RECIPES

Precaution • Innovation • Science

WP2 Case study: Neonicotinoid insecticides

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Authors

Laura Drivdal, University of Bergen

Jeroen P. van der Sluijs, University of Bergen

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Abstract

This case will focus on neonicotinoid insecticides (in short: neonics), and how the Precautionary Principle has been applied, and contested, in the regulation of these insecticides.

In the context of increasing pest resistance to established Plant Protection Products, the industry argued that the invention of neonicotinoids signified a new and innovative era of pest management. However, some years after the introduction of neonics on the European market in the 1990s and 2000s, monitoring assessments and studies started to connect the use of neonics to large-scale bee deaths. Thus, the Precautionary Principle (PP) was applied to restrict neonics in some European countries. As studies and risk assessments accumulated, the PP was also relevant when the European Commission (EC) banned three neonics (imidacloprid, thiametoxam, clothianidin) in 2013 and again in 2018. The reasoning for taking precautionary measures was the seriousness of the possible irreversible damaging effects of neonics on important ecosystem services such as pollinating insects. The EC ban of the three neonics caused much controversy, and three agrochemical companies filed court cases against the ban.

In this case, we will outline scientific uncertainties and ambiguities regarding the effects of neonics on pollinators (but also other species), in addition to the diverging perceptions of the role of the PP that became particularly evident in the court case proceedings. Further, we will discuss how innovation and precaution may interact. We find that a narrow framing of innovation and scientific certainty seem to conflate the PP and the Prevention Principle. However, with a broader framing of innovation, one could find possibilities for balancing precautionary regulations of neonics with innovations that are more line with an Integrated Pest Management approach.

Contents

List of abbreviations

EC	European Commission
EFSA	European Food Safety Authority
EP	European Parliament
IPM	Integrated Pest Management
PP	Precautionary Principle
PPP	Plant Protection Products
TSFP	Task Force on Systemic Pesticides

1 Introduction

1.1 Introduction

In Europe, hundreds of different pesticides are allowed in farming. These are used to control fungi (fungicides), weeds (herbicides) and plague insects (insecticides) that may harm the crop. In this case we will focus on neonicotinoid insecticides (in short: neonics) and the relevance of the Precautionary Principle in the regulations of these insecticides due to the risk they pose for the environment and pollinating insects in particular.

Neonics were introduced on the European market in the early 1990s, and they are by now one of the most widely used group of insecticides in the world. In the context of increasing pest resistance to established Plant Protection Products, the invention of neonicotinoids signified a new era of pest management, with a higher versatility in application methods and a high target specificity[1] (Jeschke and Nauen, 2008). As systemic pesticides, they work differently than other pesticides by that they are taken up by the plant sap and translocated to all parts of the plant to provide long-term protection. Neonics are therefore promoted for providing cost-effective, highly targeted and long-lasting protection of crops against pests such as sucking insects, some chewing insects, insects that transfer plant viruses. In 2012, EFSA reviewed the scale of use in Europe and found that more than 200 different plant protection products with the neonics imidacloprid, thiametoxam, clothianidin, thiacloprid or acetamiprid were authorized in Europe for more than 1000 different applications, in a very wide range of crops, fruit trees, tree nurseries, ornamental plants and grass-fields such as golf courses (for complete overview, see table 1-3 in EFSA, 2012c).

In the late 1990s and the 2000s, early warnings started to emerge on that these systemic insecticides posed a risk to pollinators, which first was seen by beekeepers in their honeybees. The use of seeds coated with neonics was linked incidents of large amounts of bee deaths and honeybee colony collapses in several European countries. This led to an increasing amount of research on the un-intended effects of neonics on the environment, particularly on insects which provide significant ecosystem services such as pollination of crops. It was found that neonics not only protects the plant to potential plague insects, but also harms a wide range of non-target organisms such as bees and other pollinators, soil invertebrates such as earthworms, aquatic insects such as dragon flies, mayflies and damselflies and some species of birds (Pisa et al., 2017). However, there are large knowledge gaps and scientific uncertainties regarding residues of neonics in e.g. soil and water, routes of exposure for different species, and the sub-lethal effects of neonics on different species in complex ecosystems. However, the possible irreversible damaging effects on important ecosystem services such as pollinating insects, has led to precautionary action and world-wide controversy in science and society on whether a complete phase-out of neonics is justified.

In the EU, the PP was relevant in the regulation of neonics in 2013 and 2018. These regulations occurred much due to the Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, which entered into force in 2011[2]. With the procedures provided by this framework, pesticides already approved on the European market could be reassessed if new evidence on risks were found. As the research on risks related to neonics increased, especially regarding bees who provide significant ecosystem services, the EC requested the European Food Safety Authority (EFSA) to conduct a risk assessment. In 2013, after receiving EFSA's conclusions, the Commission Implemented Regulation (EU) No 485/2013 - banning outdoor use of imidacloprid, clothianidin and thiamethoxam, which are three of the six neonics marketed in Europe in crops attractive

[1] Note that the specificity here only means that it is highly toxic to insects and much less toxic to vertebrates such as mammals and birds, but is it not specific to plague insects versus non-target, beneficial, invertebrates such as bees, butterflies and earthworms.
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

to bees. The restrictions were reinforced in 2018 when the Commission implemented Regulations 2018/783, 2018/784 and 2018/785)[3], which limited the marketing authorisations for Plant Protection Products containing imidacloprid, clothianidin and thiamethoxam.

These regulations created much controversy. The agrochemical companies Bayer Crop Science, Syngenta and BASF, supported by industry/seed associations and different European farmers unions, filed court cases against the regulation in 2013. Their complains included that PP was wrongfully applied as the risk assessment was inconclusive, and that the principle of proportionality was neglected due to a lack of a formal economic impact assessment. Further, industry stakeholders have argued that the ban on neonics has negative consequences for innovation in the crop-protection sector in Europe, because industry will be more reluctant to invest when there is less regulative predictability when procedures can change approvals during their period of validity. Beekeepers associations, environmental NGOs and independent researchers on the other hand, have argued that all neonics should be completely banned, and that innovation should focus more on alternative means of crop protection and reduction of pesticide use (in line with the aims of reducing pesticide use as promoted in directive 2009/128/EC).

The main aim of this case is to provide insights into complexities and controversies around the application of the precautionary principle in the case of neonicotinoids in the EU, with attention to tensions between precaution and innovation. In order to provide these insights, we have reviewed academic articles and reports, stakeholder reports and press statements, and court case documents. Following the timeline of the case, we will the outline the innovative aspects of neonics, while part 3 will outline the risks, particularly focusing on scientific uncertainty in assessing the risks related to neonics. Thereafter, part 4 will outline the processes of regulating neonics and highlight controversies around the bans imposed in the EU 2013 and 2018. The last two parts will focus on how this case relates to and challenges the innovation/PP juxtaposition.

1.2 Key timeline

The timeline below[4] presents key innovation and marketing events, political events or decisions, implementations of legal frameworks or court cases, the most crucial scientific findings and risk assessments, and selected public debates. The different categories of actions are visualised by different colours.

Political	*Legal / regulative*	*Science/risk assessment*	*Public debate*	*Market/Innovation/other*

Year	Event	Relevance to case study
1985-1994	Bayer CropScience patented thiacloprid and imidacloprid as the first commercial neonicotinoids. Following this, thiamethoxam was patented in 1992, acyclic nitenpyram in 1988, acetamiprid in 1989, clothianidin in 1989, and dinotefuran in 1994 (Tomizawa and Casida, 2005: 248).	Innovations and patenting of neonics.
1991-2002	Bayer CropScience introduced imidacloprid to the market in EU member states in 1991. The following years other neonics entered the market, including Thiamethoxam by Syngenta in 1998, Thiacloprid by Bayer in 2000, and Clothianidin by Takeda/Bayer in 2002.	Different neonics introduced on the market, starting the era of neonicotinoid insecticides at a time when many pest insects had developed resistance to other pesticides like organophosphates (Simon-Delso et al., 2015).

[3] Official Journal of the European Union L132, (30 May 2018) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2018:132:FULL&from=DA
[4] An extended version of this timeline can be acquired by contacting the authors of this case.

