Biocidal Products Committee (BPC)

Opinion on a request according to Article 75(1)(g)

The evaluation of the availability and suitability of alternatives to hexaflumuron

ECHA/BPC/339/2022

Adopted

09 June 2022

Opinion of the Biocidal Products Committee

on the evaluation of the availability and suitability of alternatives to hexaflumuron

In accordance with Article 75(1)(g) 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, the Biocidal Products Committee (BPC) has adopted this opinion on the evaluation of the availability and suitability of alternatives to hexaflumuron.

This document presents the opinion adopted by the BPC, having regard to the conclusions of the rapporteur.

Process for the adoption of the BPC opinion

A request by Commission was received by ECHA on 17 May 2021. The request was confirmed by ECHA to be passed to the BPC. The BPC appointed the rapporteur at its 39th meeting on 15 June 2021. The rapporteur presented the draft opinion to the BPC at its 42nd and 43rd meetings on 9 March and 9 June 2022, respectively. Following the adoption of the opinion at the BPC meeting of 9 June 2022 the opinion was amended accordingly and delivered by ECHA to the Commission.

Adoption of the opinion

Rapporteur: Greece

The BPC opinion was adopted on 9 June 2022.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA webpage at: https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/opinions-on-article-75-1-g.

Further details of the opinion and background

1. Request for the opinion and background

On 23 September 2020, Dow AgroSciences Switzerland S.A submitted to ECHA an application for the renewal of approval of hexaflumuron for PT18 “insecticides, acaricides and products to control other arthropods” as bait against subterranean termite species (*Reticulitermes* sp., *Coptotermes* sp., *Heterotermes sp*. and *Nasutitermes* sp.), in accordance with Article 13 of Regulation (EU) No 528/2012 on Biocidal Products (the BPR). This application is currently under evaluation by the Greek eCA.

According to the Assessment Report for active substance approval, Hexaflumuron meets the criteria for being very persistent (vP), very bioaccumulative (vB) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006, and therefore meets the exclusion criteria set out in Article 5(1)(e) of the BPR.

The approval of an active substance meeting the exclusion criteria should not be renewed unless it is shown that at least one of the criteria set out in Article 5(2) is met. When deciding on whether the approval of an active substance may be renewed, the availability of suitable and sufficient alternative substances or technologies is a key consideration.

Among others, it was agreed during the 68th Standing Committee on Biocidal Products of 15 May 2020 that an opinion should be specifically requested from ECHA’s Biocidal Product Committee at the beginning of the renewal examination of the concerned active substances on whether there are suitable and sufficient alternative substances and technologies for the use(s) referred to by the applicant.

Hence, in May 2021, the BPC was requested by the European Commission to obtain such an opinion for hexaflumuron for PT 18 (insecticides) for the use(s) presented in the application for renewal.

2. Summary of information supporting the request for the opinion

Termites in Europe (Taxonomy, Biology and Socio-economic considerations)

Termites belong to the order of Isoptera. In continental Europe and in the European tropical overseas regions there are three main termite families; subterranean (Rhinotermitidae), drywood termites (Kalotermitidae) and tree termites (Termitidae).

Termites, in natural settings, work as beneficial insects by breaking down cellulose-containing materials, such as dead trees. However, termites can cause damage to living trees and many crop plants, but the fact that they can use dead wood makes them a major pest for timber used both outdoors and inside buildings. Termites become a problem to humans when they infest timber used in constructions (i.e., wood structures) in risk areas. Owing to their high moisture requirements, they usually nest in soils, but can invade buildings from underneath through cracks and seams or by building shelter tubes connecting the wood to their nest in the soil.

According to the applicant, termites are widespread in Southern continental Europe, being France, Italy, and Spain the most infested countries. Termites are very difficult to control and damage not only private homes but also historic buildings and sites.

These structures, if left untreated, would cause big financial constraints since termite infested structures have a low market value and cause significant impact on society, where historical buildings are concerned.

Many historical sites like Sorbonne in Paris (France), city center of Bourges (France), Cathedral of Santiago de Compostela (Spain), city of Bagnacavallo (Italy) were threatened to crumble. In 2000, J.L. Clément estimated that the annual cost of termites in France alone was 500 million euros per year, and that the cost of termite control in Europe, not including the cost of repair for damages, would reach 1 billion euros.

Examples of historic structures that have been treated with hexaflumuron are the Palace of Charles V (Granada) in 2018, the urban area of Villa del Río (Córdoba) in 2019 and Tacoronte (Canary Islands) in 2020, all of them in Spain; the Abbey of Fontfroide (Aude) in 2008, the Medieval Village of Monestiés (Tarn) in 2015 and the legendary music-hall Olympia, the Theatre Edouard VII, OECD building (Paris), all of them in France; and the historical centre of Bagnacavalli (Italy); among other treatments. Therefore, hexaflumuron can contribute to the maintenance of European national heritage.

Distribution of termite species in continental Europe and European tropical overseas areas

Reticulitermes is the most common genus encountered from the Rhinotermitidae family (subterranean termites) in Europe. The main species registered are: *R. flavipes (former R. santonensis), R. lucifugus, R. lucifugus corsicus, R. grassei, R. banyulensis, R. balkanensis*. They are widespread around the Mediterranean (Spain, France, Italy, Portugal, Balkans, and Greece) and Black Sea (Turkey, Rumania), though some termite spots in the UK and Germany have been reported. The main two species of drywood termites present in Europe (especially in the coastal areas of Mediterranean countries and Canary Islands) are *Kalotermes flavicollis* and *Cryptotermes brevis* (ECHA Efficacy Guidance, 2018).

