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Authorization of microbial plant protection products in the Scandinavian countries: A comparative analysis

Valborg Kvakkestad[a,*], Anette Sundbye[a], Roma Gwynn[b], Ingeborg Klingen[a]

[a] Norwegian Institute of Bioeconomy Research (NIBIO), Ås, Norway
[b] Rationale, Duns TD11 3QA, UK

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ABSTRACT

The EU has developed a Directive on Sustainable Use of Chemical Pesticides (2009/128/EC) (SUD) that aims to enhance the use of non-chemical alternatives to pesticides like microbial plant protection products (PPP). The number of authorized microbial PPP for plant protection has increased globally during the last decade. There is, however, variation between different countries. Sweden and Denmark have for example each authorized 20 microbial PPP while Norway has only authorized four microbial PPP. Norway has also received significantly fewer applications for authorization of microbial PPP than the other Scandinavian countries. We explore possible explanations for the observed differences. Our results show that that the regulations in the three countries had similar requirements for the authorisation of microbial PPP. The size of the market is somewhat smaller in Norway than in Sweden and Denmark, and could therefore explain some of the differences. We suggest, however, that the most important explanation is implementation differences in terms of different decisions made in the authorization process. By comparing the authorization process for three microbial PPP in the Scandinavian countries, we found that Norway used more time for the product authorization decisions. Norway assess the same types of microbial PPP more restrictively with respect to environmental aspects and especially human health risks.

1. Introduction

The global population is projected to increase by 30 % to 9.2 billion by 2050 and this increased population density is estimated to increase demand for food production by 70 % (Popp et al., 2013). Historically, the use of chemical pesticides to control pests made it possible to increase yields (Barzman et al., 2015) and chemical pesticides will probably continue to be a vital tool that can maintain and improve yields in future sustainable plant production systems (Popp et al., 2013) but only in combination with new technologies and non-chemical alternatives. Pest management is, however, still heavily reliant on chemical pesticides that may cause undesirable effects on human health and the environment (Barzman et al., 2015). It contributes to a plethora of issues such as farmers' health risks (Damalas and Eleftherohorinos, 2011; Pimentel and Greiner, 1997) and food safety issues (Travisi and Nijkamp, 2008). Extensive use of chemical pesticides may lead to reduced biodiversity (van der Sluijs et al., 2015), destruction and loss of pest natural enemies, pollinators, and other non-target organisms (Bommarco et al., 2011; Klingen and Westrum, 2007; Lexmond et al., 2015; Mancini et al., 2019; Zaller and Brühl, 2019) and emergence of pest resistance (Onstad, 2014). This creates conditions for target pest resurgence and also development of secondary pests (Hajek, 2004) that require further chemical pesticide use and forcing farmers into dependency on chemical pesticides, the so called "pesticide treadmill". Important policy issues in response to these observations concern how to secure increased food production, food quality, and food product appearance while also preventing negative impacts on human health and the environment (Carvalho, 2006; Holt et al., 2016). Possible policy measures include awareness raising about the adverse effects of pesticides and introducing farmers to non-chemical methods, as defined in the EU Sustainable Use of Pesticides Directive (2009/128/EC), to manage their pest problems. Further, economic policy instruments such as a pesticide tax and regulations for which plant protection products (PPP) that can be marketed may also be important policy measures (Praneetvatakul et al., 2013; Schreinemachers et al., 2015; Skevas et al., 2013). Pesticide regulation exerts a major influence on pesticide use and the development and availability of chemical pesticides and their alternatives (Uri, 1998).

The EU developed a Directive on Sustainable Use of Chemical Pesticides (2009/128/EC) (SUD) that aims to enhance the use of

* Corresponding author.
E-mail address: valborg.kvakkestad@nibio.no (V. Kvakkestad).

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Integrated Pest Management (IPM) and non-chemical alternatives to reduce the use of chemical pesticides. The SUD and the new regulation for all PPPs to be placed on the market in the EU (EC/1107/2009) introduced cut-off criteria for undesirable PPP. These cut-off criteria apply, among others, to carcinogenic, mutagenic, toxic for reproduction, endocrine disruptive and persistent substances (Czaja et al., 2014) and has resulted in the withdrawal of many chemical pesticides from the market. To support the development of less harmful plant protection active substances, the EU also introduced special provisions for Low Risk substances (EC/1107/2009). According to the SUD, IPM tools include preventive measures (e.g. crop rotation, resistant cultivars, certified seed and plants, hygiene measures), physical control (weed harrowing, insect fences, etc.), biotechnical control (semiochemicals, sterile male technique, gene modified plants, etc.), plant- and microorganism derivates and biological control (four methods as defined by Eilenberg (2007): inundative, inoculative, conservation and classical biological control). In this paper, we focus on a specific type of PPP, namely microbial PPP, which are (viable) microorganisms[1] used as the active substance in PPP and in our examples are used as inundative or inoculative biocontrol agents.

Although microbial PPP and other biological pest control methods show an increased growth in the world market share of PPP, farmers are still lacking sufficient proven and practical alternatives that may be good alternatives to chemicals (Mishra et al., 2015). Increased use of microbial PPP will probably reduce the use of chemical pesticides. Further, microbial PPP have different modes of action compared to chemical pesticides and may therefore reduce the chemical pesticide resistance pressure on pests (Villaverde et al., 2014). Further, the potential risk for adverse effects on human health and the environment are considered lower for most registered microbial PPP than for most registered chemical pesticides (Czaja et al., 2014; Glare et al., 2016; Strasser and Kirchmair, 2006). Microbial PPP may, however, cause some environmental and health risks (Montesinos, 2003). The (biological) properties of living microbial PPP differ from the properties of chemical pesticides, not least because microorganisms have the capability of propagation. Based on these differences, the type and level of regulatory requirements for microbial PPP can be challenging, particularly in the areas of: 1) proper identification and characterization of the organism, 2) mode of action, metabolites, impurities, and stability of the end-use product formulation, 3) toxicological profiles, 4) residues on food crops (of both the microorganism and any produced metabolites) and exposure of the operator (OECD, 2013). To ensure safety to human health and the environment, authorization requirements of PPP with microbial PPP as their active substances have therefore become mandatory in many countries (Desai et al., 2016; Gwynn, 2016) including the EU.

