mg/kg			0,075 kg as /ha, 2 applications, PHI: 7 days BBCH 12-49	Gap is supported by the MRL	Sent by Dupont Zonal dossier number: N29321
Brussels sprouts 0242010	2 mg/kg			0,075 kg as /ha, 2 applications, PHI: 7 days BBCH 12-49	Gap is supported by the MRL	Sent by Dupont Zonal dossier number: N29321
Head cabbage 0242020	2 mg/kg			0,075 kg as /ha, 2 applications, PHI: 7 days BBCH 12-49	Gap is supported by the MRL	Sent by Dupont Zonal dossier number: N29321
Kohlrabi 0244000	2 mg/kg			0,075 kg as /ha, 2 applications, PHI: 7 days BBCH 12-49	Gap is supported by the MRL	Sent by Dupont Zonal dossier number: N29321
Swedes 0213100	0,05 mg/kg			0,060 kg as /ha, 2 applications, PHI: 14 days BBCH 11-89	Gap is supported by the MRL	Sent by Dupont Zonal dossier number: N29321
Turnips 0213110	0,05 mg/kg			0,060 kg as /ha, 2 applications, PHI: 14 days BBCH 11-89	Gap is supported by the MRL	Sent by Dupont Zonal dossier number: N29321
Onions 0220020	0,05 mg/kg			0,075 kg as/ha, 2 applications PHI: 14 days BBCH 12-80	Gap is supported by the MRL	Sent by Dupont Zonal dossier number: N29321
Spring onions 0220040	8 mg/kg			0,075 kg as/ha, 2 applications PHI: 14 days	Gap is supported by the MRL	Zonal dossier number: N29321

				BBCH 12-80		
Leek (production field) 0270060	0,6 mg/kg SANTE/12049/ 2017			0,075 kg as/ha, 2 applications PHI: 14 days BBCH 12-80	Gap is supported by the MRL http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5124/epdf	Zonal dossier number: N29321
Leek (sowing bed) 0270060	0,6 mg/kg SANTE/12049/ 2017			0,075 kg as/ha, 2 applications PHI: 14 days BBCH 12-80	Gap is supported by the MRL http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5124/epdf	Zonal dossier number: N29321
Products of animal origin						
Product	Existing EU MRL (mg/kg) + Directive EC	Existing Belgian MRL (mg/kg)	Proposed MRL (mg/kg)	Tested animal	<i>Argumentation or study reference (title, author, year, ref n° applicant, ref n° lab). GLP: Y/N</i>	

Cyantraniliprole

Pesticide residues and maximum residue levels (mg/kg)

(* Indicates lower limit of analytical determination)

Pesticides - Web Version - EU MRLs (File created on 14/03/2017)

Code number	Groups and examples of individual products to which the MRLs apply (a)	SANTE/12049/2017	Reg. (EU) 2017/626
0152000	. (b) strawberries	0.5	0.5
0213100	. Swedes/rutabagas	0.05	0.05
0213110	. Turnips	0.05	0.05
0220020	. Onions	0.05	0.05
0220040	. Spring onions/green onions and Welsh onions	8.0	8.0
0241000	. (a) flowering brassica	2	2
0241010	. Broccoli	2	2
0241020	. Cauliflowers	2	2
0242010	. Brussels sprouts	2	2
0242020	. Head cabbages	2	2
0244000	. (d) kohlrabies	2	2
0270060	. Leeks	0.6	0.01

Legislation :
SANTE/12049/2017

0270060 : Leek

MRL applicable until 30 June 2021, after that date 0,01 (*) mg/kg will be applicable unless modified by a Regulation.

Advice of the expert concerning residues :

1°) Intended uses

An authorization for 120 days (from 15/06/2018 till 15/10/2018) is requested for the use of cyantraniliprole on strawberries, broccoli, cauliflower, Brussels sprouts, head cabbage, kohlrabi, swedes, turnips, onions , spring onions, Leek (production field) (see GAP table in appendix 1). Cyantraniliprole exhibits larvicidal activity as an orally ingested toxicant by targeting and disrupting the Ca²⁺ balance, Second generation ryanodine receptor, Foliar and systemic activity (Source: IUPAC).

2°) INTENDED USE GAPS

The intended use GAP are presented in appendix 1 to the current evaluation report

3°) MRL REVIEW, AND STATE OF PLAY

The article 12 review of the existing MRLs for cyantraniliprole is not yet finalized. The current MRL for cyantraniliprole on the crops under consideration is presented in the table below.