Cryptotermes sp. is a main genus belonging to drywood termites encountered in the European tropical overseas regions. *Coptotermes sp*. (introduced from India – Malaysia) and *Heterotermes sp.* are the main two species belonging to the Rhinotermitidae family (subterranean termites) found in European tropical overseas regions. *Nasutitermes* sp. are the main species belonging to the Termitidae family (tree termites) encountered in the European tropical overseas regions (ECHA Efficacy Guidance 2018). Specifically, according to the applicant, *Coptotermes havilandi* is the main species in La Réunion, *Heterotermes tenuis*, *Nasutitermes costalis* and *N. ephratae* are the main species in Martinique and Guadeloupe and *Heterotermes tenuis*, *Nasutitermes sp* and *Coptotermes testaceus* are the main species in French Guyana.

Tropical termite species in continental Europe

According to the databases “CABI-Centre of Agriculture and Bioscience International” (https://www.cabi.org/ISC) and “Fauna Europea” (https://fauna-eu.org/), *Coptotermes*, *Heterotermes* and *Nasutitermes* termite species found in European tropical overseas areas are not established in continental Europe. However, the tropical termite *Coptotermes gestroi* was accidentally introduced in Italy in 2011. This species was found on a yacht docked in a boatyard in Sicily for extraordinary repairs. The yacht had entered the Mediterranean Sea after having sailed the Caribbean Sea, and having visited, from 2007 to 2009, Panama, Bahamas, Barbados and Jamaica. The acclimatization of *C. gestroi* in Italy seems unlikely, but its establishment could be possible in urban areas, where microclimatic conditions are warmer than in the surrounding areas (Marini et al., 2011).

According to a review paper by Evans et al. (2013), the invasive termite species *Coptotermes* sp. and *Heterotermes* sp. are found in tropical overseas areas, but not in continental Europe. In 2013, Li et al. (2013) published a paper showing the predicting habitat suitability of *Coptotermes gestroi* with species distribution models. According to the authors six *Coptotermes* species have been recorded as invasive pests, and *C. gestroi* and *C. formosanus* have the largest distribution and are the most often occurring in tropical and temperate areas,

respectively. They state that some temperate cities with high introduction risk are located in continental Europe. They speculate that if human create a favourable environment such as indoor heating, local infestation may occur in these temperate zones, but further naturalization is unlikely. However, tropics and subtropics are under higher risk of *C. gestroi* establishment.

Hexaflumuron risk assessment

There is harmonised classification for hexaflumuron concerning environmental hazards (https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/70428). Hexaflumuron is classified to aquatic life as “Acute Cat 1” (H400) and “Chronic Cat 1” (H410) (Acute M factor =1000, Chronic M factor =10000).

Hexaflumuron is not classified for human health hazards (RAC35, Feb 2016).

It is very Persistent (vP), very Bioaccumulative (vB) and Toxic (T).

Hazard and risk of hexaflumuron will be further assessed in the context of hexaflumuron renewal.

3. Potential alternatives to hexaflumuron

Intended uses of Hexaflumuron (as claimed by the applicant)

Hexaflumuron is a PT18 insecticide acting as insect growth regulator (IGR) by stopping the insect’s growth. It interferes with chitin synthesis, which termites need to form a new exoskeleton. Hexaflumuron containing products are intended to be used by trained professionals for termite control. Hexaflumuron is formulated in solid cellulose baits and is used in two types of tamper resistant bait stations - wall mounted and below ground. The product is intended for the protection of terrain and structures, both indoor and outdoor. Workplace descriptions include structures such as, but not exclusively: houses, apartments, studios, mansions, castles, churches, restaurants, hotels, business premises, public and community buildings as well as terrain such as, but not exclusively; gardens, parks, fields, avenues and landscaping. Target organisms to be controlled, as claimed by the applicant, are subterranean termite species: *Reticulitermes* sp., *Coptotermes* sp., *Heterotermes* sp. and *Nasutitermes* sp.

Prior to the installation of the bait station, the level of termite activity and the extent of damage should be determined. The above ground stations should be installed on the walls and the in-ground stations into the ground. Then the bait product should be placed into the station. Once termites start feeding, baits should be replaced as needed. When no termites are feeding anymore, bait should be removed in the case of indoor stations or outdoor stations; in the case of outdoor stations, these can be left in place for monitoring and termite prevention.

There is a time interval of approximately 6-24 months between baiting and elimination when the active substance hexaflumuron is used. This duration is reflective of the mode of action of hexaflumuron where termite workers must go through their moult for the product to be effective and not all workers moult at the same time. This mode of action is important as a termiticide, because termites are able to acquire a lethal dose, return to the colony, and pass it on to other members prior to dying, insect to insect by trophallaxis. This also prevents an aversion to the treated area since termites do not die in this area. The range of the time delay is dependent on the rate of metabolism or excretion of the active substance from the termite and the size, caste ratio, feeding pattern, and the activity of the colony due to temperature (extremes of heat or cold can reduce activity).

Criteria for alternatives

No guidance is currently available that establishes criteria for what is considered a "suitable and available alternative" for an active substance that meets the BPR exclusion criteria. The following criteria, including those taken from ECHA's Article 10 public consultation website, were identified as being critical for the assessment of alternatives:

- Technical feasibility: can the alternative offer the same level of protection and functionality?
- Financial aspects of feasibility: can the alternative offer the same level of protection and functionality at the same price point?
- Hazards and risks of the alternative: do the alternatives reduce the hazard and risk to man and the environment compared to the use of hexaflumuron-based baits? An alternative active substance should not meet the BPR exclusion criteria as this would not contribute to a lower hazard/risk;
- Availability: is the alternative widely and readily available or is capacity a problem?

Resistance

According to "IRAC: Arthropod Pesticide Resistance Database" (https://www.pesticideresistance.org/search.php), no resistance cases for hexaflumuron have been reported so far for termites or other insect species, while no resistance cases on any active substance have been reported in the order of Isoptera (termites).

Based on the information available the occurrence of resistance is not considered a critical factor when deciding on the renewal of hexaflumuron.