Generally, interdisciplinary research on the registration process for microbial PPP is very limited. A handful studies have identified explanations for the rate of registration of microbial PPP in specific countries or regions (Bailey et al., 2010; Chandler et al., 2008, 2011; Greaves, 2009; Kabaluk et al., 2010; Li et al., 2010; Mascarin et al., 2019; Mishra et al., 2015; Moshi and Matoju, 2017; Robin and Marchand, 2019; Skovmand, 2007). Very few studies have examined variation across countries. This paper therefore examines reasons for variations between countries regarding the registration of microbial PPP. Previous studies have identified the size of the potential market for microbial PPP as an important factor explaining their availability (Bailey et al., 2010; Chandler et al., 2008; Greaves, 2009; Robin and Marchand, 2019). Microbial PPP are often niche products with very specific application areas, and the market size for a product is therefore often too small to provide economies of scale and encourage companies start producing these products (Kessler, 2018).

Equally important are the authorization-procedures. Applying for approval is costly in terms of registration fees and costly risk assessment studies (Robin and Marchand, 2019). The regulatory system of microbial PPP is originally designed for chemical pesticides and this has created market entry barriers by imposing burdensome costs on the biological PPP industry (ACP, 2004; Grant, 2005; Greaves, 2009). This has historically also been the case in the EU (Villaverde et al., 2014). There are, however, some indications that the situation for biological pest control methods are improving in the EU. The number of approved non-chemical active substances in the EU have increased since 2011 and have increased more than chemical substances (Robin and Marchand, 2019). Microorganisms were the category of non-chemical alternatives that increased the most (Robin and Marchand, 2019).

The three Scandinavian countries Denmark, Norway and Sweden are examples of countries that differ significantly concerning the number of microbial products that are authorized. While Norway has currently authorized four microbial-based products, Sweden and Denmark have each authorized 20. We will explore possible explanations for the differences between Norway, Sweden and Denmark by: 1) examining market size differences, 2) examining regulatory differences and 3) a case study analysis of the regulatory process and decisions that have been made on three microbial PPP in the three Scandinavian countries.

2. Methodology

The methodology used in this paper consists of four steps. The first step was to get an overview of the regulatory decisions on product-authorization of microbial PPP in the three Scandinavian countries (per 31st of December 2018). We used official databases in the three countries (DEPA, 2018a; KEMI, 2018; Mattilsynet, 2018, SEGES, 2018). The databases contained information on 1) products that have been authorized, 2) the active substances (microorganisms) in the products 3) authorization periods and 4) in which crops the products could be used (according to labels or decision letters). The same active substances are sometimes used in different products. The overview of the decisions could therefore be given per product or active substance. We have chosen per active substance (strain), because products that contain the same active substance are almost identical, and it should be noted that microbial regulation is strain specific. In order to gain information on products that have been rejected, withdrawn or are pending, we had to contact the national authorities by e-mail. There might be small errors in the regulatory databases for approved active substances and/or products, like the first date of product authorization.

The second step was an analysis of market size differences between the Scandinavian countries. Ideally, we should have compared the total market value of different crops produced in Scandinavia or the potential sales value of biopesticides on the various target crops. Due to lack of these data, we have however used crop area as an indirect measure of market size. We used data from FAO (2018) for average annual area harvested for different crops for the year 2013–2016. We calculated the percentage of area harvested for each crop in the three countries out of the total area harvested for these crops in Scandinavia. Next, we used the official databases (DEPA, 2018a; KEMI, 2018; Mattilsynet, 2018; SEGES, 2018) to find out which crops[2] were included in the different product applications and calculated how many times specific crops were included in product applications in each country. We decided to use the total number of product applications (and not the number of applied active substances) as this number indicate the interest in

[1] While the majority of microbial PPP on the market in the EU have a mode of action derived from viable microorganisms, there are examples of non-viable microorganisms approved where the mode of action is based principally on the microorganism derivatives.

[2] When the companies apply for product approval they need to specify area of use (i.e. which crops that the PPP can be used in and the pest the PPP can be used for).

product authorizations in different countries. The FAO database did not contain information on area harvested for all crops that are included in product applications and these crops are therefore excluded from the analysis. Other factors like type of target pests and the profitability of farming also influence the market for microbial PPP. These factors are however, not included in the analysis due to lack of data.

The third step was an analysis of regulatory differences between the three Scandinavian countries. This was based on qualitative interviews with experts in the Norwegian Food Safety Authority, document analysis and previous literature.

The fourth step was a comparative case study analysis to explore reasons for the differences between Norway, Sweden and Denmark more in detail. We selected three active substances authorized in microbial-based products in Sweden and Denmark, but not in Norway. We have used document analysis, qualitative interviews and one focus group with bureaucrats from the food safety authority, importers, suppliers and producers of microbial PPP to get information on the decisions made in each of the three cases.

3. Decision making on microbial PPP in Scandinavia

Registration requirements for microbial PPP have been in place in the three Scandinavian countries for about three decades, although Norway only recently (2015) joined the EU system under Regulation EC 1007/2009. During the three decades, Norway has authorized products from seven (four of them are currently authorized) microbial active substances, Sweden from 22 (20 of them are currently authorized) and Denmark from 23 (20 of them are currently authorized). Table 1 presents details about active substances authorized in microbial PPP in these three countries.

