Rodent repellents at a European Union Plant Protection Product level, an orphan use to consider

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Abstract
Repellent usage against rodents is almost not provided anymore. Permission to use many rodent repellent substances under European Union (EU) plant protection regulations has not been renewed in recent years. Some approval for chemical substances have not been renewed due to their toxicological properties, and for some biorational approvals have also not been renewed due to lack of financial support together with other concerns. Some other rodent repellent substances possessing accurate properties in a secondary way have also been withdrawn. Thus, the use of almost ten active substances is now illegal. The lack of support and the resultant orphan use may be explained by the relatively small market and possible business together with the expectations of modern substance application requirements. As a result, the opportunity to consider new biorational substances as candidates is therefore open. Plant based food substances are preferred candidates for plant protection considering their favourable toxicological characteristics. Capsicum oleoresin, a mixture obtained from two spice species (Capsicum annuum and C. frutescens), is one of them with appropriate repellent properties. An application under EU Plant Protection Product regulation has recently been submitted and may become a new repellent for biological control agent against seed predators.

Keywords: biorational, birds, mammals, plant protection, repellent

Introduction

Rodents and especially seed predators are of importance in Europe, considering sowing time and predation (Diaz 1992) from birds and mammals like wild boars. Some techniques are used to avoid predation loss (Everet et al. 1978; Brown et al. 2003). Other methods have used chemical repellents as plant protection products (Johnson et al. 1982; Koehler 1983; Werner and Avery 2017), common available substances (Mason and Bonwell 1993; Ahmad 2018) or natural substance (Hansen et al. 2016). Nowadays, rodent repellents are almost an orphan use since almost all of these substances are no longer approved or they were simply never approved. Of the previously authorised substances for this specific use and substances allowed for seed treatment and providing the same protection, some of them were not renewed such as anthraquinone, crude tall oil and pitch, pepper dust and thiram or they were simply never approved (naphthalene, bone oil, guazatine and p-cresyl acetate) at an European Union (EU) level (EU 2019a). The few that are still approved are of concern e.g. bromadiolone and they do not really protect against seed predation. The need of biorational substances (Matyjaszczyk 2018) with a positive profile for this purpose is urgent and essential. This issue is not only a loss of solutions for farmers but also a sad situation for users, and not only for organic farmers. Indeed, almost no other solution is available and legal at an EU level. At the same time, the following active substances have not been approved or renewed or they are no longer approved: naphthalene, bitertanol, anthraquinone, bone tar, guazatine, p-cresyl acetate and tall oil pitch. Only pepper dust was allowed in the
EU for the envisaged purpose, but its approval does not cover usage against birds and wild boars and this substance disappeared in 2019 (EU 2019b). Oleoresin capsicum as a foodstuff and natural substance is one of the promising biorationals for this usage (Barnett 1998).

**Materials and Methods**

**Regulation analysis**

The EU Pesticide database was used to assign the function (i.e. Repellent: RE) and the status (approved, non-approved, removal, withdrawal) of each active substance (EU 2019a). Corresponding linked Implementing regulations attached to each active substance were found by the same method and cross verification with Implementing regulation (EU) 540/2011 (EU 2011).

**Basic substance applications**

Basic substance applications were constituted using EU templates (EU 2014) and all the information, updates, knowledge and skills accumulated by our institute since 2011 (Marchand 2015, 2016, 2017a, b, c).

**Results and Discussion**

Due to interest in plant protection and the specifications of the substance, oleoresin capsicum was considered as a promising candidate for the repellence of grain predators. Since application as an active substance was not considered due to the exorbitant cost to be considered as a food substance and easily accessible for the end user, another route was taken (Marchand 2017c). Since the concept of basic substance was now operational (Marchand 2016), this pathway has been chosen for the oleoresin capsicum substance.