3.1. Biocidal products on the EU market under the BPR (528/2012)

According to the ECHA website (https://echa.europa.eu/el/information-on-chemicals/biocidal-products) and information provided by ECHA to the eCA, currently there are ten PT18 products against termites, authorized in the E.U. market under the BPR (528/2012). These products are based on seven PT18 active substances approved in EU market, namely permethrin, deltamethrin, fipronil[1], diflubenzuron, aluminum phosphide releasing phosphine, magnesium phosphide realizing phosphine and nitrogen.

Products based on permethrin and deltamethrin are applied as physico-chemical barrier, i.e., the insecticide is incorporated in a plastic film that will be laid under the concrete slab (pre-construction method). Pre-construction methods apply to new building construction in areas that are known to be infested with termites. They need to be set up before the concrete of the foundations is poured. It consists of creating a barrier that will prevent the termites to invade the structure to be protected before its construction. Permethrin and deltamethrin based products are intended to be used against European termites (*Reticulitermes* sp.) including termite species encountered in European tropical overseas regions (*Nasutitermes* sp., *Coptotermes* sp., *Heterotermes* sp., *Cryptotermes* sp.). Taking into consideration the intended uses of Hexaflumuron (application method, target organisms), permethrin and deltamethrin based PT18 products are authorized against the termite species claimed also for hexaflumuron, but these products are applied with different application method (physico-

[1] Fipronil is approved for PT 18 until 30/09/2023 but no renewal application has been received to date and is not expected to be received.

chemical barrier as pre-construction method) than hexaflumuron (bait in bait stations) and also, according to Mallis (2004) they are high-cost methods.

Fipronil is used in drench treatments (physically drenching the surrounding of the structure) or injecting the insecticide into the house walls with a hose. It is intended to be used against European termites (*Reticulitermes* spp.) and termites found in tropical overseas areas (*Coptotermes* spp.). Products containing fipronil are intended to be used against European and tropical termite species that are also claimed for hexaflumuron, however these products are used by different application methods than hexaflumuron (drenching or injecting, not as baits).

Aluminum phosphide and magnesium phosphide-based products are fumigants acting by hydrolysis against dry wood termites (*Kalotermes* spp.). Products containing Nitrogen are used as fumigants as well under the controlled atmosphere technique against the drywood termite *Incisitermes minor*. Fumigant PT18 products authorized for termites, are intended to be used with different application method and against different termite species than those claimed for hexaflumuron.

Diflubenzuron based products are used as termite baits in bait stations like hexaflumuron. The use of baits is a targeted method; baits are only applied in bait station on spots where termite activity is confirmed. Because baits are transported to the heart of the colony, they will destroy the larvae, the workers, the soldiers, and the reproducing termites and result in complete elimination of the colony. Diflubenzuron belongs to the same chemical class with hexaflumuron and has the same mode of action acting as insect growth regulator. Authorized products containing diflubenzuron are applied with the same application method as hexaflumuron, i.e. baits in bait stations. However, diflubenzuron-based products are intended to be used only against termites found in Europe (*Reticulitermes* spp.), not against termite species encountered in European overseas tropical areas which are also claimed for hexaflumuron.

It is noted that diflubenzuron is also approved as a pesticide with Commission Implementing Regulation (EU) 2017/855, but only for use in non-edible crops as the food processing may lead to formation of metabolite *p*-chloroaniline (PCA). PCA is an impurity (and metabolite in food) of diflubenzuron and it has been identified by the European Food Safety Authority (EFSA, 2015) as a genotoxic carcinogen (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4222). It is not expected that PCA will be formed as a metabolite of diflubenzuron in biocidal diflubenuron-based products used as baits in bait stations. In cases of alternative application methods, it should be demonstrated that there is no indirect exposure of edible crops.

Potential health concern from exposure to PCA may be identified due to its presence as impurity in the biocide diflubenzuron.

3.2. Non-chemical alternatives (information provided by the applicant)

Physical methods exist in pre-construction but mostly always associated with a chemical treatment. Physical-barrier method applies as pre-construction method to new building construction in areas that are known to be infested with termites. It needs to be set up before the concrete of the foundations is poured. It consists of creating a barrier that will prevent the termites to invade the structure to be protected before its construction. A very fine metal mesh is placed under the foundation that will prevent entry. According to Mallis (2004) it is a

high-cost method. Some research is being conducted in Australia with other materials that would prevent entry of termites, but these are not commercially available.

Reference to potential biological control agents of plant, fungal or nematode origin exist (Ahmad et al., 2018; Su & Scheffrahn, 2000) yet much remain to be done as per active substance(s) characterization, product formulation, delivery system definition as well as efficacy demonstration and recommendations development to achieve control of a range of target subterranean termite species. For the time being the information provided is not sufficient to assess the suitability for these alternatives.

3.3. Biocidal products on the E.U. market under the transitional period (Article 89, BPR 528/2012)

Currently, hexaflumuron-based bait products against termites are placed in the EU market in Portugal, Spain, France and Italy under the transitional period (Art. 89 of the BPR). Current applications for hexaflumuron-based products against termites under the BPR are still under evaluation by the Portugese CA with a mutual recognition procedure in the Spanish and French CAs.

No PT18 products against termites were identified on the Greek market authorized under the transitional period. On 16 August 2021, Greek eCA and ECHA launched a consultation with all the MSCAs related to the mandate from the European Commission requesting ECHA opinions under Article 75(1)(g) of the BPR on the "Evaluation of the availability and suitability of alternatives to hexaflumuron for PT18". Replies from 19 Member States (MSs), including Greece, were received; namely Belgium, Croatia, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Latvia, Luxemburg, The Netherlands, Malta, Slovakia, Portugal, Poland, Sweden and Norway.

In Malta, Croatia, Hungary, Ireland, Norway, Sweeden, Denmark, Estonia, Latvia, Slovakia, Finland, Luxemburg, The Netherlands and Belgium there are no PT18 products on the market against termites under the transitional period.