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg. (EU) 2017/626 (mg/kg)	SANTE/12049/2017
015200	Strawberries	0.5	0.5
0241010	Broccoli	1	1
021020	Cauliflower	1	1
0242010	Brussels sprouts	1	1
0242020	Head cabbage	1	1
0244000	Kohlrabi	2	2

0213100	Swedes	0,05	0,05
0213110	Turnips	0,05	0,05
0220020	Onions	0,05	0,05
0220040	Spring onions	8	8
0270060	Leek (production field)	0.01	0,6

4°) EXISTING DATA IN SUPPORT TO THE INTENDED GAP

This 120 day authorization is needed to control *Delia radicum* (cabbage fly) in the production of cabbages. The request for a 120-days regulation is only for an application before harvest of the roots on the production fields.

Comment from residue assessor: There is an ongoing application for authorization of BENEVIA and VERIMARK containing cyantraniliprole in BE but the evaluation is not yet finalized. However the BE residue assessor has finalized his (her) evaluation and recommendation is for the authorization of the intended use.

In support to the application, the BE third submitted a residue supervised trials report that contains 4 NEU field trials. The trials report was obtained from the owner of the product BENEVIA. For more detail it is referred to the report of DF on both BENEVIA and VERIMARK (see Report N29321_1004.04.02_BEN_RES-var_df and N29359_1008.03.03_VER_RES-var_df).

5°) EVALUATION

5.1)° Strawberries and cabbages (broccoli, cauliflower, Brussels sprouts, head cabbage)

The intended use has been already evaluated by BE residue assessor. The authorization of the intended uses are recommended (see comment in section 4). The

intended use is covered by the evaluation conducted for the core dossier of Benevia (see Report N29321_1004.04.02_BEN_RES-var_df and N29359_1008.03.03_VER_RES-var_df).

5.2°) Leek (see EFSA Journal 2018;16(1):5124)

On the basis of the data and information available from the above mention EFSA RO, the use of cyantraniliprole on leek according to intended use GAP is recommended. The RO was issued in support to an application for the raising of the MRL (from 0.01* to 0.6 mg/kg. The new proposed MRL is voted and still to entry in force by August 2018.

5.3°) Spring onion (stem vegetable)

The residue behaviour can be extrapolated from leek to the spring onion. The current MRL for cyantraniliprole on spring onion is 8 mg/kg whereas the voted MRL for cyantraniliprole on leek is 0.6 mg/kg. Then the use of the product accord to the same GAP as leek would unlikely lead to incompliance the MRL of 8 mg/kg

5.4°) Onion dry harvested

Nine NEU residue trials submitted by DUPONT are available for the support of the use and are summarized below.

All trials were carried out with a more critical GAP (2 x 100 g a.s./ha; PHI = 14d) than the intended GAP but within the allowed 25% deviation.

The following levels of parent cyantraniliprole were detected in onions (dry) at a PHI of 14 days:

0.007; <0.003; 0.014; <0.003; <0.003; <0.003; <0.003; <0.003; 0.007

Based on these results, the OECD-calculator proposes a MRL of 0.02 mg/kg (STMR = 0.003 mg/kg; HR = 0.014 mg/kg).

The current MRL of 0.05 mg/kg. the use is recommended.

5.5°) kohlrabi, swedes, turnips (Root & tuber vegetables) (see EFSA Journal 2015;13(10):4263)

On the basis of the data and information available from the above mention EFSA RO, the use of cyantraniliprole on leek according to intended use GAP is recommended.

The EU GAPs result in a lower MRL proposals on carrots (0.03 mg/kg) and on the “Other root and tuber vegetables” crops (0.02 mg/kg) than the CXL of 0.05 mg/kg transposed in Reg. (EU) 2015/845. The intended use is recommended.

6°) CONCLUSION:

- On the basis of the available data and information, it is likely that the intended use of cyantraniliprole in/on strawberries, broccoli, cauliflower,

Brussels sprouts, head cabbage, kohlrabi, swedes, turnips, onions, spring onions is unlikely to lead to non-compliance of the current MRL (2 mg/kg) for cyantraniliprole on these cabbages.

- For leek (production field) a new MRL of 0.6 mg/kg for accommodation of the use has been voted but still to entry in force. However, it comes to us that the time elapsing from voting to publication of the kind of MRL is about 4 months to which 20 days must be added before entry in force (almost by August 2018). Then, seeing the period foreseen for the use and the vegetation period of leek it is likely that the voted MRL will enter in force prior to harvest. The new MRL would likely be in force by August 2018. The above explained aims at helping the Committee for decision making. Decision is up to the Committee

Advice:

- Positive for strawberries, broccoli, cauliflower, Brussels sprouts, head cabbage, kohlrabi, swedes, turnips, onions and spring onion
- To be discussed for leek (see above the comment from Evaluator)

5. FATE AND BEHAVIOUR

Advice of the expert concerning fate and behaviour:

18_02_08, DUPONT BENEVIA (...../B)

Insecticide, SE, 100 g/L cyantraniliprole

Application for authorisation for 120 days (Art. 53 – Emergency situations in plant protection products – Regulation 1107/2009).