**Capsicum spice a biorational candidate**

Plants of the *Capsicum* genus are native to America but they are now cultivated worldwide. Extracts from *C. annuum* or *C. frutescens*, also called oleoresin capsicum, have become important food flavouring in many cuisines. Oleoresins are the concentrated liquid form of the spice. They are obtained by extraction with a non-aqueous solvent followed by removal of the solvent by evaporation. Capsicum spice is an oil soluble extract from the fruits of *C. annuum* or *C. frutescens*. For spice consideration, hardness of the oleoresin capsicum mixture is defined by the Scoville scale (Scoville 1912). This property, useful for food seasoning, may be used for other purposes such as protecting human foodstuffs from being eaten by pests. In fact, seeds used by farmers for crop sowing may be food or considered as food by birds and other wild animals including deer and boars. The damage caused by these animals on seedlings of many crops is often very significant. Methods are available to scare off these animals to limit these attacks, but they are not always effective. Therefore, crop yields of economically important plants species are particularly threatened at the seedling period. Oleoresin capsicum with its repellent properties (Morgan 2018) could reduce crop losses at the seedling stage. These sown seed targets may be coated by this oleoresin capsicum substance before sowing to be protected from being eaten as food by marauders, so as to avoid interrupted rows in fields due to crop predation and disappearance of seeds.

**Use in plant protection**

Thus, oleoresin capsicum turns out to be useful in crop protection for repelling animals which cause damage to crop emergence, especially maize, sunflower, wheat, canola and cabbage. Therefore, it should be approved as a crop protection substance considering EU Plant Protection Products (PPP) regulations (Marchand 2015).

The French Institute of Organic Food and Farming (ITAB) is currently working for the approbation of Capsicum spice application Dossier by the European Union for Peyraud Nature, a small company and an early popularizer of the substance. Using our expertise in the field of natural substances for crop protection, we attempted to legalize its use in agriculture in Europe as a basic substance (Marchand 2016).

Capsicum spice is a slightly viscous, homogenous red liquid with good flow properties, extracted from *C. annuum* or *C. frutescens* (Project 294). Oleoresin capsicum preparations contain various components such as capsanthin, capsorubin and especially capsaicinoids like capsaicins and dihydrocapsaicin. The ratio of dihydrocapsaicin to capsaicin is generally around 1 : 1 to 1 : 2 (Govindarajan and Sathyanarayana 1991). The capsaicinoid content in the whole dried powdered fruit can vary from 0.11–1.5% (Evans and Evans 2009). The capsaicin content typically ranges from 0.1 mg·g⁻¹ dry weight in chilli pepper to 2 mg·g⁻¹ dry weight in red pepper and 60 mg·g⁻¹ in oleoresin red pepper (Parrish 1996).

**Food status of capsicum oleoresin**

Oleoresin capsicum is mainly used in food for seasoning. It is a food additive (flavouring substance) in EU and many other countries. Indeed, the substance is...
registered in the feed additives list under Regulation (EC) No. 231/2012 (EU 2012). Oleoresin capsicum also fulfils the criteria of food as described in Regulation (EC) No. 178/2002 as we previously experienced (Markai et al. 2002). In Asian countries such as Malaysia, oleoresin capsicum is also recognized as a “flavouring substance” by the Ministry of Health (Ministry of Health 2003). Similarly, in the USA, oleoresin capsicum is registered by the U.S. Food and Drug Administration as a food additive (FDA 2015). Therefore, the substance is compliant with Article 2 of Regulation EC No. 178/2002 (EC 2002a) as “a foodstuff”. According to Regulation EC No. 1107/2009 (EC 2009a) “an active substance which fulfils the criteria of a “foodstuff” shall be considered as a basic substance” (Marchand 2016).