1991	Implementation of Council Directive 91/414/EEC that provided an authorisation procedure for plant protection products in the EU	This was the first harmonised authorisation procedure for plant protection products in the European Union.
1993	The Maastricht Treaty came into force.	The treaty states that community policy on the environment shall aim at a high level of protection, and that it shall be based on the **precautionary principle** (Article 130r. 2)
1994 France	Bee-colony losses were reported by French beekeepers in areas near fields sown with neonic-coated seeds (Gaucho®), and evidence of the risk caused by imidacloprid emerged in independent research *(*Maxim & Sluijs 2007, 2013).	Early warnings indicating that neonics posed risks for bees.
1999, France	A two-year ban on the use of Gaucho in sunflower seed dressing was implemented and renewed in 2001 and in 2004 for 3 years (Maxim and Sluijs, 2007: 3-4).	The first precautionary based regulation in an EU member state.
2000, March-May	Beekeepers in Northern Italy started reporting events of bee mortality and colony weakening in spring, associated with maize sowing (Mutinelli et al., 2009)	Early warnings on risks of neonics to bees.
2002, Feb. 21	The European Food Safety Authority **(EFSA)** was established by the EU under the General Food Law – Regulation 178/2002, following a series of food crises in the late 1990s.	EFSA was to provide scientific advice on risks associated with the food chain. EFSA was mandated to carry out EU peer review of active substances used in plant protection in 2003.
2003	French Scientific and Technical Committee for the Multifactor Study of the Honeybee Colonies Decline publishes a scientific assessment report, concluding that seed-dressing sunflower and maize posed serious risks to honeybee colonies via larvae feeding, pollen consumption by nurses, nectar ingestion by foragers, and honey consumption by honeybees (CTS, 2003)	The by that time most comprehensive risk assessment the risks of neonics to bees, based on the analysis of 338 publication.
2004	The French Minister of Agriculture temporarily bans Gaucho® (containing imidacloprid) in maize seed-dressing.	The first PP based restrictions on neonics implemented in a European country.
2008	Serious bee-colony losses were reported in many European countries. Linking the incidents to use of neonics, national authorities restricted neonics in Italy, Germany, Slovenia.	Precautionary based regulations in several EU countries.
2009 Oct.	**Implementation of Regulation (EC) No 1107/2009** of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. The regulation enters into force in 2011, June 14.	Article 1, p 4 states that the Regulation is underpinned by the **precautionary principle.** This regulation marked a significant change in regulative policy on pesticides (from risk to hazard based) and in the procedures for risk regulation (Bozzini, 2017: 58).
2011, March 18	Due to concerns expressed European Parliament members and beekeeper associations on appropriateness of the risk assessment scheme of the European and Mediterranean Plant Protection Organisation (EPPO), the EC asks EFSA to review this scheme. Particularly, chronic risks to bees, exposure to low doses, exposure through guttation and the cumulative risk assessment were to be reassessed (EFSA, 2012a)	This process resulted in a new draft guidance scheme for risk assessments of plant protection products on bees (EFSA. 2013e). Popularly called 'EFSAs Bee Guidance Document', this risk assessment scheme received much controversy as it was applied in EFSAs risk assessments in 2018.
2012	3 Scientific articles were published in peer-reviewed journals suggesting that field-realistic levels of the neonicotinoids imidacloprid (Whitehorn et al., 2012), thiamethoxam (Henry et al., 2012) and clothianidin (Schneider et al., 2012) significantly affected bee colony stability and survival of honeybees and bumblebees.	These studies gained much attention and were regarded as new knowledge on the risks of neonics to risks to bees. This enabled the EC to follow up on **Article 21 of Regulation (EC) No 1107/2009** stating that approval of active substances should be reviewed in light of new scientific knowledge.

2012, April 25	The EC requests **EFSA** to provide conclusions as regards the risk to bees for the uses of thiamethoxam, clothianidin, and imidacloprid (EFSA, 2013a)	Thereby a thorough and controversial risk assessment processes was initiated.
2013, Jan 16	**EFSA** present to the EC their risk assessments of clothianidin, imidacloprid and thiamethoxam (EFSA, 2013b, 2013c, 2013d). For some uses, a high acute risk for honeybees was found (e.g. from exposure via dust drift of the sowing of maize and cereal seeds coated with clothianidin, imidacloprid, thiamethoxam). It was also noted that due to shortcomings of data and a lack of a finalised risk assessment guidance document, uncertainty remained.	On this basis, the EC proposed to implement **Regulation 485/2013** – on the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances.
2013, May 24	After two rounds of inconclusive voting by the Member States, the EC decided to implement **Regulation (EU) No 485/2013 - banning outdoor use of 3 of the 6 neonicotinoids** that are marketed in Europe in crops attractive to bees. Uses in greenhouses, of treatment of some crops after flowering and of winter cereals were excepted.	The first regulations of neonics were implemented in the EU.
2013, July 4	EFSA publishes the **Bee Guidance Document** (EFSA 2013e). This document was intended at providing guidance for the review of plant protection products (PPPs) and their active substances under Regulation (EC) 1107/2009.	This document created much controversy on the risk assessment process.
2013, August	**Bayer** Crop Science and **Syngenta Crop Protection** – file legal cases against the EC (**Cases T-429/13 and T-451/13** seeking to annul the Commission's Implementing Regulation (EU) **No 485/2013.**	Many of the claims contested the application of the PP for restricting neonics.
2015, Jan.	The **Task Force on Systemic Pesticides (TFSP)** (group of independent scientists convened by the International Union for Conservation of Nature, IUCN) produced a comprehensive scientific assessment of the ecological effects of neonicotinoids, based on a synthesis of over 800 published peer-reviewed including industry-sponsored ones.	TSFP concluded that the levels of pollution with neonicotinoids are likely to have a wide range of negative biological and ecological impacts (van der Sluijs et al., 2015). Regulatory agencies were recommended to consider applying the principles of prevention and precaution to further tighten regulations on neonicotinoids.
2015, Feb. 11	As foreseen in recital 16 of Implementing Regulation (EU) No 485/2013, the Commission initiated a review of new scientific information on 11 February 2015 by mandating **EFSA** to organise an open call for data (EFSA 2015d).	The open call enabled all interested parties to contribute.
2015 April	European Academies Science Advisory Council (EASAC) publishes an influential report " Ecosystem services, agriculture and neonicotinoids" (EASAC, 2015).	The report concluded that the widespread prophylactic use of neonicotinoids has severe negative effects on non-target organisms that provide ecosystem services.
2017	The Bee Coalition was created as a platform for NGOs to join forces and resources at EU level for the protection of bees and pollinators.	Their aim is to make EU decision-makers to completely ban all neonicotinoids, and that the Member states approve the Bee Guidance document.
2017, June	Two papers published in *Science* (Woodcock et al., 2017 and Tsvetkov et al., 2017) received much public attention. The Woodcock study was the largest field study of neonics effects on bees ever conducted, and was sponsored by Bayer and Syngenta	Especially, the study in Woodcock et al., (2017), which was assumed to increase the knowledge on field realistic effects of neonics, was highly debated and received very different interpretations.
2017, Oct.	A worldwide survey of neonicotinoids in honey, found at least one of five tested neonic compounds in 75% of all samples (Mitchel et al., 2017).	This study gained much attention in media as it increased the knowledge on residues of neonics.
2018, Feb.	EFSA presents to the EC its updated risk assessments of clothianidin, imidacloprid and thiamethoxam	For all the outdoor uses of these substances, there was at least one aspect of the

		assessment indicating a high risk to bees. (EFSA, 2018e).
2018 May 29	The EC implements Regulations (EU) 2018/783, 2018/784 and 2018/785, extending the ban on imidacloprid, clothianidin and thiamethoxam.	The bans on 3 neonics in the EU were continued and reinforced.
2018, May 17	Judgment of the General Court of 17 May 2018 on the Cases T-429/13 (Bayer CropScience AG and Others) and T-451/13 (Syngenta Crop Protection AG). The Court dismissed entirety the actions brought by Bayer and Syngenta in relation to the neonicotinoids clothianidin, thiamethoxam and imidacloprid.	In the judgment, the EC was supported, and it was underlined that the PP was not beached.
2018 July	Appeal /Case C-499/18 P): Bayer CropScience AG against the judgment of the General Court (First Chamber, Extended Composition) in Case T-429/13	The allegations were similar, also disputing the PP, in addition to promoting more regulatory certainty for innovators.
2018, Dec. 18	The European Parliament publishes the report on the Union's authorisation procedure for pesticides (European Parliament 2018/2153(INI). It highlights flaws in the authorisation practice and the effectiveness of Regulation (EC) 1107/2009, and calls for changes in the pesticide approval procedure.	The report calls on the Commission and the Member States in their role as risk managers to duly **apply the precautionary principle**, and highlights that the widespread and prophylactic use of plant protection products is of concern.
2019, 23.10	MEPs block member states' move to weaken bee protection from pesticides (EP Press release, 2019)	Member States opposed the full implementation of EFSAs Bee Guidance document
2020 Jan 13	EC decided not to renew the approval of thiacloprid, following scientific advice by EFSA that the substance presents health and environmental concerns.	This is the 4th out of 5 neonics that first were approved for use in the EU, but that later were restricted since 2013.[5]