We observe from Table 1 that Denmark and Sweden have authorized many more microbial PPP than Norway. An important question is why Norway differs from Sweden and Denmark. The next section explores the role of market size differences for the observed differences.

3.1. Market size differences

Table 2 presents the area harvested for different crop and the number of different crops applied for in product authorization applications. The data for percent of area harvested in each country for different crops show that the area harvested could not be the only explanation for the lower number of applications and product authorizations in Norway. For eight of the crops the area harvested was lowest in Norway, for nine of the crops the area harvested was lowest in Denmark and for six of the crops the area harvested was lowest in Sweden.

3.2. Regulatory differences

In the previous section, we concluded that the market size could not be the only explanation for the lower number of applications and product authorizations in Norway. In this section, we examine whether regulatory differences could explain the differences observed. Denmark (since 1972) and Sweden (since 1994) are members of the EU and therefore obliged to follow the EU-regulation of microbial PPP. Norway are not a member of the EU, but became a member of the European Economic Area (EEA) in 1994. Norway were, however, not a part of the EU-regulation of PPP before June 2015.

In order to respond to social and political concerns regarding chemical pesticides, the EU established directive 91/414/EEC for the placing of PPP on the market in order to harmonizing the registering of pesticides in 1991 (Montesions, 2003). The regulatory arrangements were a two-step system where the active substance was evaluated and approved at EU level and EU Member States evaluated and authorized products containing them (Greaves, 2009). Member States could only authorize PPP that contained active substances that were authorized at the EU level. According to the Directive member States should ensure that a PPP is not authorized unless it is safe for humans and the environment and is sufficiently effective. Directive 91/414/EEC was originally developed for chemical pesticides. This Directive was however, amended by the Commission Directive 2001/36/EC regarding the data requirements for the Annex I inclusion of microorganisms as active substances and national authorization of products (Ehlers, 2007).

After the implementation of directive 91/414/EEC it quickly became evident that mutual recognition between different member states was not working (Chandler et al., 2011) and Directive 91/414/EEC had adverse consequences on some of the natural biological substances that were used in a number of countries prior to their EU membership (Robin and Marchand, 2019). Some were not profitable enough to cover the costs of the registration, and in some cases, producers were not able to pay the costs involved in their substance and product registration, and were obliged to abandon them (Matyjaszczyk, 2011). Directive 91/414 was revised, and Regulation EC 1107/2009 came into force in June 2011. While maintaining the basic principle of protection of health and the environment as well as agronomic efficacy, the main objectives were focused toward a better harmonization of the procedures concerning the regulation of pesticides (Pelaez et al., 2013). Importantly, the new regulation set timelines for processing the product applications. The EU were divided into three climatically different zones, namely northern, central and southern zone, where registration in one member state facilitates registration in other member states in the same zone (Chandler et al., 2011). For greenhouses, there is one EU-wide zone.

In Norway, until 2004, pesticides were subject to a pesticide act (Bugge, 2011). This act was replaced by a new Act on Food Production and Food Safety in 2003 and the legislation for pesticides were laid down in a regulation on pesticides (Bugge, 2011). According to this regulation, all pesticides had to be authorized by the Norwegian Food Safety Authority (Ministry of Agriculture and Food, 2004). Authorization was only issued if the pesticide had proper agricultural effect and did not have unacceptable effect on humans and the environment.

When Norway joined the EEA in 1994, they decided not to be a part of the EU pesticide regulations, because the Norwegian regulations were assumed to provide higher protection of health and the environment (Ministry of Foreign Affairs, 2015). In June 2015, Norway implemented Regulation EC 1107/2009. The Norwegian Parliament claimed that it would be wise to implement the EU-regulation, because the criteria for pesticide assessment would be similar to current practice in Norway (Energi og miljøkomiteen, 2015). The implementation of the EU regulation was expected to cause major changes in the authorization process, but minor changes on which pesticides would be authorized (Energi og miljøkomiteen, 2015).

Table 3 presents the criteria for product approval of PPP in the three different regulatory systems. We observe that the provisions regarding protection of health (human and animal) and the environment, as well as agronomic efficacy are included in all the three regulations and that the provisions are quite similar. An important difference between the three legislations is, however, the authorization process for microbial PPP and the facilitation of harmonization across countries. It is also important to note that the Norwegian pesticide regulation from 2004 to 2015 emphasized that agricultural efficacy should be tested in Norway, and that that the PPP should be equally suitable or has advantages over already approved products. Table 4 presents the decision made under the three different legislations.

In Table 4 we observe that Norway has authorized significantly fewer active substances and that they have rejected more active substances than the other countries. We further observe that for Sweden the number of active substances that was authorized for the first time is highest under directive 91/414/EEC while the opposite is the case for Denmark (both in total and per year). In total, Norway has most authorizations prior to the implementation of Regulation EC 1107/2009. Per year, the number is, however, highest for Regulation 1107/2009.

Table 1
Active substances in microbial plant protection products authorized in Norway[1] (NO), Denmark[2] (DK) and Sweden[3] (SE) per 31.12.2018.

