

## **Biocidal Products Committee (BPC)**

Opinion on the application for renewal of the approval of the active substance:

**Dinotefuran**

**Product type: 18**

ECHA/BPC/423/2024

Adopted

28 May 2024

**BPC**  
BIOCIDAL PRODUCTS  
COMMITTEE



## Opinion of the Biocidal Products Committee

### on the application for renewal of the approval of the active substance dinotefuran for product type 18

In accordance with Article 14(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the application for renewal of the approval in product type 18 of the following active substance:

<b>Common name:</b>	<b>Dinotefuran</b>
<b>Chemical name:</b>	<b>(RS)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine</b>
<b>EC No.:</b>	<b>605-399-0</b>
<b>CAS No.:</b>	<b>165252-70-0</b>

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

### Process for the adoption of the BPC opinion

Following the submission of an application by LKC Chem-Regs Ltd (on behalf of Mitsui Chemicals Crop & Life Solutions, Inc.) on 11 November 2020, the evaluating Competent Authority Belgium submitted an assessment report and the conclusions of its evaluation to the Agency on 1<sup>st</sup> September 2023, after performing a full evaluation of the renewal application. In order to review the renewal assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-51) and its Working Groups (WG-I-2024). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at [https://echa.europa.eu/fr/potential-candidates-for-substitution-previous-consultations/-/substance-rev/74904/del/50/col/synonymDynamicField\\_1527/type/desc/pre/1/view](https://echa.europa.eu/fr/potential-candidates-for-substitution-previous-consultations/-/substance-rev/74904/del/50/col/synonymDynamicField_1527/type/desc/pre/1/view)

On November 3, 2024, in accordance with the requirements of Article 10(3) of the BPR. Interested third parties were invited to submit relevant information by January 4, 2024.

## **Adoption of the BPC opinion**

### **Rapporteur: Belgium**

The BPC opinion on the application for renewal of the active substance dinotefuran in product type 18 was adopted on 28 May 2024.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage.

## Detailed BPC opinion and background

### 1. Overall conclusion

The overall conclusion of the BPC is that the approval of the **dinotefuran** in product type **18** may be renewed. The detailed grounds for the overall conclusion are described in the renewal assessment report.

### 2. BPC Opinion

#### 2.1. BPC Conclusions of the evaluation

##### a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of dinotefuran in product type 18. dinotefuran is a neonicotinoid in the nitroguanidine class. Dinotefuran acts as an agonist of insect nicotinic acetylcholine receptors, but it is postulated that dinotefuran affects the nicotinic acetylcholine binding in a mode that differs from other neonicotinoid insecticides. Dinotefuran is a mixture of isomers R and S present in 1:1 ratio, with 0.05% (or 500 ppm) R-isomer and 0.05% (or 500 ppm) S-isomer, and consists of two tautomers which can be regarded as E/Z isomers where the protons are in equilibrium. Specifications for the reference source are established.

The physico-chemical properties of the active substance and representative biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and representative biocidal product. The addition of a bittering agent at a level of 0.01 % was agreed as unlikely to have any adverse effects on the storage stability of the representative product. Acceptable fully validated analytical methods are available for the determination of dinotefuran in the technical material, impurities in the technical material, and dinotefuran in soil, drinking water, ground water and surface water. No analytical methods were required for air, animal and human body fluids and tissues, or residues in food or feeding stuffs.

The classification and labelling for **dinotefuran** according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

<b>Classification according to the CLP Regulation</b>	
Hazard Class and Category Codes	Acute Toxicity 4 Aquatic Acute 1 Aquatic Chronic 1
<b>Labelling</b>	
Pictogram codes	GHS07 GHS09
Signal Word	Warning
Hazard Statement Codes	H302: Harmful if swallowed H400: Very toxic to aquatic life H410 : Very toxic to aquatic life with long lasting effects
<b>Specific Concentration limits, M-Factors</b>	Acute: M=10 Chronic: M= 10

##### b) Intended use, target species and effectiveness

Dinotefuran is intended to be used by professionals in products to control insects and other arthropods including cockroaches. The data on dinotefuran and the representative biocidal product have demonstrated sufficient efficacy against cockroaches.