2 Neonicotinoids - Innovation and potential benefit

The invention of neonicotinoids in the late 1980s and 1990s, is often highlighted as a significant technological advancement in pesticide developments, signifying a new era of pest management, with a higher versatility in application methods and a high target specificity[6] (Jeschke and Nauen, 2008). They are the newest of the five major classes of insecticides (the others are chlorinated hydrocarbons, organophosphorus compounds, methylcarbamates, and pyrethroids), and by 2011 it was estimated that they make up one-fourth of the world's insecticide market (Tomizawa and Casida, 2011). The most widely used Neonics include the active substances Imidacloprid, Clothianidin and Thiacloprid (by Bayer Crop Science), Thiamethoxam (by Syngenta) and Acetamiprid (by Aventis Crop Science). As systemic insecticides, they work differently than contact pesticides which make the surface of plants toxic to plague organisms. Instead, they are they are taken up by the plant sap and translocated to all parts of the plant to provide long-term protection from piercing-sucking insects (Tomizawa and Casida, 2005).

The importance of innovating new Plant Protection Products (PPP) is often highlighted in the context of food security and the increasing weed and pest resistance to well established PPP (Bozzini, 2017). Most of the neonics were introduced on the EU marked between 1991-

[5] https://ec.europa.eu/commission/presscorner/detail/en/mex_20_38

[6] Note that the specificity here only means that it is highly toxic to insects and much less toxic to vertebrates such as mammals and birds, but is it not specific to plague insects versus non-target, beneficial, invertebrates such as bees, butterflies and earthworms.

2002, at a time when many pest insects had developed resistance to other pesticides like organophosphates (Simon-Delso et al., 2015).

Since their introduction to the market, neonics have become the most widely used group of insecticides in the world. They are promoted for providing a cost-effective for increasing yields, but it is also argued that their targeted use has decreased the use of other pesticides. As summed up in the industry magazine European Seed, "they have dramatically changed farming in Europe and reduced risks for farmers, both because they have improved pest control and have decreased additional chemical applications".[7] Reports and studies have identified such benefits of the use of neonics (e.g., North et al., 2016; Hurley and Mitchell, 2017) and it has been argued that restrictions on neonic has had negative consequences for crops and farmers (HFFA, 2018; Budge et al., 2015; Dewar, 2017; Kathage et al., 2018). Budge et al., (2015) found that farmers who use neonicotinoid seed coatings reduce the number of subsequent applications of foliar insecticide sprays and may derive an economic return. Summing up the negative consequences of implementing restrictions on neonics the UK, Dewar (2017:1308) lists that it increased applications of alternative insecticides, increased evolvement of resistance in target pests, increased level of damage caused by flea beetles, led to a decrease in yield at harvest, a decrease in the area of oilseed rape grown – which has the knock-on effect on the area of flowering crops available to foraging bees in the spring when flowering plants in general are scarce in the UK landscape.

Countering this, other studies have not found clear and consistent evidence on yield benefits from the use of neonicotinoids on different crops (Hladik et al., 2018; Furlan et al., 2017; Milosavljevic et al., 2019; Lundin et al., 2020). For example, it is found that neonic seed treatments offered little yield benefit for soybean production (Seagraves and Lundgren, 2012; EPA, 2015) and for wheat crops (Macfadyen et al., 2014). For oilseed rape, a recent field study found that neonic seed treatments were only economically justified in one year out of three (Lundin et al., 2020). A review of the precautionary regulation of neonics in Italy in 2008 found the average annual maize production per hectare remained unchanged after the regulation was implemented (Sgolastra et al., 2017). Another issue is that due to the widespread use of neonics, some species have started developing resistance to some neonics (see Bass et al., 2015 for review of literature on pest resistance to neonicotinoids). Additionally, a decline of pollinators may have huge consequences for yields of crops that depend on them (Van der Sluijs and Vaage, 2016; Furlan et al., 2017). In sum, there are many uncertainties on the relationship between the use of neonics and yield benefits of different crops, which also may be impacted by unpredictable changes in the density and developments of both pollinating and pest insects.

3 Risks and scientific uncertainty

3.1 Risk/threat

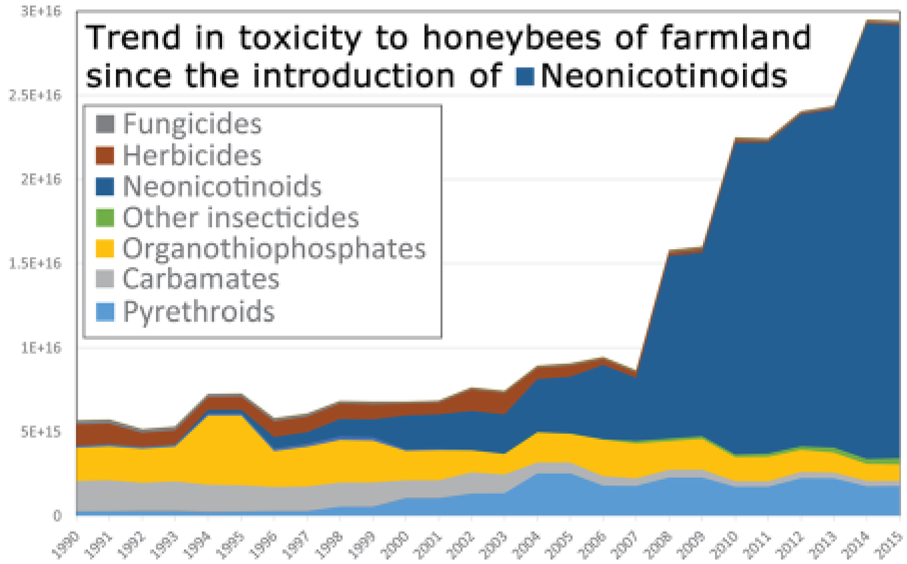
The risk discussed in relation to neonics are mostly environmental, as the residues in the environment are found to be high and diverse. Water surveys in more than a dozen countries have documented widespread contamination of surface waters around the world at levels that frequently exceed water quality norms (Giorio et al., 2017). Studies also confirm wide spread environmental contamination by neonics in soil, air, wild plants (including pollen and nectar), agricultural produce, bees, beehives, honey, human urine and effluent of waste water treatment plants (ibid). Neonics are persistent in soil and can accumulate from one planting season to the next and are taken up by non-treated follow-

[7] https://european-seed.com/2017/12/impact-ban-neonicotinoids/

up crops. It has been found that although the technique of coating seeds with neonics is designed to be taken up into the target crop plant, only 1.6–20% of the active ingredient is absorbed, with the majority remaining in the soil from where it leaks to the surface water and groundwater (Wood and Goulson 2017). Wild trees (most of which are flowering plants that are visited by pollinators) in or around agricultural fields and along polluted surface water also take up neonics and have become contaminated. Soil and foliar runoff are the most common pathways for neonic contamination of surface and groundwater (Wood and Goulson, 2017).