Active substance (S = strain)	Product name and year of first authorization and year of authorization ceased	Status CA[4] = currently authorized AR[4] = application rejected AW[4] = application withdrawn P[4] = pending PA[5] = previously authorized NA[6] = not applied for		
		NO	**DK**	**SE**
Adoxophyes orana granulovirus, S: BV-0001	Capex (DK 2012-24)	NA	CA	NA
Ampelomyces quisqualis, S:AQ10	AQ-10 (DK 2012-19)	NA	CA	NA
*Aureobasidium pullulans,*S: DSM 14940 and DSM 14941	Boni Protect (DK 2010-13)	NA	PA	NA
Bacillus amyloliquefaciens, S: MBI 600	Integral Pro (DK 2018-27)	NA	CA	NA
Bacillus firmus, S: I-158	Flocter WP5 (DK 2017-24) (SE 2017-24)	NA	CA	CA
Bacillus subtilis, S: QST 713	Serenade ASO (DK 2015-19) (SE 2016-19) (NO 2017-19)	CA	CA	CA
Bacillus thuringiensis subsp. *kurstaki,* S: ABTS 351	Dipel DF (DK 2014-19) (SE 2016-20)	NA	CA	CA
Bacillus thuringiensis subsp. *kurstaki/ aizawai,* S: GC-91	Turex 50 W P (SE 2002-20) (NO P since 2012)	P	CA	CA
	Turex WG (DK 2015-20)			
	Turex WP (DK 2015-20)			
Bacillus thuringiensis subsp. *israelensis*, serotype H-14, S: AM65-52	Gnatrol SC (DK 2014-19) (SE 2016-20)	AR	CA/PA	CA/PA
	Vectobac12 AS (DK before 1991–2014) (SE 2001-13) (NO AR in 2002)			
	Bactimos L (DK before1991-2015)			
Bacillus thuringiensis subsp. *israelensis,* S: NB31	Skeetal WP (SE 2001-04)	NA	NA	PA
Beauveria bassiana, S: GHA	BotaniGard WP (DK 2015-20) (SE 2018-20) (NO AR in 2018)	AR	CA/AR	CA/PA
	Botani Gard ES (SE 2001-13) (DK: AR)			
	Botani Gard 22 W P (SE 2001-13) (DK: AR)			
Beauveria bassiana, S: ATCC 74040	Naturalis (DK 2012-19)	NA	CA	NA
Coniothyrium minitans, S: CON/M/91-08	Contans WG (DK 2004-15) (NO P since 2018) (SE 2005-18)	P	CA/PA	PA
	Contans (DK 2015-19)			
Cydia pomonella granulovirus	Madex3 (DK 2007-xx)	AW	CA/PA	CA
	Madex (DK 2012-19) (SE 2010–2019) (NO AW in 2015)			
	Madex Top (DK 2018-20)			
Gliocladium catenulatum, S: J1446	Prestop Mix (DK 2012-17) (SE 2009-20)	NA	CA/PA	CA/AW
	Prestop (DK 2012-17) N (SE 2010-20)			
	Prestop Mix WP (DK 2018-19)			
	Prestop WP (DK 2018-19)			
	Turf WPG (DK 2016-17)			
	Turf G + (DK 2018-19) (SE: AW)			
Isaria fumosorosea, S: Apopka 97	PreFeRal WG (NO 2008-31)	CA	NA	CA
	PreFeRal (SE 2002-31)			
Lecanicillium muscarium, S: Ve6	Mycotal (DK 2015-29) (NO 1998-2004)	PA/AR	CA	0[7]
Metarhizium anisopliae var. *anisopliae,* S: F52	Met52 OD (DK 2018-20)	NA	CA	NA
	MET52 Granular (DK 2011-19)			
Phlebiopsis gigantea, S: VRA 1835	Rotstop (SE 1998–2020)	CA	CA	CA
	Rotstop WP (DK 2015-19) (NO 2007-19)			
	Rotstop SC (DK 2015-19) (NO 2014-19)			
Phlebiopsis gigantea, S: VRA 1984	Rotstop S (SE 2003-20)	NA	NA	CA
	Rotstop S Gel (SE 2008-20)			
Phlebiopsis gigantea, S: VRA 1985	Rotstop V (SE 2003-20)	NA	NA	CA
Phlebiopsis gigantea, S: VRA 1986	Rotstop E (SE 2003-20)	NA	NA	CA
Pseudomonas sp.,S: DSMZ 13134	Proradix (SE 2011-25)	NA	NA	CA
Pseudomonas chlororaphis, S:MA342	Cerall (DK 2010-19) (SE 2006-20) (NO 2008-2015)	PA	CA	CA
	Cedomon (DK 2005-19) (SE 1997–2020) (NO at least from 1998 to 2015)			
	Cedress (SE 2010-20)			
Streptomyces K61	Mycostop WP (DK 2018-19)	AR/PA	CA/PA	CA
	Mycostop (DK 2015-17) (SE 1998–2020) (NO 1998-2015, AR for renewed authorization in 2015)			
	Turf WPS (DK 2016-17)			
	Turf S + (DK 2018-19)			
*Trichoderma atroviride,*S: IMI 206040	Binab TF WP (SE 2001-19) (DK 1999–2014)	NA	PA/AR	CA
*Trichoderma polysporum,*S: IMI 206039	Binab TF WP (SE 2001-19) (DK 1999–2014)	NA	PA/AR	CA
Trichoderma harzianum, S: T22	Supresivit (DK 1999–2017)	NA	CA/PA	CA
	Tri 003 (DK 1999–2018)			
	Trianum P (DK 2015-19) (SE 2011-19)			
	Trianum G (DK, 2015-19) (SE 2016-20)			
	Trichodex (DK 1999–2018)			

(*continued on next page*)

Table 1 (*continued*)

Active substance (S = strain)	Product name and year of first authorization and year of authorization ceased	Status CA[4] = currently authorized AR[4] = application rejected AW[4] = application withdrawn P[4] = pending PA[5] = previously authorized NA[6] = not applied for		
Verticillium albo-atrum, S: WCS850	Dutch Trig (DK 2017-20) (SE 2010-20) (NO 2017-21)	CA	CA	CA

[1] The source for NO is Mattilsynet (2018).
[2] The source for DK is DEPA (2018a), c; SEGES (2018).
[3] The source for SE is KEMI (2018).
[4] Means that the active substance is CA (Currently Authorized), AR (Application Rejected), AW (Application Withdrawn) or P (Pending) in at least one product.
[5] PA (Previously Approved) means that the authorization holder has not applied for renewal of the product in at least one product.
[6] NA (Not applied for) means that the active substance is not applied for in any products.
[7] 0 could mean: not authorized (denied), withdrawn, authorization expired, not applied for, or pending.