In Germany there are two PT18 products on the market under the transitional period which contain hexaflumuron, but they are not used against termite species. In Poland, there are two PT18 products on the market under the transitional period which are used against termites, but none of them is bait; these products are liquid insecticides containing extract from *Chrysanthemum cinerariifolium*, for indoor and outdoor use by non-professionals.

3.4. Stakeholders' and interested third parties' consultation

In summer 2021, the eCA and ECHA identified 60 stakeholders at EU or national level in relation with wood protection, termite control or alternatives to hazardous substances (industry associations, providers or installers of termite control products, chemical manufacturers, a technical institute and an NGO). These stakeholders were informed by ECHA about the interested third parties' consultation organised according to Article 10(3) of the BPR from 16 August until 15 October 2021 concerning the renewal of hexaflumuron. A total of 125 replies2 from stakeholders (companies' downstream users, manufacturers, industry, or trade associations etc.) were received.

[2] Available here: https://echa.europa.eu/potential-candidates-for-substitution-previous-consultations/-/substance-rev/66201/del/200/col/synonymDynamicField_1527/type/asc/pre/1/view.

Except for chemical alternative active substances, no additional non-chemical alternatives for the use of hexaflumuron were identified in the consultation. Most respondents are in favour of not renewing hexaflumuron or in favour of restricting it to non-permanent baiting.

Almost one third (42/125) of responders, supported the renewal of hexaflumuron. Most of them indicated that other substances which are currently on the market (fipronil and diflubenzuron) cannot be considered alternatives for the use of hexaflumuron. Specifically, it is noted that the use of fipronil (injection treatments) requires the injection of hundreds of litres of insecticide into the walls of a building, which increases exposure risks, compared to the bait method. Also, with the use of fipronil, labour cost is higher and efficacy is lower than using hexaflumuron bait systems. Furthermore, it is mentioned that this method is not targeted. The product solution is injected in the wall, but it is not known where the product goes.

One company from France stated that the chemical barrier treatment with fipronil, drives out termites from buildings without eliminating the colonies, which then reside in the earth. This drives termites in trees, or neighbouring houses. The treated house is protected but the infestation continues elsewhere. On the contrary, giving support to Hexaflumuron, they indicate that when they use the hexaflumuron baiting system it is possible to eradicate the termite colony(s), without repelling termites in the neighbourhood. They prefer this defensive system since the bait remains in the stations, without being washed out by the rain.

Regarding diflubenzuron as an alternative to hexaflumuron, it is pointed out that it is marketed in a powder, dusty formulation3, which increases the potential for inhalation exposure and potential water and crops contamination via air transportation or flooding and is not effective against tropical termites, which are a serious danger in the French oversea territories (La Réunion and Caribbean islands). Also, some companies from France state that diflubenzuron based-baits have lower efficacy than hexaflumuron based-baits.

However, most of the respondents oppose to the renewal of hexaflumuron. The majority (2/3) supports that there are technically and economically possible alternatives available to hexaflumuron and especially, diflubenzuron-based baits and fipronil. They support that these alternative products can be used either for baiting (diflubenzuron) or liquid injection treatments (fipronil). They specify that these techniques have been applied by professionals for more than twenty years with satisfactory results. Alternatives are suitable and viable for termite control companies in continental Europe.

Regarding diflubenzuron-based baits, which is the closest alternative to hexaflumuron in terms of its mode of action and application method, they support that they are easy to use and economically feasible, although they are not authorized for uses against tropical termites.

One Spanish company stated that hexaflumuron was authorized considering its efficacy against Coptotermes species, which are only present in French overseas areas. Therefore, the company suggested restricting the use of hexaflumuron to the French overseas departments for the application against Coptotermes species but banning its use in continental Europe.

Some of the stakeholders from Reunion Island, France and Spain indicated as alternatives the active substances bistrifluron and chlorfluazurol, which are not approved in EU. Chlorfluazurol, belongs to benzyl-ure class and they state that it is used as bait in Australia and Mauritius against all termites, including tropical termite species. Bistrifluron belongs to

[3] No information was available whether diflubenzuron could be formulated in a non-powder form which would reduce emission and exposure potential.

benzyl-ure class as well, and they state it is used as bait in Asia against subterranean termite species.

Other active substances, namely permethrin, cypermethrin, a-cypermethrin, acetamiprid, fenoxycarb, chlorphenapyr and flufenoxuron4 were indicated by some stakeholders as alternatives, however, no further information was provided to assess their suitability as alternatives to hexaflumuron.

Many of responders indicate the necessity to ban the use of hexaflumuron, because it is used in permanent baiting. One company states that this permanent baiting use is not necessary for elimination of the termite colony(s) and requires around 10 times more active ingredient in the ground than application of alternative products. Also, it does not eliminate the termite colonies faster and exposes the building to higher risks than with non-permanent baiting or liquid injections (fipronil). Some of the reactions claim that they normally use hexaflumuron-based products as non-permanent baits. The provided information for the use of hexaflumuron-based products as non-permanent baits is not sufficient to assess the suitability for this type of application method.

A company sent confidential information about a new chemical alternative product (PT18), which is under development, showing excellent efficacy as a termiticide (please see tables 1 & 2). According to the company, it has been already extensively tested for its efficacy not only against termites but also against wood borers. Formulations of this active substance are currently available in commercial quantities but as it is not yet approved or product authorizations granted, the placing on the market will be possible only when both procedures are finalized.

Overall, based on the replies received by stakeholders during the interested third parties' consultation, there are currently approved active substances as potential alternatives for the use of hexaflumuron. Most of the reactions support that there are available suitable chemical alternatives for the use of hexaflumuron, noting however that each alternative has its own limitations.

3.5. Other information

During the commenting period, the applicant, to support the renewal of hexaflumuron, provided information which involved published papers, where hexaflumuron was compared with other chitin synthesis inhibitors, including diflubenzuron, in terms of efficacy against termites including *Reticulitermes* species.