The known mechanisms for development of resistance against other neonicotinoid active substances do not seem to affect dinotefuran insecticidal activity. However, the possibility of the development of a cross-resistance or a specific resistance to dinotefuran cannot be discounted. Rare cases of resistance to dinotefuran have been recorded in a field population of bedbugs and in lab-selected German cockroaches. Strategies to reduce the risk of resistance developing should be implemented at product authorisation. Similarly, monitoring programs to confirm that target pests remain susceptible to dinotefuran will need to be implemented.

### **c) Overall conclusion of the evaluation including need for risk management measures**

The overall conclusion from the evaluation of dinotefuran for use in Product Type 18 (insecticides, acaricides and products to control other arthropods) is that it may be possible to issue authorisations of products containing dinotefuran in accordance with the conditions laid down in Article 19 of the BPR.

#### **Human health**

The Dinotefuran 2 % bait is a ready to use gel applied indoors by professionals against cockroaches. It is supplied ready to use in a syringe style applicator tube and so is not diluted before use. The biocidal product containing no substances of concern.

Based on the available data generated on Dinotefuran 2 % no classification has been triggered.

#### Primary exposure (professional user only) :

Dinotefuran 2 % bait should be applied in 0.1 g spots in cracks and crevices. The gel should be applied at a rate of 0.2 g to 0.4 g per m<sup>2</sup>; 0.2 g/m<sup>2</sup> for small cockroach species and 0.4 g/m<sup>2</sup> for large cockroach species. Professionals would typically use the syringe in a trigger operated applicator (caulking gun) and the operator would usually control the size of the spots, however the syringe is supplied with a narrow gauge pointed nozzle to facilitate placement of small spots. Professional operators recognise that bead application is wasteful and not as efficient as small spot treatment. In cases of heavy infestations, a second application may be performed after 7 days. Therefore, only dermal exposure is considered relevant for primary professional exposure.

#### Secondary exposure (professional and general public) :

Professional and general public may be exposed to volatilised residues from treated surfaces when the product is applied indoor. However, according to the HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance, the exposure to volatilised residues indoor can be considered negligible.

Regarding professional exposure by dermal route secondary exposure is assumed to be covered by the primary exposure of these user category.

Regarding general public exposure a reverse scenario taking into account that occupants of treated premises could be dermally exposed to the gel should they be in contact with applied gel or gel that has become dislodged from treated areas. The scenario has been considered to be a short-term dermal exposure.

Exposure to dislodged or applied gel-paste via the oral route is possible if toddlers or infants came into contact with the treated area, they could contaminate their hands and ingest the

gel. The gel bait will contain a bittering agent that could discourage ingestion. The scenario has been considered to be a short-term oral exposure.

The table below summarises the exposure scenarios assessed.

<b>Summary table: human health scenarios</b>			
<b>Scenario</b>	<b>Primary or secondary exposure and description of scenario</b>	<b>Exposed group</b>	<b>Conclusion</b>
Application	Primary exposure. Dermal exposure of professional applying insecticidal gel bait product as a spot or crack and crevice treatment (long-term).	Professionals	Risk is acceptable without PPE
Post-application	Secondary dermal exposure to dislodged or applied insecticidal gel bait product (acute).	Bystanders (Adults, Children, Infants)	Risk is acceptable
Post-application	Secondary oral exposure to dislodged or applied insecticidal gel bait product (acute).	Bystanders (Infants)	Risk is acceptable

For the human health risk assessment, one primary exposure scenario has been identified, which is the application of insecticidal gel bait product using spot treatment and crack and crevice application by professionals. The risk assessment indicates that the risks from primary exposure to dinotefuran as formulated in the representative product are acceptable, without the use of Personal Protective Equipment (PPE). The risk assessment also indicates that the risks from secondary exposure to dinotefuran are acceptable. Nevertheless, secondary exposure scenarios considered using the reverse reference method indicate that contact with, or the consumption of, a relatively low number of spots of insecticidal product by infants and companion animals would result in the acute systemic Acceptable Exposure Level (AEL) being achieved, so it is recommended that the product is labelled with the following phrases: i) "Place inaccessible to children, pets and non-target animals" (N-171); and ii) "Keep out of reach of children and non-target animals/pets." (N-316).