Use applied for :

Crop	Application number	Application rate (L product/ha)	Application rate (g a.s./ha)	Growth stage	Interception (%)
Strawberries	2 (7d interval)	0.75	75	BBCH 12-89	30 - 50
Cabbages	2 (7d interval)	0.75	75	BBCH 11-89	25 - 40
Onions	2	0.75	75	BBCH 12-80	10 - 25

(7d interval)

Evaluation:

The EFSA Scientific Report for cyantraniliprole (EFSA journal 2014;12(9):3814) is considered to provide the relevant review information or reference to where such information can be found.

PEC in soil

The nectarines, citrus and olives calculation considered during the assessment for Annex I inclusion is sufficient to address the proposed uses on strawberries, cabbages and onions at a lower application rate of only 2 x 75 g a.s./ha.

Application data	Crop: nectarines, citrus and olives (worst-case GAP) Depth of soil layer: 5 cm. Soil bulk density: 1.5 g/cm ³ % plant interception: 0% assumed as a conservative first tier Number of applications: 1 Application rate: 300g as/ha (GAP of 2 x 150 g a.s./ha modeled as a single application event)
Actual PEC _{soil}	0.400 mg/kg (parent)
Accumulated PEC _{soil}	0.449 mg/kg (parent) 0.217 mg/kg (IN-JCZ38) 0.414 mg/kg (IN-JSE76) 0.049 mg/kg (IN-K5A79) 0.383 mg/kg (IN-PLT97) 0.914 mg/kg (IN-J9Z38) 0.094 mg/kg (IN-K5A77) 0.567 mg/kg (IN-K5A78) 0.204 mg/kg (IN-QKV54) 0.139 mg/kg (IN-RNU71)

PEC in groundwater

Reference is made to the previous risk assessment performed in the framework of the authorisation process for the product 'Benevia' (PV1004r, R_17_04_02, N29321 Benevia).

The predicted environmental concentrations in ground water (PEC_{GW}) have been calculated for the critical use patterns of the risk envelope, using FOCUS PEARL v4.4.4. Appropriate application dates have been chosen (first application 10 days after emergence/transplantation for all crops) and the EU agreed endpoints were used. Photodegradation and degradation other than photodegradation have been simulated separately as two different pathways.

The maximum PEC_{GW} values obtained in the scenarios relevant for Belgian conditions (Châteaudun, Hamburg, Kremsmünster and Okehampton) are summarised below.

The maximum 80th percentile PEC_{GW} values (µg/L) of Cyantraniliprole and its metabolites

	Cyantraniliprole	IN-JCZ38	IN-JSE76	IN-K5A79	IN-PLT97	IN-J9Z38
2 x 75 g a.s./ha	0.045 (tier-2)*	0.007	16.279	3.244	0.694	0.003

* Tier 2 groundwater assessments used the following regression to estimate soil specific degradation rates of cyantraniliprole : $DT_{50} = -21.268 * pH_{(water)} + 186.36$

The maximum 80th percentile PEC_{GW} values (µg/L) of Cyantraniliprole and its metabolites – continued

	IN-K5A77	IN-K5A78	IN-M2G98	IN-NXX70	IN-RNU71	IN-QKV54
2 x 75 g a.s./ha	< 0.001	0.587	2.347	0.060	0.097	0.053

The PEC_{GW} values obtained for cyantraniliprole are below 0.1 µg/L at tier-2, but some uncertainty remains regarding the leaching potential of cyantraniliprole when vulnerable aquifers are overlaid by predominantly acidic soils. A data gap on DegT₅₀ values in the soil pH(water) range 4.8-5.9 has been identified during the EU review since degradation is expected to be slower in acidic soils. Therefore, a risk of groundwater contamination with cyantraniliprole cannot be excluded for applications on soils with pH < 6.

PEC_{GW} values > 0.1 µg/L are predicted for metabolites IN-JSE76, IN-K5A79, IN-M2G98, IN-PLT97 and IN-K5A78. A relevance assessment according to SANCO/221/2000 rev. 10 has been performed for these metabolites. A trigger values in groundwater of 10 µg/l for each of these five metabolites were previously agreed for Belgium. For metabolite IN-JSE76, PEC_{GW} values > 10 µg/L are predicted for the intended use. Nevertheless, the simulations are based on lab data. The comparison of the maximum occurrences in lab and field studies indicates that lower formation fractions can be expected under field conditions. It is therefore likely that the simulations overestimate the PEC_{GW} values of IN-JSE76 and that the 10 µg/L trigger will not be exceeded in field conditions.