Norway have more microbial PPP approved per year under Regulation 1107/2009 than Sweden, but fewer than Denmark. Given that Regulation EC 1107/2009 aimed to improve the mutual recognition between different member states, one could expect that the approvals per year for Norway should be more similar to Denmark than for Sweden. Both Denmark and especially Norway approved quite few microbial PPP prior to Regulation 1107/2009.

3.3. Case study of decisions made

The two previous sections show that market size differences and provisions in the regulatory frameworks cannot fully explain the differences in Table 1 and Table 4. In order to gain more in-depth knowledge about the reasons for these differences, we examined the decisions made for three active substances in the three Scandinavian countries.

3.3.1. Case 1 - Cydia pomonella Granulovirus

Importers have applied for authorization of products that contain the active substance *Cydia pomonella Granulovirus* (CpGV) for the control of codling moth larvae in apples and pears in all the three countries. Table 5 presents the timeline for the decisions made on these products.

In 2005 the Danish Environmental Protection Agency received an application for the authorization of Madex3 (DEPA, 2007). They concluded in 2007 that Madex3 "*is not particularly dangerous to human health when used as prescribed or particularly harmful for the environment*" and that "*Madex can be used for controlling codling moth larvae in apples and pears with very limited side effects on the environment*" and the product was authorized (DEPA, 2007).

In 2008, both the Swedish Chemicals Agency and the Norwegian Food Safety Authority received an application for the authorization of Madex. In 2010 the Swedish Chemicals Agency concluded that: "*The product is not expected to cause unacceptable risks to human health and the*

Table 2
The area harvested, percent of total area harvested, number of product applications for different crops and percent of product applications for different crops in Scandinavia per 31.12.2018.

	Area harvested in Scandinavia km^2 [a]	% of total area harvested in Scandinavia for each crop			Number of product applications in Scandinavia[b]	% of total number of product applications in Scandinavia for each crop		
Crop		DK	NO	SE		DK	NO	SE
Plums and blackthorn	5.4	11	**80**	9	4	**50**	25	25
Raspberries	5.4	3	**72**	25	8	**38**	25	**38**
Cabbages and other brassicas	23.9	38	**46**	16	3	**67**	0	33
Cauliflowers and broccoli	23.3	27	**44**	30	1	0	0	**100**
Onion	35.2	**35**	34	31	3	33	33	33
Strawberries	47.0	23	34	**43**	18	**50**	22	28
Apples	41.3	33	33	**34**	10	**60**	20	20
Tomatoes	1.1	30	33	**37**	16	31	31	**38**
Cherries	5.9	**42**	32	26	4	**50**	25	25
Carrots and turnips	55.5	**36**	29	35	8	**50**	13	38
Lettuce and chicory	29.8	24	26	**51**	11	**36**	27	**36**
Leeks, other alliaceous vegetables	6.1	**53**	25	22	2	**50**	0	**50**
Forest area	305 800.0	2	25	**74**	13	15	23	**62**
Oats	2 952.2	18	24	**58**	2	0	**50**	**50**
Cucumbers and gherkins	4.1	19	21	**59**	19	**37**	26	**37**
Potatoes	778.8	**54**	16	30	3	33	0	**67**
Currants	20.6	**75**	13	12	4	25	25	**50**
Barley	11 331.3	**58**	12	30	3	33	33	33
Pears	5.4	**65**	11	24	10	**60**	20	20
Peas	374.0	19	7	**74**	2	0	0	**100**
Wheat	11 037.0	**55**	6	38	3	33	33	33
Rapeseed	2 797.3	**63**	1	36	4	**75**	25	0
Triticale	472.7	29	1	**70**	1	**100**	0	0

Bold numbers indicate which country that have the highest percent share of the crop area and number of product applications.
[a] Source: FAO, 2018. Average for the years 2013–2016 (for all except Forest area) and Northern European database of long-term forest experiments (2018) (only for Forest area, year is 2004).
[b] Source: see Table 1. It should be noted that while Table 1 presents information both on active substances and product, Table 2 only presents information on total number of product applications. By the 'number of product applications in Scandinavia' we mean the number of applications for microbial PPP authorizations that include the specific crops in Table 2 in the area of use for the PPP.

Table 3
Criteria for product approval of PPP in the three different regulatory systems.

Norwegian pesticide regulation (2004–2015) § 4	Directive 91/414/EEC (1991–2011) Article 4(1)	Regulation EC 1107/2009 (2011) Article 4(3)
"Approval of the PPP is subject to: (a) that the PPP has a satisfactory agronomic effect. This shall, when deemed necessary, be tested in Norway at an institution approved by the Norwegian Food Safety Authority, (b) that the PPP does not have unacceptable adverse effects on humans, livestock, flora and fauna, biodiversity, as well as the environment in general and is thus found to be satisfactory in an ecological and toxicological context. The risk assessment shall be carried out by the Scientific Committee for Food Safety, (c) that the formulation, quality and durability of the PPP are satisfactory, (d) that the PPP, after an overall assessment, has been found to be equally suitable or has advantages over already approved products, or other methods for the same purpose (the substitution principle)."	"Member States shall ensure that a PPP is not authorized unless: … (b) it is established, in the light of current scientific and technical knowledge and shown …., that when used in accordance with Article 3(3), and having regard to all normal conditions under which it may be used, and to the consequences of its use: (i) it is sufficiently effective; (ii) it has no unacceptable effect on plants or plant products; (iii) it does not cause unnecessary suffering and pain to vertebrates to be controlled; (iv) it has no harmful effect on human or animal health, directly or indirectly … or on groundwater; (v) it has no unacceptable influence on the environment, having particular regard to the following considerations: - its fate and distribution in the environment, particularly contamination of water …, - its impact on non-target species;	"A plant protection product … shall meet the following requirements: (a) it shall be sufficiently effective; (b) it shall have no immediate or delayed harmful effect on human health … or animal health, directly or through drinking water …, food, feed or air, or consequences in the workplace or through other indirect effects … or on groundwater; (c) it shall not have any unacceptable effects on plants or plant products; (d) it shall not cause unnecessary suffering and pain to vertebrates to be controlled; (e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations.: i) its fate and distribution in the environment; ii) its impact on non-target species…; iii) its impact on biodiversity and the ecosystem."