In addition, it has been agreed that the representative product will contain a bittering agent that may discourage ingestion.

To avoid any food contamination, the following statement should be added as risk management measure (RMM) to labels of products containing the active substance:

"Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets (N-127)."

Endocrine-disrupting properties were assessed in accordance with the current Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No528/2012 and (EC) No1107/2009 (2018). Based on available information, it can be concluded that dinotefuran does not have endocrine disrupting properties in humans.

## **Environment**

Dinotefuran is very persistent (vP) in fresh water, and persistent (P) in sediment and soil. Based on toxicological studies on fresh and seawater organisms, it is concluded that dinotefuran meet the T criteria and as a noenicotinoid insecticide it is also dangerous for bees.

The degradation of dinotefuran in the different environmental compartment leads to the formation of several metabolites, which may be present in amount above 10% of parent compound (metabolite of concern).

The representative product is a gel bait product containing 2% A.S. applied indoor. The scenario assessed was the used of the product by professional user in domestic houses as well as in larger building in normal and heavy treatments by targeted crack and crevice or spot application. In order to identify a worst-case scenario, emissions from domestic houses and large building following heavy treatment uses were summed up.

The application of the representative product may result in environmental emission through sewage treatment plant (STP) following wet cleaning. The targeted compartments were STP, atmosphere, surface water and sediment as well as soil and ground water following sludge application on arable and or grassland. In addition, in-situ contact with foraging bees was also assessed.

For the metabolites of concern, an evaluation for the respective compartment where they appear was performed based on the emission of the parent compound.

The table below summarises the exposure scenarios assessed.

<b>Summary table: environment scenarios</b>		
<b>Scenario</b>	<b>Description of scenario including environmental compartments</b>	<b>Conclusion</b>
Scenario 1: Ready for use gel-bait product for use indoors by professionals against cockroaches, applied as spot treatment and crack and crevice application of gel-bait at an application rate of 0.2-0.8 g product/m <sup>2</sup> .  Step: Application	Ready for use gel-bait product for use indoors by professionals against cockroaches, applied as spot treatment and crack and crevice application of gel-bait	Acceptable
Scenario 1: Ready for use gel-bait product for use indoors by professionals against cockroaches, applied as spot treatment and crack and crevice application of gel-bait at an application rate of 0.2-0.8 g product/m <sup>2</sup> .  Step: Post-application emission through surface water	Surface water through losses to STP via drains after wet cleaning	Acceptable
Scenario 1: Ready for use gel-bait product for use indoors by professionals against cockroaches, applied	Sediment through losses to STP via drains after wet cleaning	Acceptable



<b>Summary table: environment scenarios</b>		
<p>as spot treatment and crack and crevice application of gel-bait at an application rate of 0.2-0.8 g product/m<sup>2</sup>.</p> <p>Step Post-application emission through water-sediments</p>		
<p>Scenario 1: Ready for use gel-bait product for use indoors by professionals against cockroaches, applied as spot treatment and crack and crevice application of gel-bait at an application rate of 0.2-0.8 g product/m<sup>2</sup>.</p> <p>Step Post-application; emission to soil following sludge application</p>	Soil through losses to STP via drains after wet cleaning and following limited sorption to sewage sludge	Acceptable
<p>Scenario 1: Ready for use gel-bait product for use indoors by professionals against cockroaches, applied as spot treatment and crack and crevice application of gel-bait at an application rate of 0.2-0.8 g product/m<sup>2</sup>.</p> <p>Step post application</p>	Emission to ground water via leaching from arable and grassland soil following following sludge application	Acceptable
<p>Scenario 1: Ready for use gel-bait product for use indoors by professionals against cockroaches, applied as spot treatment and crack and crevice application of gel-bait at an application rate of 0.2-0.8 g product/m<sup>2</sup>.</p> <p>Step Post-application</p>	Atmosphere through losses to STP via drains after wet cleaning	Acceptable
<p>Scenario 1: Ready for use gel-bait product for use indoors by professionals against cockroaches, applied</p>	In-situ contact with foraging bees	Acceptable