PEC in surface water and sediment

Reference is made to the previous risk assessment performed in the framework of the authorisation process for the product 'Benevia' (PV1004r, R_17_04_02, N29321 Benevia).

The predicted environmental concentrations in surface water (PEC_{SW}) and sediment (PEC_{SED}) have been calculated for the critical use patterns of the risk envelope according to the FOCUS Surface Water recommendations, taking into account substance entry via spray-drift, run-off and drain flow.

The results of the simulations are summarised in the tables below.

Summary of the minimum assessment tier and level of risk mitigation required to achieve a PEC_{sw} value below the RAC of 1 µg/l

scenario	2 x 75 g a.s./ha	
	PEC _{sw} (µg/l)	Assessment tier and mitigation

D3 ditch	0.476	Step 3
D4 pond	0.671	Step 3
D4 stream	1.058	Step 3
R1 pond	0.214	Step 3
R1 stream	0.915	Step 4 (10m BZ + VFS)

Summary of the minimum assessment tier and level of risk mitigation required to achieve a PECsed value below the RAC of 2.41 µg/kg

scenario	2 x 75 g a.s./ha	
	PECsed (µg/kg)	Assessment tier and mitigation
D3 ditch	0.173	Step 3
D4 pond	1.939	Step 3
D4 stream	1.862	Step 3
R1 pond	0.436	Step 3
R1 stream	0.640	Step 3

Summary of maximum PECsw (µg/L) values for the metabolites of cyantraniliprole (Step 2)

Substance	IN-J9Z38	IN-K5A77	IN-JCZ38	IN-JSE76	IN-K5A79	IN-K5A78
2 x 75 g a.s./ha	0.591	0.119	2.182	3.697	0.720	1.387

Summary of maximum PECsw (µg/L) values for the metabolites of cyantraniliprole (Step 2) – continued

Substance	IN-PLT97	IN-RNU71	IN-QKV54	IN-NXX70	IN-M2G98
2 x 75 g a.s./ha	0.867	1.002	0.425	0.338	0.150

Advice concerning the registration certificate :

A use restriction to soils with pH \geq 6 should be mentioned (leaching of cyantraniliprole into groundwater in concentrations above 0.1 µg/L cannot be excluded when the product is used on soils with pH < 6).

Global advice concerning the application : Positive

6. ECOTOXICOLOGY

Advice of the expert concerning ecotoxicology:

Insecticide, OD (Oil Dispersion), 100 g / L cyantraniliprole, professional use

Background:

Application for a 120d emergency authorisation of BENEVIA. The RR of UK (June 2017) is available at CIRCABC (Cyantraniliprole registration FINAL 1107 Benevia Du Pont UK 2017-06-23.zip). CLP proposal is available in the dRR Part A.

The product contains the active substance cyantraniliprole, which is authorised at EU level till 14/sep/2026. An EFSA conclusion (EFSA Journal 2014;12(9):3814) is available. BENEVIA was the representative formulation during the EU review of cyantraniliprole.

Uses applied for in BE:

Crop	BBCH	Max. application rate (L product/ha)	Max. Application rate (g a.s./ha)	Number of applications	Min interval time (d)
Strawberries	BBCH 12 - 89	0.75 L/ha	75 g a.s./ha	2	7
Cauliflower, Broccoli, Head cabbage, Brussels sprouts, Kohlrabi	BBCH 12 - 49	0.75 L/ha	75 g a.s./ha	2	7
Turnip, Swedes	BBCH 11 - 89	0.6 L/ha	60 g a.s./ha	2	10
Onions, Spring onions, Leek	BBCH 12 – 80	0.75 L/ha	75 g a.s./ha	2	7

All requested uses are similar to / are covered by the uses requested for the zonal authorisation of the formulation BENEVIA (OJ1004). Reference can be made to the ecotox evaluation for the zonal approval.

Ecotox evaluation:

BIRDS

- The risk assessment for effects on birds has been performed in accordance with the recommendations of the “Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12):1438).

Acute and long-term risk assessment

- Since the short-term endpoint (> 1343 mg/kg bw) is lower than the acute endpoint (> 2250 mg/kg bw), the short-term endpoint will be used in the acute risk assessment (according to the EFSA guidance).
- Both the acute and long-term TER values are above the trigger value of respectively 10 and 5 at the screening assessment step. The risk on birds is considered to be acceptable.
- No major metabolites were identified in the rat and poultry metabolism studies.
- Since Benevia is a single active substance formulation, risk for the formulation can be considered covered by the active substance.

Secondary poisoning and bioaccumulation

- As the Log Pow of cyantraniliprole is $1.97 < 3$, no risk for bioaccumulation and secondary poisoning need to be considered.