Usages as a repellent

Mode of action in fields
Oleoresin capsicum has repulsive properties. Capsaicin, one of the main components of oleoresin capsicum, has been shown to have antifeedancy properties to various invertebrates (Warthen and Morgan 1990). For example, capsaicin from capsicum in an oleoresin has been used against cotton pests (Mayeux 1996). Extracts of capsicum were also repellent to one species of stored-products beetle (Sitophilus zeamais), although not so much to another (Tribolium castaneum) (Ho and Fauziah 1993). Repellent products containing the active ingredient capsaicin are available in New Zealand as an invertebrate and vertebrate repellent for protection of buildings, citrus trees, and nursery stock (Spurr and McGregor 2003).

Other studies showed that the oleoresin capsicum has repellent properties against various mammals. For instance, it appeared to have a significant aversive effect on seed consumption by squirrels, even when the substance was poorly concentrated (Govindarajan and Sathyarayanaya 1991). Finally, oleoresin capsicum has repulsive properties against invertebrates, mammals and birds (USEPA 1992). Capsaisin, one component of oleoresin capsicum, is also known to be repellent for deer mule (Andelt 1994). Other forest mammals such as wild boars, badgers (Baker et al. 2005) and prairie mammals such as mice (Nolte and Barnett 2000) may be repellent as well.

Application in fields
Oleoresin capsicum is mainly used as a seed coating for sweet maize, wheat and sunflower. The substance is applied at 14–15 g · ha⁻¹ with a formulation rate at 94 g · l⁻¹. As a seed treatment, oleoresin capsicum is efficient against boars and birds, including ravens. Oleoresin capsicum can also be sprayed from the seedling growth stage to 2 leaves (BBCH 02 to BBCH 12 stages). In that case, the substance is an emulsion (oil in water). The application rate treatment is at 30 g · hl⁻¹ with water from 80 to 120 l · ha⁻¹ (Table 1). Capsicum spice is therefore applied from 24 to 36 g · ha⁻¹. A single application is sufficient to protect plants. Foliar spraying can be applied to many crops: sweet maize, canola, cabbage, sunflower and wheat. This treatment can repel boars, stags, rabbits, hares and many birds such as ravens, pheasants and pigeons as described in Table 1.

Oleoresin capsicum is therefore known to be efficient in crop protection. The French company Peyraud Nature was looking for a better status than the regular active substance at PPP regulation, in terms of cost and file/dossier processing (Marchand 2017c). Biorationals are encouraged as plant protection products, if they meet the requirements of Directive 128/2009 (EC 2009b) which encourage efficient use of pesticides and promote biocontrol. As a foodstuff, it is considered to be eligible as a basic substance under Regulation EC No. 1107/2009. Capsicum spice was thereby submitted as a basic substance application (BSA) under this regulation (Marchand 2016).

Application as rodent repellent

BSA as repellent
We worked for the approbation of Capsicum spice by the European Union as a “basic substance”, according to provisions of article 23 laid down by EC Regulation 1107/2009 on placing plant protection products on the market. Capsicum spice was thereby submitted as a basic substance application (BSA) and declared eligible (admissible) in 2016.

EFSA outcome
After the eligibility and the assessment by Europe, EFSA (European Food Safety Authority) issued a negative opinion on the Capsicum spice dossier. The EFSA considered that scientific studies and data were insufficient for some characteristics of the substance (EFSA 2016). For example, they estimated that the recipe of the product was unclear and ambiguous. The repulsive properties of oleoresin capsicum in Capsicum spice was not considered to be sufficiently documented, especially the effects against birds. The EFSA also claimed that there was not enough information regarding the toxicological effects on non-target organisms and especially phytotoxic properties of the substance. They also criticized the genotoxic effect of capsaicin. A substance is toxic when it contains more than 0.025% of capsaicin according to the committee of experts on flavouring substances Panel (EC 2002b). However, oleoresin capsicum, an active matter of the Capsicum spice proposed substance, is used as a food additive, thus it is understood that the substance
contains only a small amount of capsaicin (less than 0.025%). Finally, the substance was renamed “paprika extract, capsanthin, capsorubin E 160 c” by the EFSA during evaluation. Based on the E 160 c specifications and qualification as a colouring substance, the food status was not contested; however, the repellent properties were refuted. Repellent claims as plant protection were contested and a negative outcome was delivered in 2016 (EFSA 2016).