Risks for bees and pollination ecosystem services

In both research and in public debate, the main attention has been on the risks that neonics pose to pollinators, especially bees. Since the early warnings in the 1990s, evidence has been mounting that the large scale use of these chemicals play a key role in colony collapses and are an important driver of the pollinator decline observed over the past decades (Van der Sluijs et al., 2013; 2015; EASAC, 2015; Rundlöf et al., 2015). As a direct consequence of its systemic action, unintendedly the pollen and nectar of treated crops and of wild flowers in or around the fields with treated crops also contain traces of the nerve poison in non-deadly, yet harmful concentrations. Subsequently, not only plague insects are exposed but also beneficial insects such as bees, butterflies and other pollinators get exposed to low doses as they forage. Neonics are over 7 000 times more toxic to honeybees than the insecticide DDT (Simon-Delso et al., 2015). Prolonged exposure to very low doses is ultimately fatal for insects. This is because neonics have the rare property that the duration of the exposure amplifies its toxicity (Tennekes, 2010). Further, so-called sublethal doses disturb navigation and flight behaviour of bees, causing bees to get lost, and weakening the entire colony (Van der Sluijs et al., 2013). Thereby, the large-scale prophylactic use (application of pesticides to all seeds even when there are no signs of pests) of neonics, in combination with their high toxicity, has transformed the agrochemical landscape for pollinators (Van der Sluijs et al., 2013). Recent studies have shown that neonics are the dominant factor driving the increase in toxicity for insects of farmland (Goulson et al., 2018) as is illustrated for UK farmland in figure 1. However, it should be noted that the widespread use of neonics is only one of multiple stressors that are related to pollinator decline. It is the combination of parasites, pesticides, and low availability of floral resources in present day landscapes and lack off suitable nesting places that together produce the present pollinator declines (Goulson et al., 2015). At present, there is substantial uncertainty, complexity, ambiguity and disagreement around which factors are more important and how these factors relate to each other. This will be explained in more detail in section 3.2.



Prophylactic pesticides: # of honeybee lethal doses (LD_{50}) in pesticides applied to UK farmland 1990-2015 DOI: 10.7717/peerj.5255/fig-2

Figure 1: Toxicity to honeybees of farmlands in the UK (Goulson et al., 2018: 4)

Pollinator decline is a serious risk because they provide key ecosystem services as many important agricultural crops depend on them. Additionally, 94% of all flowering wild plants depend on insect pollinators for reproduction (IPBES 2016), and a decrease in insect abundance can in turn have consequences for insect eaters such as birds. There is a concern that a tipping point will be reached, where pollinator decline cannot be reversed, despite their seemingly robust structure (Potts et al., 2010: 347). Viewed as essential ecosystem services in food production, pollinator decline can threaten both global and local food security and can destabilize ecosystems that form our life support system (van der Sluijs and Vaage, 2016). It is often referred to that the United Nations Food and Agriculture Organisation (FAO) have estimated that 84% of the 264 crop species in Europe are dependent on pollinators[8]

Risks for other species and ecosystem services

There is also a growing amount of research demonstrating risks for other species and ecosystem services. The findings from the "World Wide Integrated Assessment of the Impacts of Systemic Insecticides on Biodiversity and Ecosystem Services" in 2017, summarized in figure 2, show that at the present scale of world-wide use, the impacts of neonics on insect pollinators and on terrestrial and aquatic insects, cascade into impacts on population level and communities levels and put key ecosystem services at risk.

[8] http://www.fao.org/news/story/en/item/384726/icode/

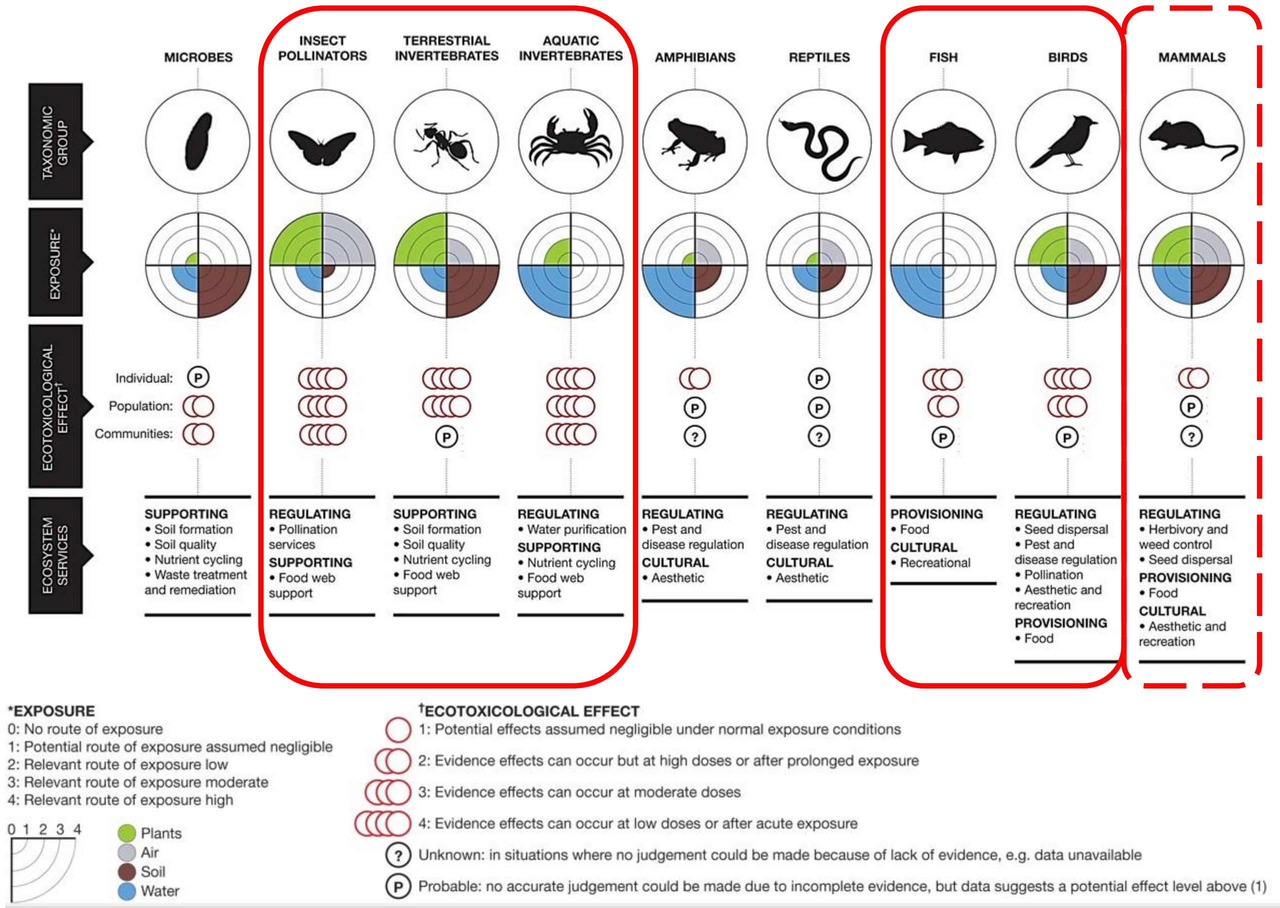


Figure 2: Infographic summarizing the main findings of the WIA study on the state of knowledge on impacts of neonic insecticides on biodiversity and ecosystem services (Pisa et al., 2017:36).

The infographic in figure 2 shows for example that effects are found on **vertebrate wildlife (birds):** Some bird species may consume seeds coated with neonics or forage on plants or seeds with residues, but indirect effects on insectivorous birds as a consequence of reduced insect abundance is also a ground for concern, but there is still limited evidence and many uncertainties remain because the impacts have only been examined in a handful of species. Since 2014, studies have found negative impacts of the neonicotinoids imidacloprid and clothianidin on vertebrate wildlife, such as birds who ingest treated seeds left on the surface at sowing (Gibbons et al., 2015; Hallman et al., 2014). A recent study shows that field-realistic imidacloprid exposure reduces fueling and delays migration in songbirds (Eng et al, 2019). Effects are also found on **Terrestrial invertebrates such as earthworms**_(see Chagnon et al., 2015), which provide a range of ecosystem services (e.g. decomposition of organic matter in soils for nutrient cycling). Another increasing worry is the effects of neonics on **Aquatic invertebrates**, which also provide significant ecosystem services (van Dijk et al., 2013; Sánchez-Bayo et al., 2016A). Entire ecosystems may be impacted as invertebrates constitute the main food source for many insectivorous vertebrates and fulfil an essential role in recycling organic matter in the soil as well as in water (Pisa et al., 2017)

Lastly, risks on the effects of neonics on **human health** remains poorly understood. While highlighting that more research is needed, the limited literature on this field suggest concerns for neurodevelopmental effects on brain development during prenatal and early life exposure (possibly leading to increased incidence of autism, schizophrenia and ADHD) and a possible role in Parkinson and Alzheimer’s disease (Cimino et al., 2017; Zang et al., 2018). There is also emerging evidence that at least some neonicotinoids are not only nerve poisons but are also endocrine disruptors (Caron-Beadoin et al., 2017).