Drinking water risk assessment

- The risk to birds from drinking water that may contain residues from the use of the product at a maximum dose rate of 0.75 L/ha is acceptable according to both the puddle and leaf scenario. All other crops with a lower dose rate are also covered.

MAMMALS

- The risk assessment for effects on mammals has been performed in accordance with the recommendations of the “Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12):1438).

Acute and long-term risk assessment

- The acute TER values are above the trigger value of 10 at the screening assessment step, indicating an acceptable acute risk to mammals.
- The experts at the Pesticides Peer Review Meeting 115 (May 2014) agreed to use the lower endpoint of 25 mg a.s./kg bw per day from the rabbit developmental study as relevant for the mammalian long-term risk assessment.
- The long-term TER values are above the trigger value of 5 at the screening assessment step, indicating an acceptable chronic risk to mammals.
- No major metabolites were identified in the rat and poultry metabolism studies.
- Since Benevia is a single active substance formulation, risk for the formulation can be considered covered by the active substance.

Secondary poisoning and bioaccumulation

- As the Log Pow of cyantraniliprole is $1.97 < 3$, no risk for bioaccumulation and secondary poisoning need to be considered.

Drinking water risk assessment

- The risk to mammals from drinking water that may contain residues from the use of the product at a maximum dose rate of 0.75 L/ha is acceptable according to the puddle scenario. All other crops with a lower dose rate are also covered.

AQUATIC ORGANISMS

- The risk assessment for aquatic organisms has been conducted according to the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290).
- For the active substance cyantraniliprole, the most sensitive species are *Daphnia* and *Chironomus*. The other organism groups like fish, algae and macrophyte are at least 100x less sensitive.
- Acute and chronic fish, algae and *Lemna* are all acceptable at FOCUS Step 3.
- For all uses, the risk for acute *Daphnia* remains unacceptable at FOCUS Step 3. As a refinement for the acute *Daphnia*, the applicant calculated the HC5 value (15.64 µg a.s. /L) which is acceptable at FOCUS Step 3. For chronic *Daphnia* and *Chironomus*, the risk remains also unacceptable at FOCUS Step 3. If a 10m vegetated buffer strip is considered, the risk to aquatic organisms becomes acceptable.

Metabolites

- Only endpoints with *Daphnia* are available. All metabolites are at least 10x less sensitive than the active substance and all metabolites are acceptable at FOCUS Step 2. The most sensitive species for the active substance is *Chironomus* (10 µg/L ; *Daphnia*: 20 µg/L). According to the aquatic guidance document, as a worst case scenario, the endpoint of the active substance divided by 10 should be used for the metabolites. Using the a.s. endpoint/10, the risk is considered acceptable for Fish, Algae and *Lemna*. Using an endpoint of 1 µg/L for *Chironomus* the TER values are still below the trigger value of 10 indicating an unacceptable risk. In addition, according to fate, the metabolites IN-JSE76, IN-K5A78, IN-K5A79, IN-PLT97 and IN-M2G98 can occur in groundwater. With a PEC value of 10µg/L the risk remains unacceptable as well for these metabolites. However, considering that the metabolites are 10x more toxic than the active substance is very worst case. The data for the metabolites on *Daphnia* show that the metabolites are at least 10x less sensitive than the active substance. In addition the EFSA conclusion states that no 'ecologically relevant' metabolites were noted in the Annex I evaluation. Therefore, the risk for the metabolites is considered covered by the active substance and is considered acceptable.

Secondary poisoning

- Since the LogPow of cyantraniliprole is 1.97 and the BCF < 1, no risk for secondary poisoning need to be considered.

Risk Mitigation Measures for aquatic organisms:

All uses: a vegetative buffer zone of 10m is necessary. In Belgium, instead of a "vegetative buffer zone" for a specific use, a no-spray buffer is mentioned for a specific use and the SPe2 phrase that applies for the whole GAP is mentioned on the registration certificate.