Vote issue
A vote by the Standing Committee on Plants, Animals, Food and Feed (PAFF committee) was taken according to the EU official vote procedure (Marchand 2015). Before the vote, Capsicum spice basic substance application was renamed “Paprika extract (capsanthin, capsorubin E 160 c)” by the EU Commission and proposed draft was rejected. There was an unanimous vote by the 28 EU Member States in October 2017 for a “negative issue of the BSA”, thereby rejecting the initial proposal (EU 2017). This issue was based on repellence efficacy disagreements mentioned by the EFSA attached to “paprika extract, capsanthin, capsorubin E 160 c” name which was assimilated to be a colouring substance and not a pungent spice. Non-approval of basic substance candidates is not unusual since 11 applications have been rejected (EU 2019a) since 2014. Some other candidates as basic substances like milk, propolis, Vitis & Castanea tannins, L-cysteine and Saponaria officinalis root extract (Pavela 2017; EFSA 2017) have not yet been accepted as basic substances since the whole process and the timeframe has been quite unclear since the end of 2017.

Conclusions and Perspectives

The first application of capsicum extract as Capsicum spice within EU pesticide regulations as a repellent was attempted without success. Nevertheless, oleoresin in capsicum is a condiment used all over the world. Thanks to its pungent properties, it can also be used to protect seeds from animal attacks. Therefore, oleoresin capsicum used as a seed coating can be an efficient solution to protect seeds from predation (Fitzgerald et al. 1995). As a foodstuff, it is considered to be eligible as a basic substance under Regulation EC No. 1107/2009. In addition, oleoresin capsicum, approved as a basic

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<tr>
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<th>Application</th>
<th>Application rate per treatment</th>
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<td>Wheat seeds</td>
<td>Triticum vulgare Triticum aestivum Durum wheat Triticum durum Spelt Triticum sputa</td>
<td>repulsive for feeding animals and birds: boar, ravens seed treatment L.S (solution for seed treatment)</td>
<td>g a.i. · ha⁻¹ (min–max) water l · ha⁻¹ (min–max)</td>
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<td>(Sweet corn) Zea mays Sunflower Helianthus annuus</td>
<td>repulsive for feeding animals and birds: boar, stag rabbit, hare, pigeon, ravens, pheasant foliar spray treatment EW (emulsion oil in water) seedling/from 1 to 2 leaves</td>
<td>1.5 dose (225 ml) to 2 doses (300 ml)</td>
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Table 1. Usages table (GAP) for Capsicum spice as basic substance

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substance, could also be used by all EU farmers and perhaps farmers worldwide depending on national Plant Protection Product (PPP) regulations. According to the non-approval issue of "Paprika extract (capsanthin, capsorubin E 160 c)" by the PAPF Committee (EU 2017) previously mentioned (9) "This Regulation does not prejudice the submission of a further application for the approval of paprika extract (capsanthin, capsorubin E 160 c) as a basic substance in accordance with Article 23(3) of Regulation (EC) No. 1107/2009". Therefore, a new submission of a new basic substance application was submitted with "Oleoresin Capsicum" as a new name. Of course, the oleoresin capsicum application is slightly different from the first one and was thereby submitted as a basic substance application (BSA) under this new name. Again, admissibility has to be declared by DGHealth and Food Safety (Marchand 2015). If this new application is successful, later transfer to organic farming regulations will be automatic (Marchand 2016, 2017a, 2017b, 2017c) due to a recent EU regulation (EU 2016). Later, due to the non-overlapping usages of the pepper dust substance, it would be a worthy goal to consider subjecting this abandoned substance under the same status with the same application pathway as basic substance.

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FLAVOUR/8 ADD1 Final: 1–12.