Despite the accumulating amounts of studies, there are many uncertainties and large controversies. The controversies will be further explained in the following section, highlighting that the complexity of the issue.

3.2 Scientific analysis

The first observations (early-warnings) of the negative effects of neonics on pollinators came from beekeepers in different European countries, who started to report large amounts of bee-deaths (and colony losses) in hives located near fields sown with neonicotinoid-coated seeds. During the 1990s, the first early-warning reports emerged linking neonics bee-colony losses in France, and the PP was applied to ban products containing neonics for certain crops (Maxim and van der Sluijs, 2007; 2013). Of particular importance was the scientific assessment by the French Scientific and Technical Committee for the Multifactor Study of the Honeybee Colonies Decline (CST)[9] from 2003. Based on the analysis and synthesis of 338 scientific publications, the CST concluded that seed-dressing sunflower and maize posed serious risks to honeybee colonies via larvae feeding, pollen consumption by nurses, nectar ingestion by foragers, and honey consumption by honeybees living inside the hive. The CST based the assessment on comparison between the levels of exposure (Predicted Exposure Concentration — PEC) and toxicity (Predicted No Effect Concentration — PNEC) of imidacloprid for honeybees considering both lethal and various sublethal effects. It concluded that the exposure in the field exceeds the known no-effect concentrations and are therefore of concern (CST, 2013).

The use of different types of neonics in different kinds of crops expanded in Europe during the 2000s. In the spring of 2008, serious bee-colony losses were reported in Italy, Germany, Netherlands, Slovenia and France. This led to national bans or restrictions of products containing neonics for certain kinds of crops. Further, the incidents of colony collapses in Europe were followed by increased research and monitoring on the effects of neonics on bees. In Italy, a 3-year monitoring research project (APENET) was conducted between 2009 as initiated by Italian authorities in order to clarify the causes bee-deaths (EFSA, 2012a).

Independent peer-reviewed research: Beekeepers suspicion that colony collapses were related to the use of neonics in the fields close to beehives, inspired independent researchers to investigate the matter. Particularly three studies received much attention, finding that imidacloprid (Whitehorn et al., 2012), thiamethoxam (Henry et al., 2012) and clothianidin (Schneider et al., 2012) at field-realistic concentrations had significant impacts on bee colony stability and survival of honeybees and bumblebees. Since 2012, and especially after the decision of EC to implement a partial ban on three neonics in 2013 (outdoor use on crops that are attractive to bees), research on the risks of neonics expanded massively. There have been several review studies assessing and evaluating the amount of detailed studies generated, including Godfray et al., (2015), Lundin et al., (2015), and Wood and Goulson (2017), EASAC (2015). As example, Lundin et al. (2015) provide a systematic review of research approaches, evaluating 268 publications on bees in general (honeybees, bumblebees, solitary bees). The International Task Force on Systemic Pesticides published a synthesis of 1,121 published peer-reviewed studies spanning the last 5 years at that time, including industry-sponsored ones in 2015. This seminal report is called the "World Wide Integrated Assessment of the Impacts of Systemic Insecticides on Biodiversity and Ecosystem Services" (WIA). The WIA was published in the form of 8 scientific papers in the journal *Environmental Science and Pollution Research*

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[9]Comité Scientifique et Technique de l'Etude Multifactorielle des Troubles des Abeilles, installed by the French Ministry of Agriculture

(Simon-Delso et al., 2015; Bonmatin et al., 2015; Gibbons et al., 2015; Chagnon et al., 2015; Furlan and Kreutzweiser 2015; Van der Sluijs et al., 2015). In 2017, the same task force published an update of the WIA in 3 papers based on more than >700 publications that had appeared since the first WIA study (Giorio et al., 2017; Pisa et al., 2017; Furlan et al., 2017).

EC mandated EFSA reviews: Mandated by the European Commission (EC), EFSA has provided a conclusion of the risk assessment for the active substance clothianidin (EFSA 2013b, 2015a, 2018d) thiamethoxam (EFSA 2013c, 2015c, 2018c) imidacloprid (EFSA 2013d, 2015b, 2018b) and thiacloprid (EFSA 2019). The context for the risk assessment was that the EC mandated EFSA, in accordance with Article 21 of Regulation (EC) No 1107/2009, to review the approval of active substances considering new scientific knowledge. Further, in accordance with Article 31 of Regulation (EC) No 178/2002, EFSA organised an open call for data in order to collect new scientific information as regards the risk to bees from the neonicotinoid pesticide active substances clothianidin, thiamethoxam and imidacloprid applied as seed treatments and granules in the EU. The EFSA also performed an extensive updated literature search for their 2018 assessment instead of only relying on the dossier provided by the industry, as would occur in a normal authorization procedure (EFSA, 2018b). It should be noted that for re-evaluations of imidacloprid, thiamethoxam and clothianidin published in 2018, EFSA not only used far more data sources, but also got the explicit mandate to apply its new 2013 Bee Guidance (EFSA 2013e), even if it was (and at the time of writing, mid 2020, still is) not yet put into force. If the limited (and scientifically outdated) authorization tests that were in force (found in the Guidance Document on Terrestrial Ecotoxicology 2002[10]) had been used, it is unlikely that any risks would have been identified. This highlights a major problem in pesticide authorization, namely that the authorisation tests that are in force typically lag many years behind the scientific progress in the field, in this case at least 18 years.

3.3 Scientific Uncertainty

3.3.1 Complexity

Several complexities contribute to the challenges of estimating and analyzing the risks connected to neonics (esp. choosing variables and samples for analysis), and we have here categories these complexities into four categories:

First, there are complexities of the **types and applications** of neonics. There are different types of neonics and different kinds of products (including cocktails of pesticides), and different neonics are applied to different types of crops, in indoor or outdoor facilities. With a definition focusing on how the compound works, the neonicotinoid family includes imidacloprid, clothianidin, thiamethoxam, dinotefuran, thiacloprid, acetamiprid, sulfoxaflor, nitenpyram, imidaclothiz, paichongding and cycloxaprid (van der Sluijs et al., 2015). There is some ambiguity on the names of families of these chemicals, as evident in the current debate on **sulfoxaflor** (approved in 2015) (EFSA 2018f). The TFSP classifies sulfoxaflor as a neonicotinoid (Giorio et al., 2017), but the authorization dossier sent by Dow Chemical to the EFSA classified it as a sulfoximine. It has however the same mode of action, acts on the same receptor in the insect nervous system and has similar toxicity to bees as imidacloprid.

Regarding applications, neonics can be applied though either spaying, seed coating/seed-dressing, soil treatment, injection, and drenching. Seed-dressing is the most common application method and was estimated to make up 60% of the global use in 2010 (Jeschke et al., 2010). The advantage of seed-dressing is that it requires no action from the farmer, prophylactically protecting all parts of the crop for several months following sowing (Jeschke et al., 2010). Further, neonics may be applied in different seasons, which is related to routes of exposure for bees, especially in foraging season. Particularly two

[10] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

seasons are important: Seeding seasons, when bees and other insects may be exposed to neonics through dust drift during the sowing/application of the treated seeds, and flowering seasons, when residues of neonics are found in nectar and pollen, exposing pollinating insects. It should also be noted that neonics may be applied not only to crops, but also in **biocides and in veterinary medicine.** Consequently, there are different regulative regimes for different uses of the same chemical – e.g. neonics as applied on crops are regulate under a different regime than neonics applied in biocides (for instance to kill flies in cattle stables) and veterinary medicine (for instance to kill fleas in pets).