In the commenting period after the BPC-42, Spain provided a document "BPC draft Opinion Art. 75 – hexaflumuron", where the distribution of the invasive termite species *Reticulitermes flavipes* in the Canary Islands is reported (García Hernández, 2022). *R. flavipes* is currently present in the Canary Islands, specifically on the islands of Tenerife and Lanzarote. Its presence in Tenerife has been known since at least 2009. Canary Islands have the favourable climatic conditions (high temperature and humidity) and abundant food (structural wood or living trees) for *R. flavipes* to increase its distribution and impacts, both on the island of Tenerife or other regions through exports. The report highlights the impacts and threats by feeding activity of *R. flavipes*, namely impacts on biodiversity and natural ecosystems due to feeding on agricultural and ornamental plant species; socioeconomic impacts due to damages

[4] Flufenoxuron was approved in the EU for PT8 until 31/01/2017 but no renewal application has been received to date.

caused to buildings, street furniture and trees; impacts on human health due to falling trees, street furniture such as electricity poles etc.

In the document it is stated that for the eradication of these termite species in Tenerife, only hexaflumuron-based baits products have been applied. This choice was relied on the consideration of the particular sub-tropical climate conditions present in the Canary Islands, the related high growth rate of termites in these islands and the assumption that hexaflumuron-based baits have a better efficacy performance than diflubenzuron-based baits against *R. flavipes* based on i) published papers and ii) data provided by manufacturers for treatments in France (elimination of colonies is achieved a year earlier with hexaflumuron using 23 times less active substance than diflubenzuron), noting however that the environmental conditions in France are unfavourable for *Reticulitermes flavipes*. However, according to the report no treatment has been carried out in the the environmental conditions of the Canary Islands with diflubenzuron against termites, and there are plans to carry out field tests to evaluate its effectiveness and assess its possible inclusion in the eradication project of *R. flavipes*. Hence, there is no evidence for ineffective use of diflubenzuron or better efficacy of hexaflumuron against *R. flavipes* in Tenerife islands. The Spanish report also indicates that the termite distribution area extends through a zone of great agricultural activity, where the population centres are in the middle of crop areas, limiting the use of diflubenzuron due to the possible translocation of the active substance and metabolites to crops.

Another document on the comparison between diflubenzuron and hexaflumuron products in Tenerife (Canary Island) originally submitted in Spanish by Spain by to the BPC[5] describes the results obtained with hexaflumuron 0.5% (number of sites non specified) and two sites with diflubenzuron 0.25% w/w. The report concludes that the treatment with hexaflumuron was successful on all investigated sites with colony activity practically non-existent after 4-6 months, whereas the efficacy of diflubenzuron could not be confirmed due to no significant decrease of termite activity observed after several months or years of treatment.

The BPC considers that the abovementioned information is not sufficient to support the limited performance of diflubenzuron against *Reticulitermes* termites, considering that diflubenzuron-based products are already authorized in the EU against *Reticulitermes* termites based on norms and criteria set in relevant efficacy guidance under the BPR. For product authorization stage purposes, diflubenzuron-based products were proved as efficacious in laboratory and field studies conducted in mainland Spain and France against *Reticulitermes* termite species including *Reticulitermes flavipes* (field tests in mainland France) fulfilling the requirements of the efficacy guidance. Nevertheless, the BPC recognises that no efficacy tests of diflubenzuron performed according to the efficacy guidance under the BPR with the climatic conditions prevailing in the Canary Islands are available and, if existing, could have led to different results.

The BPC highlights that the comparison of efficacy between the products based on hexaflumuron and the ones based on the diflubenzuron is challenging since the efficacy tests have been performed according to different standards (authorisations under the transitional periods under Art. 89 versus authorisation under the BPR respectively). However, it shoud be noted that even if efficacy of the alternatives is not tested against tropical termite species,

[5] Documentación relativa a la comparación de los productos de diflubenzurón y hexaflumurón y final elección de hexaflumurón para la eliminación de la termita subterránea reticulitermes flavipes que afecta a la isla de tenerife (Islas Canarias, España), 2020.

this doesn’t necessarily imply that the alternatives are not efficacious against these organisms.

Tables 1 and 2 below summarise the information collected on hexaflumuron and its alternatives for termite control[6]. The conclusions on the suitability of the alternatives are based on the availability of the alternatives on the EU market, their application method, their technical and economic feasibility and the target organisms. The alternatives assessed include chemical and non-chemical, preventive and curative methods. A particular focus of the analysis has been made on alternatives with similar purpose and application method to hexaflumuron (i.e. curative treatment using baits). The closest alternative to hexaflumuron in terms of mode of action, formulation type and application method (curative treatment – bait in bait stations), is diflubenzuron. Other alternatives could be considered suitable for certain purposes and use conditions (e.g. prevention) since products are available on the market but might not be suitable to replace hexaflumuron (see details in tables 1 and 2).

Table 1. Chemical alternatives to hexaflumuron: active substances approved in the EU, used in products against termites, non-chemical alternatives (for which eCA had enough information collected) & products under development (information collected from Stakeholders' and interested third parties' consultation).

Active sub-stance / method	**hexaflumuron**	**permethrin**	**deltamethrin**	**fipronil**	**aluminum phosphide releasing phosphine**	**magnesium phosphide releasing phosphine**	**nitrogen**	**diflubenzuron**	**chemical alternative under developme nt**	**physical barrier**
Status	Approved-RNL[7] Under assessment	Approved	Approved	Approved[8]-Candidate for substitution	Approved-RNL Under assessment	Approved-RNL Under assessment	Approved -Annex I of the BPR	Approved	Under assessment	Non-chemical method
Chemi-cal Class	Benzyl-urea	pyrethroids	pyrethroids	Phenyl-pyrazoles	Inorganic compound	Inorganic compound	Inorganic compoun d	Benzyl-urea	confidential	N/A
Mode of Action	IRAC Class 15 (inhibitors of chitin biosynthesis affecting CHS1)	IRAC Class 3A (sodium channel modulators)	IRAC Class 3A (sodium channel modulators)	IRAC Class 2B (GABA-gated chloride channel blockers)	hydrolysis	hydrolysis	through the exclusion of oxygen which the target insects require for respiratio n	IRAC Class 15 (inhibitors of chitin biosynthesis affecting CHS1)	Acts on the feeding behavior of insects.	N/A

[6] The absence of efficacy tests for certain alternatives against specific termite species (e.g. tropical termites) does not necessarily imply that the products would not be efficacious against these organisms.
[7] RNL- Renewal (of the approval).
[8] Fipronil is approved for PT 18 until 30/09/2023 but no renewal application has been received to date and is not expected to be received.