Table 4
Number of active substances applied for product authorization and authorized or not authorized under the three regulatory frameworks in total and per year (in parenthesis). CA = currently authorized, AR = application rejected, AW = application withdrawn, P = pending, PA = previously authorized.
Source: see Table 1.

Regulatory framework	Authorization status (decision made)	DK	NO	SE
Directive 91/414[a]	PA and first authorized under Directive 91/414	1 (0.05)	–	2 (0.12)
	CA in at least one product and first authorized under Directive 91/414	6 (0.30)	–	16 (0.97)
	PA under Directive 91/414 and renewal of authorization rejected under Regulation 1107/2009	2[d] (0.10)	–	0
Norwegian regulation before Norway decided to be a part of the EU regulations in 2015[b]	Application submitted prior to 2015 and still pending	–	1 (0.06)	–
	AW by the authorization holder	–	1 (0.06)	–
	AR	–	1 (0.06)	–
	PA and withdrawn by the authorization holder	–	1 (0.06)	–
	PA and renewal of authorization rejected	–	2 (0.11)	–
	CA in at least one product and first authorized under Norwegian regulation	–	2 (0.11)	–
Regulation 1107/2009[c]	AR	0	1	0
	CA in at least one product and first authorized under Regulation 1107/2009	14 (1.87)	2 (0.57)	4 (0.53)
Total for all regulations	Active substance that are applied for, but not authorized currently or previously as PPP	0	4	0
	CA or PA active substance in product authorizations	23	7	22
	PA active substances in product authorizations	1	1	2
	PA active substances in product authorizations, but renewal of authorization rejected	2	2	0
	Number of CA active substance in product authorizations	20	4	20

[a] This Directive was in force in 20 years in DK and 16,5 years in SE.
[b] This regulation was in force in NO in 17,5 years.
[c] This Regulation has been in force in 7,5 years in DK and SE and 3,5 years in NO.
[d] These products were authorized under Directive 91/414, but renewed authorization was rejected under Regulation 1107/2009.

environment" and the product was authorized (KEMI, 2010a). Norway conducted efficacy evaluation of Madex in 2009. The application was, however, not processed until 2015 because of difficulties finding scientific expertise on microbial PPP, and the Norwegian Food Safety Authority waited for a final conclusion from the European Food Safety Authority (EFSA) regarding the risk assessment of the active substance (Mattilsynet, 2014). Based on this EFSA review, in 2015 the Norwegian authorities demanded new documentation. Due to the limited Norwegian market size (Mogan, 2016) and the demand for new documentation after seven years the application was withdrawn by the applicant. In 2016 the Norwegian Food Safety Authority received a derogation application for the use of Madex in organic apple production. The Norwegian Food Safety Authority was concerned about a *"dangerous bacterium"*[3] in the product (Mattilsynet, 2016a), and the applicant decided to withdraw the application. It should be noted that to get EU approval of an active substance, the applicant would already have provided data confirming there were no unacceptable microbial contaminants in the product.

In 2011 the Danish Environmental Protection Agency received an application for the authorization of Madex. In 2012 the Danish Environmental Protection Agency concluded that «*Madex is not particularly hazardous to health or harmful to the environment if it is used for the intended purpose and in the quantities stated*" and Madex was authorized

[3] This is a direct quote from (Mattilsynet, 2016)

Table 5
Timeline for decisions made in Denmark, Norway and Sweden regarding CpGV products.

Year	Denmark	Norway	Sweden
2005	Application for Madex3		
2007	Madex3 authorized[2]		
2008		Application for Madex	Application for Madex
2010			Madex authorized
2011	Application for Madex		
2012	Madex authorized		
2015		Application for Madex withdrawn	
2016		Derogation application for Madex. Application withdrawn same year.	
2018	Madex Top authorized		

Table 6
Timeline for decisions made in Denmark and Sweden on product from *Gliocladium catenulatum* strain J1446.

Date	Sweden	Denmark
2009	*Prestop MIX* authorized	
2010	*Prestop* authorized	
2012		*Prestop* and *Prestop Mix* authorized
2016		*Turf WPG* authorized
2018		*Prestop Mix WP, Prestop WP* and Turf *G* + authorized

in Denmark (DEPA, 2012a). A similar product named Madex Top was authorized in Denmark in 2018.

For the Madex-case we observe important differences between the three Scandinavian countries. While the Swedish and the Danish authorities used between 1 and 2 years to approve the products, the Norwegian authorities had not made a decision after seven years and had demanded extra documentation.

3.3.2. Case 2 - Gliocladium catenulatum strain J1446

Importers have applied for authorization of products that contain the active substance *Gliocladium catenulatum* strain J1446 in Sweden and Denmark, while no applications have been submitted to the Norwegian authorities. The products are used against plant pathogens in vegetables, herbs, ornamental plants, strawberries, raspberries, cucumbers, golf courses and plant nurseries. Table 6 presents the timeline for the decisions made on these products.