Secondly, and linked to the variety of applications, there is a complexity of **residues and possible routes of exposure for** non-target species. Neonics residues are found not only in treated crops, but also in nearby wild flowering plants, including arable weeds, trees and shrubs. Research has revealed that insects may be exposed through residues of pesticides in nectar, pollen, honeydew, extrafloral nectar, guttation fluid, surface water, puddle water, soil, sediments, leaves, and through dust produced during the seeding of coated seeds or spraying (Bonmantin et al., 2015). There is therefore uncertainty on the level of chronical exposure of non-target organisms to sublethal levels of neonics also after planting, and indicated that pollinators may face cumulative exposure to neonics from combined residues in pollen, nectar and water (Samson-Robert et al., 2014). In a field study in Canada, it was found that honey bees in corn-growing regions were exposed to toxicologically significant levels of neonics for the majority of the active bee season despite the mandated use of dust-reducing seed lubricants during planting (Tsvetkov et al., 2017:3).

Third, there is a complexity of **species affected,** as also highlighted in section 3.1. Honey bees (managed bees) are the most researched species, but wild bees like bumblebees and solitary bees are also affected and may show different levels of sensitivity. As most European wild bees are smaller than honeybees, they may be more sensitive on a basis of a few nanogram/bee exposure (Pisa et al., 2017). The effects on solitary bees may be different than on bees living in colonies that store larger amounts of food. Bumblebees have a different biology, behaviour and ecology from honey bees, and may for example be exposed to neonics via soil or plant materials used for nesting materials (EFSA 2013c, p7). Further, as elaborated earlier, neonics may affect other wild pollinators such as butterflies, on invertebrates (like earthworms), on aquatic animals (fish, molluscs) and on birds, through various routes of exposure like residues in water, soils and seeds.

Fourth, there is a complexity of **ecological contextual factors** that affect the consequences of neonics exposure for different species. Here, we will focus on bees, as these have been given the largest amount of public and scientific attention in this case. It is found that neonics can weaken bee colonies in various ways, as the sub-lethal effects may affect the complex social and collaborative structures of a bee colony (van der Sluijs et al., 2013). As an example, bees depend on communication and collaboration, and neonics may weaken the general health of worker bees, and their ability to communicate on where to find food. Moreover, is well known that that reasons for bee deaths / decline cannot only be linked to neonics, but to a complex set of factors that may interact; it is the combined stress from parasites, pesticides, and lack of flowers that contribute to bee decline (Goulson et al., 2015). Loss of habitat is a major factor contributing to bee-deaths, as bees require access to flowering plants in their adult flight season, and undisturbed nesting sites (wild bees). The conversion of rich habitat to farmland, but also urbanization has contributed to the loss of habitat. Then there is the problem of diseases. Bees naturally suffer from a broad range of parasites, fungi, bacteria, and viruses, especially Nosema ceranae and the Varroa mite. The main general understanding there is not one cause of bee-deaths, but that the different factors work together, e.g. by that the lack of access to flowering plants decreases reduces the bee’s ability to cope with both toxins and pathogens and that neonics may make bees less resilient towards these diseases (Sánchez-Bayo et al., 2016B). Further, bees are often chronically exposed to a cocktail of different pesticides (e.g. bees can be exposed both neonics and fungicides simultaneously), and this ‘cocktail effect’ remains poorly understood (Goulson et al., 2015).

3.3.2 Uncertainty

Scientific uncertainty may stem from a lack of data or inadequate models for risk assessment, and from the complexity of factors that may complicate determining the causal relations. In the case of neonics and its effects, the extended overview of the complexity as outlined above indicate several uncertainties. Some of these uncertainties could be attributed to a lack of data or knowledge gaps, that hamper evaluation of the full extent of risks associated with the ongoing use of systemic insecticides. However, even the fields where extensive amounts of research have been carried out, such as the effects of neonics on bees, there are many knowledge gaps and uncertainties. These uncertainties are related to the complexity of insect biology (including insect behaviour and colony mechanisms), and the environment they inhabit which increases the difficulty of determining causal relations. We will here give an overview of uncertainties related to the different aspects of complexity outlined above.

Even if bees, and especially honeybees, are well researched in relation to neonics, knowledge gaps and uncertainties remain on both the extent to which bees are exposed to neonics, and on the various effects of the exposure. The **uncertainty of exposure** is related to the **lack of knowledge on residues** of neonics. It is well known that neonic residues persist and accumulate in both soil and water, nectar, and pollen (Goulson, 2013), but there is limited knowledge on the exact residues in different areas, as they may vary significantly. In 2017, a field study identified widespread contamination of agricultural land by neonicotinoids (Tsvetkov et al., 2017), however this may vary geographically and over time. In the TFSP study, it was found that for most countries, there are few or no publicly available data sources on the quantities of systemic pesticides being applied, nor on the locations where these are being applied (Van der Sluijs et al., 2015). Thereby, realistic assessments of ecological impacts and risks becomes challenging. Additionally, the screening of neonicotinoid residues in environmental media (soils, water, crop tissues, non-target vegetation, sediments, riparian plants, coastal waters, and sediments) is extremely limited. Therefore, even if a worldwide survey found residues of neonics in 75% of honey samples (Mitchell et al., 2017), uncertainty remains on the extent of exposure in different areas.

Further, there are uncertainties on the consequences of different levels of exposure, especially of **lower sub-lethal exposure over time.** Sub-lethal effects are documented as summarised in several meta-studies to have negative effects on e.g. their growth and behavior (Cresswell, 2011; Main et al., 2018). However, effects of long-term, acute and chronic exposure are less well known, as long-term consequences of exposure under environmentally realistic conditions have not been studied (Van der Sluijs et al., 2015). It is also challenging to estimate the effects of neonics on colony strength and resilience. It has been found that exposure to neonics can affect the strength of the bee colony in different ways, for instance when forager bees are affected in a sub-lethal manner by e.g. making navigation errors, show impaired social communication, thus weakening the colony (Pisa 2017, p3-4). However, there are multiple stressors that affect bee health and colony strength, but there are few studies on synergic effects of systemic insecticides and other stressors, such as other pesticides, disease, and food stress (van der Sluijs et al., 2015). Bee diseases such as the Varroa mite and Nosema may weaken the colonies significantly, and these diseases are often seen as the main causes of colony collapse disorder. An indirect relation between neonics and such diseases have been found, by that the neonics supresses the immune system and thereby opens the way to parasite infections and viral diseases, fostering their spread among individuals and among bee colonies at higher rates than under conditions of no exposure to such insecticides (Sánchez-Bayo et al. 2016B). Clearly, there can be many reasons for weak colonies. This uncertainty is also drawn on by agrochemical companies, who argue that there is no causal relation between neonics and colony collapses, but that bee health problems like the varroa mite is the main cause (see e.g. Bayer's home pages dedicated to on bee health[11]).

The largest knowledge gaps seem to be that the **long-term toxicity to certain species**, such as hoverflies or butterflies and moths has not been investigated. The same holds for soil organisms (beyond earthworms) (van der Sluijs et al., 2015). In addition, there is a high degree of uncertainty around possible **'cocktail effects'** of the combination of different pesticides that bees to varying degrees are exposed to. In a review from 2015 it was found that no studies had addressed the additive or synergistic effects of simultaneous exposure to multiple compounds of the neonicotinoid family, i.e. imidacloprid, clothianidin, thiamethoxam, dinotefuran, thiacloprid, acetamiprid, sulfoxaflor, nitenpyram, imidaclothiz, paichongding and cycloxaprid (van der Sluijs et al., 2015). As all neonicotinoids bind to the same receptors in the nervous system, a cumulative toxicity could be expected, however assessments are done for each chemical separately. This is problematic because in field situations, organisms will almost invariably be simultaneously exposed to multiple pesticides as well as other stressors, so our failure to understand the consequences of these interactions is a major knowledge gap (van der Sluijs et al., 2015).