Active sub-stance / method	**hexaflumuron**	**permethrin**	**deltamethrin**	**fipronil**	**aluminum phosphide releasing phosphine**	**magnesium phosphide releasing phosphine**	**nitrogen**	**diflubenzuron**	**chemical alternative under development**	**physical barrier**
							(asphyxia)			
Appli-cation method	Bait in bait stations	Physico-chemical barrier	Physico-chemical barrier.	Physically drenching the surrounding of the structure/ or injecting the insecticide into the walls with a hose.	Fumigation	Fumigation	Fumigation Controlled atmosphere	Bait in bait stations	-Chemical barrier. Ready to use product to be applied by injection on walls and by spreading in soil. -Bait in bait stations.	A very fine metal mesh is placed under the foundation that will prevent entry of termites. It needs to be set up before the concrete of the foundations is poured.
Target orga-nisms	European termites *Reticulitermes* spp. Tropical Overseas termites *Coptotermes* spp. *Nasutitermes* spp. *Heterotermes* spp.	*Nasutitermes* spp. *Coptotermes* spp. *Heterotermes* spp. *Reticulitermes* spp. *Prorhinotermes* spp. *Cryptotermes* spp.	*Coptotermes* spp. *Heterotermes* spp. *Reticulitermes* spp.	Tropical Overseas termites *Coptotermes* spp. European termites *Reticulitermes* spp.	*Kalotermes* sp.	*Kalotermes* sp.	*Incisitermes minor*	European termites *Reticulitermes* spp.	Tropical Overseas termites *Coptotermes* spp. European termites *Reticulitermes* spp.	Subterranean termite species

Table 2. Advantages (+) and disadvantages (-) of identified alternatives for the use of hexaflumuron-based baits (information provided by ECHA to the eCA, ECHA Website, Stakeholders' and interested third parties' consultation and literature search)

Active substance / method	hexaflumuron	permethrin	deltamethtrin	fipronil	aluminum phosphide releasing phosphine	magnesium phosphide releasing phosphine	nitrogen	diflubenzuron	chemical alternative under development	physical barrier
Technical feasibility	Curative treatment Against subterranean termites including termites encountered in European tropical overseas regions. Targeted method. Easy to use by professional PCOs.	(-) Preventive treatment (Pre-construction method), not curative (+) Against subterranean termites including termites encountered in European tropical overseas regions.	(-) Preventive treatment (Pre-construction method), not curative (+) Against subterranean termites including termites encountered in European tropical overseas regions.	(+) Curative treatment (+) Against subterranean termites including termites encountered in European tropical overseas regions. (-) Not targeted method. (-) Laborious. (-) Candidate for substitution	(+) Curative treatment. (-) Not against subterranean termites including termites encountered in European tropical overseas regions. (-) Highly trained personnel is required. (-) Hazardous for the user. (-) Laborious.	(+) Curative treatment. (-) Not against subterranean termites including termites encountered in European tropical overseas regions. (-) Highly trained personnel is required. (-) Hazardous for the user. (-) Laborious	(+) Curative treatment. (-) Not against subterranean termites and tropical termites claimed for hexaflumuron. (-) Highly trained personnel is required. (-) Hazardous for the user. (-) Laborious.	(+) Curative treatment. (+) Same application method with hexaflumuron based products. (+) Against subterranean termites (-) Not against termites encountered in European tropical overseas regions. (+) Targeted method. (+) Easy to use by professional PCOs.	(+) Preventive and curative treatment. (+) Same application method with hexaflumuron based products. (+) Against subterranean termites, including termites encountered in European tropical overseas regions. (+) Targeted method.	(-) Preventive treatment (Pre-construction method), not curative (+) Against all subterranean termite species, including termites encountered in European tropical overseas regions.
Economic feasibility	N/A	(-) Expensive	(-) Expensive	(+) Similar to hexaflumuron based baits.	(-) Large scale process, and therefore expensive.	(-) Large scale process, and therefore expensive.	(-) Large scale process, and therefore expensive.	(+) Similar to hexaflumuron based baits.	N/A	(-) Expensive
Availability	Available	(+) Available	(+) Available	(+) Available	(+) Available	(+) Available	(+) Available	(+) Available	(-) There are no products available in the EU market.	(+/-) No info regarding availability in the market.

Active substance / method	**hexaflumuron**	**permethrin**	**deltamethtrin**	**fipronil**	**aluminum phosphide releasing phosphine**	**magnesium phosphide releasing phosphine**	**nitrogen**	**diflubenzuron**	**chemical alternative under development**	**physical barrier**
Hazard, risk and PBT assessment	The a.s. is classified to aquatic life as "Acute Cat 1" (H400) and "Chronic Cat 1" (H410) (Acute M factor =1000, Chronic M factor =10000). It is not classified for human health hazards (RAC35). Very Persistent (vP), very Bioaccumulative (vB), Toxic (T). Hazard and risk can be further assessed at product level if considered necessary.	Not suitable alternative (please refer below)	Not suitable alternative (please refer below)	Not suitable alternative (please refer below)	Not suitable alternative (please refer below)	Not suitable alternative (please refer below)	Not suitable alternative (please refer below)	The a.s. is classified to aquatic life as "Acute Cat 1" (H400) and "Chronic Cat 1" (H410) (M factor =100) and may cause specific target organ toxicity to humans after repeated exposure (STOT RE 2; H373). Not Persistent and not Bioaccumulative. Hazard and risk can be further assessed at product level if considered necessary. Note: Possible PCA (*p*-chloroaniline) impurity or metabolite (genotoxic carcinogen)	-	-