The Swedish Chemicals Agency received an application for mutual recognition of Prestop Mix in 2007 and for authorization of Prestop in 2009 with Finland as the reference country (KEMI, 2009; 2010b). The Swedish Chemicals Agency concluded that *"there are similar environmental and agricultural conditions in Finland and Sweden"* (KEMI, 2009; 2010b). For Prestop Mix the KEMI (2009) concluded that "*the risk for users are low, that there are no risks for consumers and that the risks for terrestrial and aquatic organisms is considered minimal"*. The application was authorized by the Swedish Chemicals Agency in 2009.

In 2010 the Danish Environmental Protection Agency received an application for mutual recognition of Prestop and Prestop Mix and in 2012 the two products were authorized (DEPA, 2012b, 2012c). It was concluded that "*Prestop and Prestop Mix is not particularly hazardous to human health or the environment if used as applied for"* (DEPA, 2012b, 2012c). Turf WPG was authorized in 2016 and Prestop Mix WP, Prestop WP and Turf G + was authorized in 2018.

No companies or growers' associations have applied for the authorization of Prestop products in Norway. Relevant applicants have reported that regulatory barriers are the main reason why they have not applied for authorization of Prestop products in Norway (Borregaard BioPlant, 2018). The regulatory barriers and the costs are too high, compared to the relatively small Norwegian market.

3.3.3. Case 3 - Bacillus thuringiensis subsp. israelensis

Importers have applied for authorization of products that contain the active substance *Bacillus thuringiensis* subsp. *israelensis,* (Serotype H-14), strain AM65-52 for the control of fungus gnats in ornamentals and *Tipula paludosa* in grassland and lawns in all the three Scandinavian countries. Table 7 presents the timelines for the decisions made on these products in the three Scandinavian countries.

Vectobac and Bactimos L was on the Danish marked before 1991 when the PPP directive 91/414/EEC entered into force and it was therefore allowed to market after 1991 (DEPA, 2018b). The product is no longer authorized in Denmark because the company did not want to market the product anymore (DEPA, 2017).

The Swedish authorities received an application for authorization of Vectobac in 1994 (Cillus, 1994). The authorities concluded with "*no human health risks*" (Smittskyddsinstitutet, 2000) and Vectobac was authorized in 2001 (KEMI, 2017). The product is no longer authorized as Vectobac has been replaced by Gnatrol. According to the applicant the application process took many years as the application "*was never followed up as there was no business opportunity*" (Sumitomo Chemical Agro Europe, 2018).

The Norwegian Agricultural Inspection Service received an application for the authorization of Vectobac in 2000. An efficacy evaluation was undertaken and authorization against fungus gnats in ornamentals was recommended, but not in grassland and lawns due to lack of practical experiences and field trials data with Vectobac against crane flies. For human toxicology the Norwegian Agricultural Inspection Service concluded that "*"The present documentation is not sufficient to make a toxicological assessment"* (SLT, 2001a). For environmental toxicology, they concluded that the documentation was sufficient, but their assessment contained no clear conclusion whether it was safe or not. Based on these assessments the Norwegian Pesticide Council emphasized that: "*Submitted documentation, independent literature and statements from national microbiological expertise show that the uncertainty about possible adverse effects of Vectobac 12 AS is very high. The submitted documentation is so inadequate in important areas that it is not possible to make a risk assessment for health and the environment.*" (SLT, 2002). Based on this conclusion the application was rejected in 2002 (SLT, 2002).

In 2001 a dispensation application for the use of Vectobac in poinsettias was sent to the Norwegian Agricultural Inspection Service. The applicant argued that Vectobac could replace the use of two harmful chemical pesticides[4] that were used in poinsettias (Felleskjøpet Øst Vest, 2001). The dispensation application was rejected in 2001 based on the argument that the Agricultural Inspection Service did not want sale of pesticides that had not been through a full Norwegian assessment (SLT, 2001b).

In 2014, Gnatrol was authorized by the Danish Environmental Protection Agency. In the Registration Report the Danish Environmental Protection Agency concluded that a toxic effect of Gnatrol SC on the operator, worker, or bystander was unlikely and that Gnatrol SC were not expected to present any hazards to the environment (DEPA, 2014).

[4] Gusathion and Basudin. These pesticides are no longer allowed in Norway due to health and environmental risks.

Table 7
Timelines for decisions made in Denmark, Norway and Sweden on products with *Bacillus thuringiensis* subsp. *israelensis* (Serotype H-14) strain AM65-52.

Date	Denmark	Norway	Sweden
Before 1991	Vectobac and Bactimos L used before regulation enter into force		
1994			Application for Vectobac
2000		Application for Vectobac	
2001			Vectobac authorized
2001		Dispensation application for Vectobac submitted and rejected	
2002		Application for Vectobac rejected	
2012	Application for Gnatrol		
2014	Gnatrol authorized		
2015			Application for Gnatrol
2016			Gnatrol authorized

In 2015 an application for authorization of Gnatrol was submitted to the Swedish Chemicals Agency and in 2016, Gnatrol was authorized (KEMI, 2016). The product was authorized through the procedure of mutual recognition, with Denmark as the reference country and the Swedish authorities accepted the conclusions made by the Danish authorities (KEMI, 2016).

We observe that the Norwegian authorities reached different conclusions from the national authorities in Sweden and Denmark. While the Norwegian Food Safety Authority concluded that, the uncertainty about possible adverse effects to human health is large, the Swedish and the Danish authorities concluded that the products are not expected to present any hazards to the environment and human health.

4. Discussion and conclusion

The market size differences and the differences in the criteria for product authorization are quite small between the three Scandinavian countries. This indicates that the implementation of the regulations may be the main cause of differences between the countries for microbial product availability. What we observed from the three case studies are major differences between Norway on one side and Sweden and Denmark on the other side. Norway has taken a very long time for their evaluation and decisions of applications, while this is not the case in the other countries. Lack of appropriate scientific expertise may explain the long timeframes used in Norway (as was the case for Madex). A civil servant in the Norwegian Food Safety Authority, Mattilsynet (2016b) emphasised that "*There are not so many experts on alterative products*" and that "*Norway is a small market. We have the right expertise to handle the applications that we get for microbial PPP*[5] *. I think it is not easy to argue to build up competence if there are no applications.*" We also observe that the Swedish and the Danish authorities have trusted risk assessments made in other countries, while risk assessments from other countries has played a minor role in the Norwegian decisions in the three cases. Especially for health risks, one would expect that using risks assessments from other Nordic countries would be unproblematic.