With the high degree of contextual complexities, there are several uncertainties connected to the **methods chosen for measuring the effects of neonics on pollinators**. A main method is conducting **lab studies** (or experimental studies) under controlled circumstances (inside of a lab), by feeding bees with different types of neonics and measuring their responses. Such studies have the advantage that they allow for causal arguments about exposure-effect relationships, and many of these seem to highlight a negative effect of neonics on bees. A disadvantage of lab studies is that there is a high degree of uncertainty on what a field-realistic doses of neonics would be, due to many contextual complexities. As example, bees may be more exposed to neonics in some seasons more than others (also depending on farmers methods of seeding), there may be different availabilities of other flowering plants in different areas, and it is uncertain and may vary how far bees fly when foraging (while some argue 1 km, others 3 km, Beekman and Ratnieks (2000) found a median foraging distance of 6.1 km with 10% of the bees foraging over 9.5 km.). Therefore, lab-studies have been critisised for giving bees unrealistically high doses of neonics compared to what they would get in a real life (see e.g. Carreck and Ratnieks, 2014; Löfsted and Schlang, 2017). Contrasting lab-studies, **field studies** may encompass more contextual complexity, making the study more field realistic. Disadvantages of such studies are that they are challenging to reproduce and do not enable good estimations of causal effects as a multitude of factors may impact the specific case that is studied. Weather, nutrition, genetics, pathogens and diseases, presence of multiple toxic compounds, potentially contrasting behavioural characteristics of the studied colonies, and very different methodological approaches, may affect the results of the study (Pisa et al., 2017:3). The specific location of the field study may impact the study because the floral resources (containing different mixtures of pesticides) that bees can forage on, usually within a 3 km radius around a hive, varies between locations. This becomes evident when we look at figure 3 below. Consequently, it is difficult to reproduce field experiments.

[11] https://www.cropscience.bayer.com/people-planet/biodiversity/bee-health

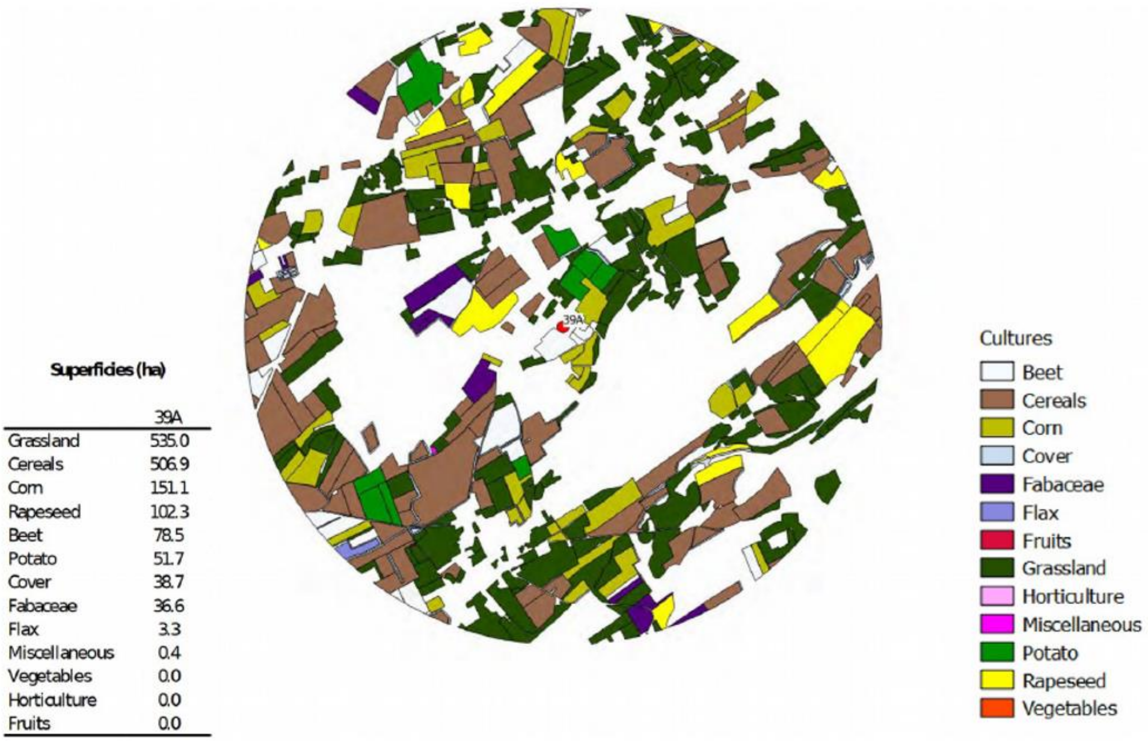

Figure 3: high variability in land-use (a key confounder) in a typical 3 km foraging area (in Belgium) around a honeybee hive, puts fundamental limitations to the reproducibility of field studies (figure source: Simon-Delso, 2017).

Field studies on the effects of neonics on bees have come to different conclusions. While some found no or little effects on bees and bumblebees (Pilling et al., 2013; Thompson et al., 2013; Peters et al., 2016), others have found varying and worrying effects (Rundlof et al., 2015; Tsvetkov et al., 2017; Woodcock et al., 2017). The uncertainty of the effects of neonics in field realistic studies are evident when comparing two of the most debated peer-reviewed articles in 2017: While Tsvetkov et al (2017) demonstrated that field-realistic chronic exposure to neonics reduced the health of honey bee colonies near corn crops in Canada, a large scale field study in Europe found more contradictory results (Woodcock et al., 2017). These studies both accounted for some of the complexity of the environment and included behavioural / sub-lethal effects.

Many of the uncertainties discussed here are reflected in the conclusions EFSA risk assessments from 2018. The conclusions on risk varied according to factors such as the bee species, the intended use of the pesticide and the route of exposure (residues in bee pollen and nectar; dust drift during the sowing/application of the treated seeds; and water consumption) (EFSA 2018b; 2018c; 2018d). For example, the 2018 review on imidacloprid found that there was a low risk of exposure through both dust drift and residues in pollen and nectar for honeybees, but a high risk when bumble bees and solitary bees were included (EFSA, 2018b). The current focus in EFSA is to improve the risk assessment process by including larger spatial scales, multiple stressors, and different pesticide uses (Streissel et al., 2018). This is also evident in EFSA's MUST-B project, which aims to develop a holistic approach to the risk assessment of multiple stressors in honeybees[12].

[12] http://www.efsa.europa.eu/en/topics/topic/bee-health , http://www.efsa.europa.eu/en/press/news/170522-0

3.3.3 Ambiguity

Ambiguity arises when different actors both interpret the knowledge and frame the issue at hand differently. Involved actors in the controversies over neonics include beekeepers and beekeeper associations, farmers and farmers associations, agrochemical companies and chemical industry associations, environmental NGOs, politicians, policy advisors and different groups of scientists. With the amount of stakeholders engaged and the multiple sources of uncertainties around the effects of neonics on bees, it should be no surprise that there is a high level of ambiguity – reflected by the highly contradicting interpretations of the context, the problem, and the research on the problem.

Ambiguity on the context and the problem (what is at stake)

The risks that different stakeholders relate to neonics should be seen in light of two diverging ways of framing Plant Protection Products (PPP) (Bozzini, 2017): One way of framing PPPs is to see them as threats to conserving biodiversity and ecosystem services. With this frame, the focus is on how industrial farming and the increased use of pesticides has decreased biodiversity, and the case of DDT is often drawn in as an example of the destructive consequences of PPPs. Another way of framing PPPs is seeing them as vital tools in providing food security. With this perspective, the historical and ongoing advances in food production that are necessary to ensure sufficient food production for a growing world population is central. Often, a different contextual story used to illustrate how vulnerable food production is, e.g. referring to the Irish potato famine (Bozzini, 2017).

In the case of neonics, the risk these PPPs pose to the ecosystem services and biodiversity is particularly highlighted by beekeeper organizations and environmental NGOs. Beekeepers and beekeeper associations, including Apimondia, European Professional Beekeepers Association, BeeLife and European Beekeeping Coordination. The most outspoken (Environmental) NGOs involved in this case include Pesticide Action Network, Greenpeace, Buglife, and Slow Food[13]. In 2017, more than 80 NGOs, covering most of the European Union and comprising beekeepers, environmentalists and scientists, officially launched the 'Save The Bees Coalition', where it is stated that

> "Neonicotinoids and other pesticides are major factors causing the decline in populations of honey bees, wild bees and other pollinators. This jeopardises our food sustainability and biodiversity. Neonicotinoids have been authorised more than 20 years ago because their impacts on bees were not fully assessed as the procedures for testing the safety of pesticides used rules that were partly written by the pesticide industry itself »[14].