Active substance / method	hexaflumuron	permethrin	deltamethtrin	fipronil	aluminum phosphide releasing phosphine	magnesium phosphide releasing phosphine	nitrogen	diflubenzuron	chemical alternative under development	physical barrier
Conclusion on suitability and availability	N/A	Not suitable alternative considering that it is used in preventive treatments only, not curative, which are usually expensive application methods. Suitable considering the target organisms. There are available products.	Not suitable alternative considering that it is used in preventive treatments only, not curative, which are usually expensive application methods. Suitable considering the target organisms. There are available products.	Not suitable alternative considering that the application method is laborious and is not targeted. Suitable considering the target organisms and economic feasibility. There are available products.	Not suitable alternative considering that the application method is laborious, hazardous for the users, expensive and requires highly trained personnel. Not suitable considering the target organisms. There are available products.	Not suitable alternative considering that the application method is laborious, hazardous for the users, expensive and requires highly trained personnel. Not suitable considering the target organisms. There are available products.	Not suitable alternative considering that the application method is laborious, hazardous for the users, expensive and requires highly trained personnel. Not suitable considering the target organisms. There are available products.	Suitable in terms of technical and economic feasibility considering that diflubenzuron-based products are applied with the same application method as hexaflumuron-based products (baits in bait stations) having the same mode of action against target organisms. Suitable against subterranean termites. Not suitable against termites encountered in European tropical overseas regions. There are available products.	This a.s. is not approved yet and no products are available in the EU. Technical feasibility is under evaluation and therefore its suitability cannot be determined. Based on information provided by the applicant it seems suitable in terms of technical feasibility considering that the products are applied with the same application method as hexaflumuron-based products (baits). Economic feasibility and availability are N/A.	Not suitable alternative considering that it is used as preventive treatment only, not curative, which is usually expensive application method. Suitable considering the target organisms. No info regarding availability in the market.

3.6. Literature search

To identify alternatives for the use of hexaflumuron, a scientific literature search was performed considering potential chemical, physical and biological alternatives to hexaflumuron. The following alternatives were identified:

- Wood replacement – If an infestation appears to be confined to a wood member that can be readily removed, wood replacement is suggested by Mallis (2004).

- Heat treatment – Heat can be used to eliminate termites from an entire building, although, in practice it is more often used to treat localized areas. Heated air is injected via ducts attached to propane heaters located outdoors. This treatment is economical and convenient, but on the contrary hard-to-heat areas (e.g. wood adjoining concrete) can limit the effectiveness of localized treatments, while drywood termites readily move within their gallery systems from areas of high to cooler temperatures (Cabrera and Rust, 1996). Incomplete treatment of wooden members can result in some termites escaping the lethal effects of the treatment (Mallis, 2004).

- Cold treatment – Termites are susceptible to extreme cold just as they are to heat. Forbes and Ebeling (1986) were the first to demonstrate the feasibility of using liquid nitrogen to control termites in structures. Field trials indicate that extreme cold can kill drywood termites, only in limited areas, such as a single wall void. Consequently, the liquid nitrogen method is a localized treatment whose success is contingent upon being able to find and access all areas of activity (Lewis & Haverty 1996; Rust et al. 1997). The gas is a potentially dangerous material and proper safety equipment, and procedures must be followed to avoid burns to the skin and asphyxiation from breathing oxygen-depleted air (Mallis, 2004).

- Microwaves – Microwave technology is marketed as a non-chemical form of control, especially in USA. Because termites are comprised largely of water, the electromagnetic energy from the microwave unit heats faster than the surrounding wood. As a result, the termites “cook” to death. Lewis and Haverty (1996) conducted the first controlled field efficacy study on the procedure. They concluded that the microwave treatment was somewhat efficacious, but the extent and location of the infestation needed to be clearly delineated and that having access to the infested wood was essential.

- Electrocution –Termites can be killed by high-voltage electric shock treatment. Field trials from Lewis and Haverty (2001) indicate varying levels of efficacy. The authors concluded that the electric shock method appeared technique driven, labour intensive and potentially damaging to surfaces (drill holes and scorch marks).

- Biological control agents of plant, fungal or nematode origin – Most are proprietary, require specialized training and equipment and/or must be licensed or leased through suppliers. Results of field trials with these biological agents are doubted (Mallis, 2004).

- Wood preservatives (PT8) like borates – Since these products belong to different PT than hexaflumuron (PT18), they are not considered in the search for suitable alternatives to hexaflumuron.

- Barrier treatment-Liquid termiticides used in soil treatment – Several soil-applied termiticides have been widely used to control subterranean termites. Insecticides used for this purpose included in the past sodium arsenate, coal-tar, creosote, organophosphate termiticides etc. Barrier soil treatments are restricted to pre-

construction treatments and currently the only authorized insecticides with this particular use in E.U. market include pyrethroids (permethrin and deltamethrin). Notably, pyrethroids are highly repellent to termites (Mallis, 2004).

- Fumigation (Whole structure treatment) - When applied correctly, structural fumigants are an effective means of eradicating drywood termites from buildings. A couple of fumigants that are efficacious against termites are sulfuryl fluoride and methyl bromide. Methyl bromide, however, has been implicated in the depletion of atmosphere ozone and it is banned from E.U. market since 2005. The two fumigants presently registered for termite control in the E.U are aluminum phosphide releasing phosphine and magnesium phosphide realizing phosphine. They are authorized to be used against Kalotermidae family (drywood termites). Despite its effectiveness, fumigation affords no residual protection against the threat of future infestation. Moreover, treatment is disruptive, laborious, and expensive and the occupants must vacate the premises for at least 24 hours. It is a hazardous, stringently regulated procedure requiring highly trained personnel. For these reasons, other forms of treatment are increasingly being utilized and considered (Mallis, 2004).