The different safety-conclusions and different requirements for new documentation that have been made on identical products in the three Scandinavian countries illustrates the importance of scientific uncertainty. Scientific uncertainty can be understood not as a lack of scientific understanding, but as the lack of coherence among competing scientific understandings (Sarewitz, 2004). Expert risk perceptions are influenced by a range of socio-political and cultural filters (Guehlstorf and Hallstrom, 2005; Kvakkestad et al., 2007: Urquhart et al., 2017). Pelaez et al. (2013) emphasize that the relative weights attributed to agronomical performance, human toxicology and environmental toxicology, in pesticide risk assessment, will vary depending on the prevailing economic, social and political views in each country and in different historical contexts.

Whether the Norwegian society should aim to authorize more microbial PPP is a political and a value question. The challenge for the regulator is to have an appropriate system in place for microbial PPP that ensures their safety and at the same time facilitate the replacement of more harmful chemical PPP with less harmful microbial PPP (Chandler, 2011; Matyjaszczyk 2015). If farmers in Norway should fulfill the obligation concerning IPM that are promoted in the EU Directive on Sustainable use of Pesticides they need new alternative tools, such as microbial PPP. Norway also suffers from fewer microbial PPP available to organic producers than in the other countries. A survey among Norwegian stakeholders showed that reduced fees, increased political and media attention, and improved dialog and information flow between growers, importers and the Norwegian Food Safety Authority are seen as important measures to increase the availability of microbial PPP (Sundbye, 2020).

Policy implications from this study relates to three issues. *Firstly,* the results illustrate the importance of a holistic policy concerning avoiding harm from PPP. Tesfamichael and Kaluarachchi (2006) emphasize that banning a PPP in an attempt to remove target risk may introduce higher countervailing risks from potential substitute pesticides, thus exacerbating the public health risk. For the *Bacillus thuringiensis* case, the applicant argued that Vectobac could replace the use of two harmful chemical pesticides that were used in poinsettias. These chemical pesticides are no longer allowed in Norway due to health and environmental risks, and approving Vectobac would probably have reduced the use of these harmful chemical pesticides. Hence, when designing policies for PPP it is important to secure that the least harmful PPP are authorized. *Secondly*, our results show that ensuring competence on microbial PPP in the regulatory authorities and risk assessors is crucial to secure adequate risk management and adequate time used in the registration process. Inappropriate evaluation methods and disproportionate data requirements often result in a long and lengthy registration for microbial biopesticides (Arora et al., 2016). Our results also highlight the importance of the position taken by national experts in their advice to the regulators and that the scientific judgments made by these national experts becomes crucial for the final authorization decision. Millstone (2007) emphasizes that the policy makers should take democratically accountable responsibility for establishing explicit guiding principles for the deliberations of scientific policy advisors, and that scientific policy advisors should act explicitly in accordance with that guidance, for example by acknowledging explicitly the ethical and political assumptions that guided their scientific assessments. *Thirdly,* our results show that harmonization and mutual recognition between different member states is working for Sweden and Denmark, but not so well for Norway. One of the main objectives with Regulation EC 1107/2009 were better harmonization of the procedures concerning the regulation of PPP. We do for example observe that the Norwegian Food Safety Authority put little emphasis on the fact that Madex is approved in other countries in the Northern zone when they were concerned about a dangerous bacterium in the product.

An important policy issue is to build institutions that can secure that the least damaging PPP are authorized. Several countries like Canada,

[5] Which was none at the time when the interview was carried out.

the USA, and Brazil have implemented policies to facilitate the marketing and registration of microbial PPP to reduce risks from chemical pesticides. In Brazil an important step was the adoption of a new legal framework that established new streamlined criteria for registering of microbial PPP (Mascarin et al., 2019; Li et al., 2010). This policy encourages a bottom-up pathway whereby farmer organizations suggest materials in consideration for approval. The USA[6] have had a dedicated Biopesticides and Pollution Division within the EPA (Environmental Protection Agency) for over 30 years, and the Inter-Regional Research Project assist and support the agency in registration of microbial PPP (Mishra et al., 2015). In Canada[7], the Pest Management Regulatory Agency harmonized the biopesticide registration process with the USA, initiated pre-submission consultations with applicants of biopesticides, reduced the review timelines for registration of biopesticides, and exempted fees for scientific review of microbial biopesticides (Bailey et al., 2010). Hence, we observe that competence, pre-submission consultancy and low fees could be important for adequate decisions on PPP.

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CRediT authorship contribution statement

Valborg Kvakkestad: Conceptualization, Methodology, Formal analysis, Investigation, Writing - original draft, Writing - review & editing, Project administration, Funding acquisition. **Anette Sundbye:** Conceptualization, Methodology, Investigation, Writing - original draft, Writing - review & editing. **Roma Gwynn:** Conceptualization, Methodology, Writing - original draft, Writing - review & editing. **Ingeborg Klingen:** Conceptualization, Methodology, Writing - original draft, Writing - review & editing, Project administration, Funding acquisition.

Declaration of Competing Interest

None.

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Appendix A. Supplementary data

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[6] The EPA regulate pesticides under broad authority granted in two major statutes, the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act (EPA, 2019). These laws have been amended by the Food Quality Protection Act and the Pesticide Registration Improvement Act.

[7] Registration of pesticides in Canada are regulated under the Pest Control Products Act (Government of Canada, 2019).

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