BEES

- The risk assessment for bees has been conducted according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002).
- At Tier 1, all HQ_{orale} and HQ_{contact} values are highly above the trigger value of 50 for the active substance cyantraniliprole, indicating a possible risk to bees. Studies with the formulation have been performed for the active substance approval. Both HQ_{orale} and HQ_{contact} are above the trigger value for the uses with an application rate of 75 and 60g a.s. / ha. Although the derived oral and contact LD50 values from studies with the technical active substance are lower than that with the OD formulation, the derived active substance endpoints are both 'greater than' values - based on mortality effects of less than 50% in the study (ref. Section IIA 8.7.1/02 of Volume 3 DAR dated April 2014). Taking this into account it is considered more appropriate to base the risk assessment on the results of the OD formulation studies – in which high levels of mortality were reported in the highest tested oral and contact toxicity test doses - enabling more precise LD50 values to be derived (ref. Section IIA 8.7.1/02 of Volume 3 DAR dated April 2014). Further refinement is therefore required for all uses.
- No new bee toxicity studies additional to that considered in the Annex I evaluation for cyantraniliprole have been reported and therefore the bee risk assessment has been largely based on the conclusions reached in the Annex I evaluation.
- Use as a vegetal crop spray poses a risk to bees when present in the crop at the time of treatment. Low residual activity has been demonstrating (short-term duration), indicating that a low risk to bees can be expected if application are made when bees are not actively foraging (avoid application when the bees are foraging on flowering weeds).
- The zRMS considers the requested crop uses not to pose a greater risk to bees than those considered in the Annex I evaluation (also lower maximum dose). Therefore, the conclusions of the Annex I evaluation for field use also apply for the uses requested for Benevia: treatment must not be made when bees are present in the crop (either foraging on the crop or flowering weeds). Also, with respect to use during flowering, only a single application may be made at this time and this only 'after daily bee flight'.

Risk Mitigation Measures for bees: the following risk mitigation measures are needed for all uses:

- SPe8: Dangerous to bees. To protect bees and pollinating insects do not apply to crop plants when in flower or when flowering weeds are present. Do not use when bees are actively foraging. The product must therefore be applied early in the morning or late in the evening.
- Other mentions: A maximum of two applications per crop to be applied, with a maximum of one application during flowering and this only after daily bee flight.

NON-TARGET ARTHROPODS OTHER THAN BEES

- The risk assessment for NTA has been conducted according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) and to the Guidance Document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods (ESCORT 2, Candolfi *et al.*, 2000).
 - Studies with the formulated product were used to test the effects on NTA rather than the active ingredient.
 - For the representative species *Aphidius rhopalosiphi*, both the HQ_{in-field} and HQ_{off-field} are highly above the trigger value of 2 for all representative uses, indicating an unacceptable risk for non-target arthropoda. On the other hand, all HQ_{in-field} and HQ_{off-field} values for *Typhlodromus pyri* are below the trigger value. The risk is considered acceptable for *T. pyri* at Tier1.
 - Additional extended laboratory tests were submitted for *A. rhopalosiphi* and the two additional species *Chrysoperla carnea* and *Coccinella septempunctata*. *A. rhopalosiphi* was the most sensitive species compared to *C. carnea* and *C. septempunctata*. Both the in-field and off-field risk are acceptable for *C. carnea* without the need of mitigation measures. For *C. septempunctata*, only the off-field risk was acceptable for all requested uses. An aged residue study with *C. septempunctata* larvae exposed to 14 and 28 days aged residues on bean leaves following application at 2 x 100 g a.s. / ha and a 7 day spray interval, showed a reduction of 66.7% mortality to 2.6% mortality in 2 weeks demonstrating a potential for recovery.
- For the refined risk assessment of *A. rhopalosiphi*, several extended lab studies and semi-field studies were submitted. The extended lab studies DP25528 and DP28801 both had a similar methodology, but the endpoints differed greatly (> 5 times). The results of the 2 semi-field studies (DP28127 & DP29957) were of limited