- Drill and Treat Method (Fipronil) – With this method, initial probing or sounding the wood locates termite galleries. Once the area is determined, the infested member, as well as nearby adjoining wood is drilled. The number of holes drilled depends on the extend of infestation. An insecticide (e.g., fipronil) is then injected into the holes so as to contaminate the galleries. After treatment, the holes are sealed with putty, plastic wood, or other suitable sealant (Mallis, 2004). Especially fipronil has been used for more than 20 years with very good results in controlling termite colonies. The compound is highly potent by both contact and injection, but sufficiently slow acting to permit transfer of lethal amounts from termite to termite (Clement 1998; Shelton & Grace 2003).

- Termite Baits – With baits (diflubenzuron, noviflumuron), minuscule amounts of material are deployed like edible “smart missiles” to knock out or suppress colony populations or groups of termites foraging in and around buildings (Mallis, 2004)[9].

  Diflubenzuron: The formulation contains a white, flour-like material derived from purified cellulose (“alpha cellulose”) that termites find desirable. Water is added to the powder to make a dough-like consistency and the bait is then placed directly into the stations. Diflubenzuron-based baits are reported to retain their palatability under a wide range of environmental conditions (Mallis, 2004).

The literature search identified several active substances (approved and non-approved in the EU market), as well as non-chemical alternatives, as potential alternatives to the use of hexaflumuron. For non-approved active substances, the lack of availability makes them unsuitable as alternatives. Regarding the non-chemical methods, like heat/cold treatment, microwaves, electrocution, etc, since they require special equipment and their level of efficacy against subterranean termites is doubted (see info for its method above), they are considered unsuitable alternatives for the use of hexaflumuron too. Regarding the approved chemicals in EU, diflubenzuron-based products seem to be the most suitable alternatives to hexaflumuron considering its formulation type, mode of action and application method with respect to hexaflumuron, noting however that diflubenzuron-based products are intended only against subterranean termites found in continental Europe (*Reticulitermes* spp.) and not against

[9] Note: noviflumuron is not an approved biocidal active substance in the EU.

termite species encountered in European overseas tropical areas that are claimed for hexaflumuron.

3.7. Conclusions

Considering all information gathered from the ECHA website, R4BP3 database, MSs, interested third parties' consultation, and literature search for potential alternatives to hexaflumuron, the BPC highlights the following:

i) No non-chemical alternatives to hexaflumuron were identified.

ii) In the EU market there are chemical alternatives authorized under the BPR against the claimed target organisms of hexaflumuron (subterranean termites found in continental Europe and termites found in European overseas tropical areas) such as permethrin, deltamethrin and fipronil. However, permethrin and deltamethrin based products are applied only as pre-constructive (preventive) treatments, not curative ones as hexaflumuron. They are applied with very different and more expensive methods than hexaflumuron. Regarding fipronil, although these products are applied as curative treatments, their application method differs from hexaflumuron and is considered laborious and not targeted. In addition, the approval of fipronil as an active substance for PT18 expires on 30/09/2023 and no renewal application has been received to date nor expected to be received.

iii) All the chemical alternatives authorized under the BPR against the claimed target organisms of hexaflumuron (subterranean termites found in continental Europe and termites found in European overseas tropical areas) are available in the EU market.

iv) The closest alternative to hexaflumuron for PT18 in the EU market considering its mode of action, formulation type and application method (curative treatment – bait in bait stations), is diflubenzuron (IGR), noting however that diflubenzuron-based products are intended only against subterranean termites found in continental Europe (*Reticulitermes* spp.), not against termite species encountered in European overseas tropical areas that are claimed for hexaflumuron. It is noted that diflubenzuron is approved as a pesticide, but only for use in non-edible crops as the food processing may lead to formation of metabolite PCA (Commission Implementing Regulation (EU) 2017/855). PCA (4-chloroaniline) is an impurity (and metabolite in food) of diflubenzuron and it has been identified as a genotoxic carcinogen (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4222). A risk assessment related to PCA as a metabolite or an impurity has not been performed in the context of this opinion and should be made at the product authorisation stage.

v) There is no suitable alternative to hexaflumuron for PT18 in the EU market against termite species encountered in European tropical overseas areas (e.g. La Réunion, Caribbean islands, French Guyana), which belong to genera *Coptotermes, Heterotermes* and *Nasutitermes* and are included in the target organisms claimed by the applicant for hexaflumuron. Although *Coptotermes, Heterotermes* and *Nasutitermes* termite species do not occur in continental Europe, an accidental introduction (not establishment) of a tropical termite species (*Coptotermes gestroi*) has been reported in Italy. The potential of invasion, local infestation, and colonization of new termite species in continental Europe from tropical areas should be taken into consideration.

vi) Particular climate conditions pertaining to the Canary Islands (hot and humid) seem to lead to high growth rates of *Reticulitermes flavipes*. In this context products based on hexaflumuron have been preferred to control the colonies. The efficacy of diflubenzuron-based products could not be demonstrated in these conditions.

Overall, it is concluded that diflubenzuron is a suitable and available alternative to hexaflumuron for termites belonging to the *Reticulitermes* genus as target organisms in non-tropical climate conditions. Moreover, there is no suitable alternative to hexaflumuron against termite species encountered in European tropical overseas areas (*Coptotermes* spp., *Heterotermes* spp. and *Nasutitermes* spp.). It is highlighted that this conclusion is not based on evidence that diflubenzuron is not efficacious against termite species that belong to genera *Coptotermes, Heterotermes* and *Nasutitermes* but is based on the fact that there is no efficacy data available for diflubenzuron against these species.

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