<b>Summary table: environment scenarios</b>	
as spot treatment and crack and crevice application of gel-bait at an application rate of 0.2-0.8 g product/m <sup>2</sup> .  Post-application	

The indoor scenario used for the environmental risk assessment (based upon relevant Emission Scenarios and modified by refinements agreed at various Technical Meetings, the Directive predecessor and equivalent of today's BPC working groups) is based on the assumption of a treatment of the active substance onto hard surfaces not prone to frequent wet cleaning using a targeted crack and crevice or spot treatment for cockroach control in domestic dwellings and commercial, public or municipal buildings. Application of the representative product is made only by professional operators using a syringe-based delivery system capable of delivering 0.1 g spots of gel bait. It should be noted that assessment of the representative product has assumed application either for spot treatment or crack and crevice treatment into difficult to access areas (for the purposes of cleaning by householders) behind fixtures, structures and in cavities where cockroaches feed, congregate and seek harbourage. Professional operators would be recommended to apply 0.2 g of product per m<sup>2</sup> for infestations of small cockroach species and 0.4 g of product per m<sup>2</sup> for large cockroach species. However, in cases of heavy infestations, a maximum rate of 0.8 g per m<sup>2</sup> (equivalent to 0.016 g per m<sup>2</sup> of dinotefuran) would be recommended regardless of species size.

The risk assessment assumed that treatment would be applied on a small scale with treated areas in a domestic dwelling equivalent to 2 m<sup>2</sup> (equivalent to maximum treatment of 16 x 0.1 g spots of dinotefuran 2 % bait per house) and a treated area of 9.3 m<sup>2</sup> in public / commercial buildings (equivalent to maximum treatment of 74 x 0.1 g spots of product per large building). Infestations of greater severity would need alternative and more radical control measures.

Although the representative product will be delivered into cavities and ducting, behind kitchen cabinets or cupboards etc, under cooking appliances and into cracks or crevices where cockroaches will congregate, feed and seek harbourage, it is assumed that rooms where treatment occurred would be subject to wet cleaning (but where cleaning efficiency would only reach 3 % as product has been applied to areas not prone to frequent wet cleaning).

It should be noted that the use of the representative product is indoors in cracks and other places difficult to reach. For indoor uses, exposure to bees is not expected and therefore a risk assessment is normally not necessary. Endocrine-disrupting properties were assessed in accordance with the current Guidance for the identification of endocrine disruptors in the context of the BPR and the Regulation (EC) No1107/2009 (2018). Based on available information, it can be concluded that dinotefuran does not fulfil the criteria for endocrine disruption in non-target organisms.

### **Overall conclusion**

If dinotefuran in the representative product is used in the manner described by professional operators, then the risk to human health is acceptable.

If dinotefuran as formulated in the representative product is used in the manner prescribed, with targeted indoor application into areas not prone to frequent wet cleaning against cockroaches by professional operators, the risk to surface waters through losses to STP via drains is acceptable. Acceptable risks were demonstrated to local soil. Due to the low volatility of the compound ( $5.0 \times 10^{-5}$  Pa at 25 °C), no losses to the air compartment were predicted from use of the representative product.