use because there was no mortality assessment and because of the non-optimal conditions for reproduction casting doubt on the sensitivity of the test results. For the studies DP47092, DP47093, DP27934 & DP32636, apple leaves were used as test substrate, while for the studies DP25528, DP28801, DP28127, DP29957, DP29958, DP26915 and DP28802 barley seedlings were used. The applicant proposed the use of the ER50 > 19.5 g a.s./ha for the risk assessment, which was derived from an extended lab study (DP32636) conducted with apple leaves and with the SE formulation (supported by the applicant due to no significant formulation related effects, based on Tier 1 glass plate tests). The zRMS does not agree with the endpoint proposed by the applicant for several reasons. Firstly, formulation related effects may not be apparent in glass plate tests and therefore the use of an LR50 based on a SE-formulation doesn't seem appropriate. Secondly, the substrate used in this study are detached apple leaves, while *A. rhopalosiphi* is a parasitoid of cereal aphids and apple is not a crop requested in the GAP, questioning the use of apple leaves. Furthermore, apple leaves seem less sensitive than barley seedlings since the LR50s from the extended lab and semi-field studies using apple leaves as substrate (> 19.5 – > 22.5 g a.s./ha; both OD and SE formulations ; DP47092, DP47093 and DP32636) are much higher than the LR50s from the studies using treated barley seedlings (0.822 – 4.7 g a.s./ha ; DP25528 & DP28801). It is unclear for the zRMS as to whether the reported differences in LR50 values /sensitivity relates to the species of treated plant as opposed to the more realistic treatment conditions. The applicant also refers to a study by Ternes et al. (2001) to demonstrate that no effects of substrate choice on the toxicity endpoint are to be expected. This study indeed might give an indication that only little difference between substrates can be expected. However, the species of concern, *Aphidius rhopalosiphi*, was not tested in combination with leaves of cereals or other similar Poaceae. Therefore, no information is available about the behaviour of the EC50 for cereals/Poaceae compared to other plant substrates like apple leaves. Furthermore, the study itself concluded that it cannot be excluded that studies with further plant protection products may result in other ratios between various plant substrates. Since this study didn't compare apple leaves with Poaceae (and preferably cereals), nor did it tested the active substance cyantraniliprole or a similar active substance, it is difficult to conclude, based on this study, that no difference would be expected between apple leaves and barley seedlings. Moreover, the studies performed for the submission of Benevia show a large difference between apple leaves and barley seedlings, and therefore this study is not considered relevant. In addition, HSE considers exposure to adult wasps from contact with dried residues on sprayed barley seedlings as more relevant than exposure to residues on sprayed apple leaves. Furthermore, the use of ER50 > 19.5 g a.s./ha doesn't take into account higher levels of selectivity to dried foliar residues reported in other extended lab residual toxicity studies. The zRMS suggests to use LR50 = 0.822 g a.s./ha (DP25528) as previously used in the annex 1 evaluation, since not enough reasoning is given why this endpoint should be changed. This endpoint is based on the OD formulation with barley seedlings as foliar substrate, being more relevant than apple leaves. It represent the worst case situation and also covers for reproductive effects (0.123 – 0.8 g a.s./ha DP25528 & DP26915).

- Using the annex I endpoint LR = 0.822 g a.s./ha, all in-field HQ values (*A. rhopalosiphi*) are above the trigger value of 1 indicating a potential risk. However, 2 extended lab aged foliar residue studies (DP27694: OD formulation on beans ; DP32636: SE formulation on apple leaves) demonstrate a potential for recovery within 2 weeks. This is also supported by the aged residue study on *C. septempunctata*. All off-field HQ values are also above the trigger value of 1. The zRMS suggest a 10m bufferzone + 50% drift reduction for all crops. In Belgium, buffer zones are not used as a risk mitigation measure. All HQ values are still above the trigger value using the maximum of 90% drift reduction. **No acceptable risk is demonstrated.**
- In addition, an aged residue study on aphid mummies parasitized by *A. rhopalosiphi* showed no effect on protected life stages.
- In the applicant's risk assessment, a drift value of 7.23% for brassica vegetables was proposed. Since this drift value is for use with a vertical boom sprayer, the more correct drift value of 2.38% for horizontal boom sprayers is used according to the requested crops.

Risk Mitigation Measures for NTA: Unacceptable risk for all uses.

EARTHWORMS, OTHER SOIL NON-TARGET MACRO-ORGANISMS & ORGANIC MATTER BREAKDOWN

- The risk assessment for earthworms has been conducted according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002).
- Both TERa and TERIt for earthworms are highly above the trigger value of respectively 10 and 5 for the active substance cyantraniliprole, its metabolites (IN-J9Z38, IN-

JCZ38, IN-JSE76, IN-K5A77, IN-K5A78, IN-K5A79, IN-PLT97, IN-QKV54 & IN-RNU71). The acute and long-term risk to earthworms can be considered to be low.

- For the standard soil non-target macro-organisms *Folsomia candida* and *Hypoaspis aculeifer* the TERIt values are highly above the trigger value of 5 for the active substance and its major metabolites, except for cyantraniliprole for *Folsomia candida*. However, field studies on collembolan populations indicate a potential for recovery within 1 year. A litterbag study was also submitted for the active substance (0.035 mg a.s./kg + 300 mg a.s./ha) and metabolites. No significant effects on decomposition were observed over the 6 month exposure period. The risk to other soil non-target macro-organisms is considered to be low.

SOIL MICROBIAL ACTIVITY


- The risk to non-target soil micro-organisms was assessed according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) from tests on the effects of nitrogen and on carbon mineralisation.
- The active substance cyantraniliprole, its metabolites (IN-J9Z38, IN-JCZ38, IN-JSE76, IN-K5A77, IN-K5A78, IN-K5A79, IN-PLT97, IN-QKV54 & IN-RNU71) and the formulated product showed no effects > 25% on carbon and nitrogen transformation. The risk on soil microbial activity is considered acceptable.

NON-TARGET PLANTS

- The risk assessment for non-target plants has been conducted according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002).
- Studies with the formulation were submitted for the annex I submission. Both vegetative vigour and seedling emergence have a TER value highly above the trigger value of 5 at Tier 1. The risk for non-target plants is considered acceptable.