## 2.2. Exclusion, substitution and POP criteria

### 2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	No classification required	Dinotefuran does not fulfil criterion (a), (b) and (c) of Article 5(1) of the BPR
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	vP	Dinotefuran does not fulfil criterion (e) of Article 5(1) and does fulfil criterion (d) of Article 10(1) of the BPR
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B and vB	
	Toxic (T)	T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No	Dinotefuran does not fulfil criterion (d) of Article 5(1) and does not fulfil criterion (e) of Article 10(1) of the BPR
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s)	No	

Property	Conclusions
Respiratory sensitisation properties	No classification required
Concerns linked to critical effects other than those related to endocrine disrupting properties	No other concerns identified.
Proportion of non-active isomers or impurities	No

Consequently, the following is concluded:

**Dinotefuran** does not meet the exclusion criteria laid down in Article 5 of the BPR.

**Dinotefuran** does meet the conditions laid down in Article 10 of the BPR, and is therefore considered as a candidate for substitution, by being very persistent (vP) and toxic (T).

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR", "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR" and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment" agreed at the 54<sup>th</sup>, 58<sup>th</sup> and 77<sup>th</sup> meeting respectively, of the representatives of Member States Competent Authorities for the implementation of the BPR concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a), (b), (d), (e) and (f) of the BPR.

### 2.2.2. POP criteria

Dinotefuran fulfils the criteria for being vP and T. However, dinotefuran does not demonstrate the potential for long range transport. In view of this, dinotefuran does not meet the criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004.

### 2.2.3. Identification of potential alternatives substances or technologies, including the results of the public consultation for potential candidates for substitution

As the condition of art. 10(1)(d) is met for dinotefuran PT 18, a third-party consultation on potential candidates for substitution was therefore launched between 03 November 2023 and 04 January 2024. Two comments were received.

The first contribution was submitted by the applicant stating that there are no alternatives available on the market. Their analysis of alternatives for the active substance dinotefuran and authorised dinotefuran-containing biocidal products was carried out according to the "ECHA's Analysis of alternatives to biocidal active substances for applicants and authorities: a recommended framework guidance from January 2023". The attempt of the applicant to identify possible alternatives to dinotefuran and dinotefuran-containing products included a data search using publicly available tools and databases. The data search results were reviewed considering the target organisms of the products found in the search and compared to dinotefuran-containing biocidal products (currently four on the EU market): cockroaches, ants and houseflies. Secondly, the products with matching target organisms to

dinotefuran-containing products were further reviewed and a conclusion was drawn if the alternative was selected or rejected for further assessment. The alternatives were reviewed regarding the application method and category of users as well as description of use in comparison to dinotefuran-containing products. According to the applicant, only one substance, indoxacarb (enantiomeric reaction mass S:R 75:25) with CAS number: 144171-61-9 was identified as a potential alternative. It was concluded that indoxacarb (enantiomeric reaction mass S:R 75:25) cannot be considered as a suitable alternative to dinotefuran due to more hazardous and toxic properties of indoxacarb specified in the harmonised classification according to CLP. No other alternatives to dinotefuran and dinotefuran-containing products were found during the analysis of alternatives made by the applicant.

The second comment received from an individual did not contain any statement with regard to the availability of alternatives but indicate that the use "*against house flies in animal housing, by farmers*" should not be approved due to misuse risk. This specific use has only recently been present on the EU market for a short time therefore it is not possible to verify the risk of misuse at this stage.

The BPC notes the following: For PT 18, 43 active substances have already been approved. Only ten of these are not candidates for substitution and effective against the same target organisms as dinotefuran:

- Cypermethrin
- epsilon-Momfluorothrin
- Imiprothrin
- Transfluthrin
- Deltamethrin
- Silicium dioxide
- Cyfluthrin
- Indoxacarb (enantiomeric reaction mass S:R 75:25)
- Indoxacarb
- Alpha-Cypermethrin

Dinotefuran is a neonicotinoid in the nitroguanidine class. It appears that dinotefuran acts as an agonist of insect nicotinic acetylcholine receptors (nAChRs) in the Insect Resistance Action Committee (IRAC) group 4A, but it is postulated that dinotefuran affects the nicotinic acetylcholine binding in a mode that differs from other neonicotinoid insecticides (chlorinated neonicotinoid molecules). The chemical structure of dinotefuran is different from other neonicotinoids because it contains different cyclic substituent (furan instead of piridine). Dinotefuran shows good insecticidal activity against flies that are tolerant towards other chemicals (e.g. imidacloporid). Literature studies on resistance and tolerance against neonicotinoids in insects have shown resistance against dinotefuran is currently not an issue. The known mechanisms generally involved in the development of resistance against other neonicotinoids do not seem to impact resistance against dinotefuran, indicating other mechanisms are involved in the insecticidal properties of dinotefuran.

Based on the information available, it is concluded there is no other active substance available offering similarly the combination use/target-organism. In addition, dinotefuran is

an essential compound to maintain the chemical diversity as a tool against the development of resistance, in case resistance is developed against other compounds that are currently used for their insecticidal activity.

### **2.3. BPC opinion on the renewal of approval of the active substance dinotefuran in product type 18**

In view of the conclusions of the evaluation, it is proposed that the approval of **dinotefuran** shall be renewed, subject to the following specific conditions:

1. Specification: Minimum purity of the active substance evaluated is 991 g/kg (99.1% w/w). Dinotefuran is a racemic mixture.
2. Dinotefuran is considered a candidate for substitution in accordance with Article 10(1)(d) of the BPR.
3. The authorisations of biocidal products are subject to the following conditions:
  - a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
  - b. For products containing dinotefuran that may lead to residues in food or feed, Member States ensures compliance with the current MRLs values (Reg. (EU) No 491/2014) or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation No 396/2005 and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

The active substance does not fulfil the criteria according to Article 28(2)(b) to enable inclusion in Annex I of BPR. Dinotefuran is classified as toxic to the aquatic life of acute category 1 and fulfils the criteria for being very persistent and toxic (vP, T).

### **2.4. Elements to be taken into account when authorising products**

1. The active substance dinotefuran is considered as a candidate for substitution, and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for either national or Union authorisation.
2. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:
  - a. The product assessment shall pay particular attention to the implementation of resistance management strategies to reduce the risk of development of resistance against dinotefuran, especially when products against high-risk target organisms, such as bedbugs (due to rapid development of resistant populations) are considered.
  - b. An assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs.
  - c. For products that may lead to residues in food or feed a dietary risk assessment has to be performed at product authorization level.

- d. In order to reduce the secondary exposure of the children and pets, the following RMM must be mentioned: "Place inaccessible to children, pets and non-target animals (N-171)."; and "Keep out of reach of children and non-target animals/pets (N-316)." Gel-bait products authorised should contain a bittering agent that may discourage ingestion unless exposure of children (and pets) can be excluded.
  - e. Products which may be mistaken for food or feed shall contain a bittering agent.
3. Only a limited environmental risk assessment was performed on dinotefuran as formulated in the representative product due to its controlled and targeted indoor use pattern against cockroaches. Special attention should be paid to the potential risks to bees. Additional supporting environmental effects plus fate and behaviour data may also be required on both the active substance and relevant metabolites. The exposure assessment in the AR is based on a very limited exposure. If in future applications for product authorisation additional uses with soil exposure are claimed, these need to be further assessed and additional data on soil living insects and other not target organisms should be considered.
  4. To be in line with CA-Dec20-Doc.4.1final, a warning sentence must be included in the SPC of PT18 containing substances for which the LD50 (acute oral or contact) < 11 µg/bee. As an EC50 of 0.056 µg/bee was determined for Dinotefuran, which is below the trigger value set in CA-Dec20-Doc.4.1final, the following sentences must be added to the SPC : "This biocidal product contains dinotefuran which is dangerous to bees."
  5. With regard to aqueous photolysis, this route of degradation should be considered on a case-by-case basis by individual Member States depending upon local conditions, especially if use patterns were to be extended / changed and could potentially lead to direct exposure of surface waters.
  6. For treated articles no restrictions are set during the the active substance approval or renewal. Treated articles are not expected for dinotefuran.

## **2.5. Requirement for further information**

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the renewal of approval of **dinotefuran**.