Risk Mitigation Measures for NTP: /

Advice concerning the registration certificate:

- o **DPD-labelling** : R50/R53, N, S35, S61 (based on the toxicity endpoint for *Daphnia*: 48h-EC50 = 0.126 mg formulation/L)
 - o **CLP-labelling** :
 - **Signal Word** : Warning
 - **GHS code** : GHS09
- 
- **Hazard statements**: H410 (= H400 + H410)
 - **EUH statements** : EUH401
 - **Precautionary statements** : P391
 - **RSh /SP-phrases (PPP regulation)**:
 - SP1** : Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt./ Ne pas polluer l'eau avec le produit ou son emballage./ Do not contaminate water with the product or its container.
 - SPe2**: Om de waterorganismen te beschermen mag het product niet gebruikt worden op erosiegevoelige percelen. Voor het Vlaams Gewest en het Brussels Hoofdstedelijk Gewest geldt dit

voor percelen geklasseerd als "sterk erosiegevoelig". Voor het Waals Gewest komt dit overeen met percelen geïdentificeerd met een R-code. Indien voorzorgsmaatregelen tegen erosie zoals vastgelegd in de gewestelijke wetgevingen toegepast werden is het gebruik wel toegestaan./ Afin de protéger les organismes aquatiques, le produit ne peut pas être utilisé sur les parcelles sensibles à l'érosion. Pour la Région flamande et la Région de Bruxelles-Capitale, cela vaut pour les parcelles classées comme "sterk erosiegevoelig". Pour la Région wallonne, cela correspond aux parcelles identifiées avec le code R. Le produit peut néanmoins être utilisé sur ces parcelles à condition que des mesures de lutte contre l'érosion des sols telles que fixées dans les législations régionales soient mises en œuvre./ To protect aquatic organisms do not apply to parcels sensitive to erosion. For the Flemish region and the region of Brussels-capital, this applies to parcels classified as "sterk erosiegevoelig". For the Walloon region, this corresponds to the parcels identified with the code R. The product can nevertheless be used on these parcels if measures are taken against soil erosion such as fixed in the regional legislations.

SPe3: Om in het water levende organismen te beschermen mag u in een bufferzone ten opzichte van oppervlaktewater niet behandelen (zie risicobeperkende maatregelen)./ Pour protéger les organismes aquatiques, respecter une zone non traitée par rapport aux eaux de surface (voir mesures de réduction du risque)./ To protect aquatic organisms respect an untreated buffer zone to surface water (see risk mitigation measures).

SPe3: Om niet tot de doelsoorten behorende geleedpotigen/insecten te beschermen, dient u een verplicht minimum percentage driftreductie toe te passen (zie risicobeperkende maatregelen)./ Pour protéger les arthropodes/insectes non-ciblés appliquer obligatoirement un pourcentage minimum de réduction de la dérive (voir mesures de réduction du risque)./ To protect non-target arthropods/insects respect a minimum drift reduction percentage (see risk mitigation measures).

SPe8: Gevaarlijk voor bijen. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of in de buurt van in bloei staand onkruid. Gebruik dit product niet op het ogenblik dat de bijen actief naar voedsel zoeken. Het product moet dus toegepast worden vroeg in de morgen of laat in de avond./ Dangereux pour les abeilles. Pour protéger les abeilles et autres insectes pollinisateurs, ne pas appliquer durant la floraison de la culture ou lorsque des adventices en fleur sont présentes. Ne pas utiliser au moment où les abeilles sont activement à la recherche de nourriture, appliquer donc le produit tôt le matin ou tard le soir./ Dangerous to bees. To protect bees and pollinating insects do not apply to crop plants when in flower or when flowering weeds are present. Do not use when bees are actively foraging. The product must therefore be applied early in the morning or late in the evening.

- ***Other mentions*** : /

- **Hazard determining component(s) co-formulants* for labelling (Art.18 §3b CLP (EC) 1272/2008)(only for toxicology):/**
- **Source of CLP classification** : Based on the summation method (see evaluation zonal authorisation for details).

o **Risk mitigation measures:**

Use	NL	FR	EN
All uses	Unacceptable risk	Unacceptable risk	Unacceptable risk

Global advice concerning the application: Negative

Conditions for authorisation:

An unacceptable off-field risk is identified for non-target arthropods for all requested uses. The proposed endpoint of ER50 > 19 g a.s./ha (derived from an extended lab study (DP32636) conducted with apple leaves and the SE formulation) is rejected because of several reasons mentioned above. Using the more relevant annex 1 endpoint LR50 = 0.822 g a.s./ha (based on the OD formulation with barley seedlings), the off-field risk remains unacceptable. Further refinement is required.