There have also been online petitions, the most recent one demanding Bayer CropScience to drop their court case against the EC on the ban in 2018, where it is highlighted that bees are at risk of global extinction, while companies like Bayer put their profits ahead of the planet's health. [15] The petition received over 1.4 million signatures. Note that public debate is focused especially on honey bees, while e.g. bumble bees, solitary bees, hoverflies butterflies and moths, which also are significant pollinators, have received less public attention (EASAC, 2015).

The stakeholders promoting neonics as safe focus more on food production efficiency and in context of food security. Particularly outspoken on the matter are the agrochemical companies Syngenta and Bayer Crop Science. Their main position is that neonics are efficient and safe, and they highlight the economic importance of products containing neonics (see e.g. press releases regarding the restrictions implemented in 2018[16]).

[13] An international grassroots organisation that supports small-scale agriculture, based on crop rotation and sustainable pest- and weed-control methods, and works directly with beekeeping communities worldwide, creating international networks of quality honey producers.
[14] https://beecoalition.eu/
[15] https://actions.sumofus.org/a/bayer-bees-lawsuit see also https://www.euractiv.com/section/agriculture-food/news/agri-giant-under-pressure-to-drop-appeal-on-neonicotinoids-ban/
[16] Syngenta press release: https://www.syngenta.com/company/media/syngenta-news/year/2018/neonicotinoid-decision-takes-european-farming-wrong-direction

Supporters of the agrochemical companies, who also supported the court case complaints against the EC bans in 2014 (case T-429/13 ant T451/13), include industrial and farmers associations such as the British National Farmers Union (NFU), Agricultural Industries Confederations (AIC), and the European Seed Association (ESA). The European Seed Association (ESA), state in a press release regarding the ban in 2018, that neonics dramatically have improved farming in Europe and boosted yields[17]. Similarly, the head of the Agricultural Industries Confederations stated in a press release that "Effective modern crop protection products are an essential part of meeting UK government's drive to raise productivity whilst enhancing the environment"[18]. The British National Farming Union (NFU) states, in a press release commenting on the scientific report by Budge et al., (2015):

> "From this study we can see clearly that neonicotinoid use results in oilseed rape yield increases, which are vital in increasing farm productivity and profitability. This benefits everyone - as the population grows, growing the raw ingredients for affordable, wholesome food is becoming more important than ever[19].

However, the simple the dichotomy between food safety and biodiversity/ecosystem services is not clear cut between the stakeholders. As example, Bayer highlights their concern about pollinators at their webpages[20] where they focus on bee health, where they also underline that neonics is not the cause of pollinator declines. On the other hand, environmental NGOs argue that agricultural productivity can increase with other measures than with pesticides such as neonics. There is little ambiguity on the importance of pollinators as important ecosystem service providers that need to be protected – here all stakeholders seem to agree. Rather, the controversy centers more on the what the problem is, to what degree neonics contributes to pollinator decline, and what kinds of regulations that are necessary. As described by Maxim and Sluijs (2010), there is an overall ambiguity over what the causes for bee-losses are: While beekeepers and some scientists claim neonics is a relevant cause, the agrochemical industry argue that bee diseases are a determining factor. As highlighted by Kleinman & Suryanarayanan (2012), university bee toxicologists, agrochemical companies, farmers, and commercial beekeepers have contrasting approaches and make different claims about the causal role of agrochemicals in Colony collapse Disorder (CCD), because they have different stakes in the regulation of the risks.

Related to this, there is ambiguity around acceptability of risk and what a "**high level of protection**" to be achieved by the EU's pesticide regulation 1107/2009 implies for the case of neonics. For instance, Greenpeace endorsed the restrictions on neonics in 2018, but also argued that regulations should be stricter as pollinators are not sufficiently protected.[21] Independent researchers have also criticised the risk assessment scheme in the EU for reacting too late (Sgolastra et al., 2020). Agrochemical companies on the other hand, find the regulations on neonics too strict and overprotective, as they still claim that neonics are safe if used as instructed. Further, as e.g. stated in Syngenta press release commenting on the ban in 2018, it takes Europe in the wrong direction as these chemicals are essential for farmers to ensure the supply of safe and affordable food.[22] This ambiguity is also evident in the different perceptions of the role of neonics in an Integrated Pest Management (IPM) approach. IPM plays a significant role in directive 2009/128/EC on the sustainable use of pesticides, where the overarching aim is to reduce the use of pesticides

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Bayer press release: https://media.bayer.com/baynews/baynews.nsf/id/Neonicotinoid-ban-a-sad-day-for-farmers-and-a-bad-deal-for-Europe

[17] https://european-seed.com/2017/12/impact-ban-neonicotinoids/

[18] https://www.agindustries.org.uk/news-and-events/aic-disappointed-by-eu-court-ruling-on-neonicotinoids/

[19] https://www.nfuonline.com/pollinator-impacts-and-farming-benefits-of-neonicotinoids-on-osr/

[2020] https://beecare.bayer.com/home

[21]https://www.greenpeace.org/eu-unit/issues/nature-food/785/commission-takes-major-step-to-ban-three-bee-harming-pesticides/

[22]https://www.syngenta.com/company/media/syngenta-news/year/2018/neonicotinoid-decision-takes-european-farming-wrong-direction

in the EU to a minimum[23]. In relation to IPM, some researchers have claimed that neonics, with their low risk for nontarget organisms and the environment and versatility in application methods, are now essential components for integrated pest management strategies (Tomizawa and Casida, 2011). It was assumed that the use of neonics would reduce the amounts of pesticides used globally. Countering this, others argue that because neonics are mostly used prophylactically - by coating all seeds with neonics as a preventative measure even if there are no signs of pests, they are incompatible with IPM (Furlan and Kreutzweiser, 2015; Tooker et al., 2017; Sgolastra et al., 2017; Veres et al., 2020). This is because the prophylactic use of neonics has increased the use of pesticides (and actually drives the worrisome trend in farmland toxicity to insects, see fig. 1 in section 3.1), contradicting previous expectations of using fewer insecticides than a decade or two ago (Douglas and Tooker, 2015). The Netherlands Bijenstichting, a bee conservation NGO argues that: "The use of neonicotinoids in seed coating is a pre-emptive strike against a possible pest before there is any evidence that a pest would have emerged if the seed had not been coated. In other words, it is a pre-emptive strike with toxic chemicals instead of a last resort, the complete opposite of IPM."[24]

Ambiguity on validity and reliability of evidence

Another source of ambiguity centres around the uncertainties in lab-studies and field studies, which have enabled different policy conclusions to be drawn by different interest groups (Godfray et al., 2015; Löfsted and Schlang, 2017). The claims that neonics are safe often refer to specific monitoring and field studies that have found a lack of clear evidence of harm (see eg. Pilling et al., 2013; Thompson et al., 2013; Heimbach et al., 2016; Peters et al., 2016). These studies are often referred to when criticising EFSAs application of the Bee Guidance document in their risk assessment, where field studies were disqualified. Countering this, it maintained that laboratory tests should get priority over field tests in EFSAs risk assessments, because reliable, reproducible, field tests for bees are fundamentally impossible given the size of the foraging area (van der Sluijs, 2018).[25] It is also argued that the lack of clear evidence of harm in field studies should not be interpreted as evidence for that toxicological lab-studies are unrealistic (Goulson et al., 2015). Therefore, the focus on lab studies in EFSAs reviews of three neonics have been endorsed by academics and NGOs, e.g. by Greenpeace who argue that it is the most comprehensive – though by no means perfect – testing regime to assess the potential risks to bees arising from the use of pesticides (Miller et al., 2019).

Another aspect regards how to judge what constitutes high quality and trustworthy research, especially reports that are not peer-reviewed and/or are funded by the industry, or NGOs. There have been numerous allegations by various stakeholders on the lack of validity and bias in different research reports and risk assessments (see example below). It is also argued that biased, statistically underpowered and socially over-sold reports or publications is a central challenge for making policy decisions regarding neonics (Boyd, 2018).

This ambiguity over evidence is also evident at a more detailed level, where specific studies are interpreted differently. An illustrative example is the scientific and public reception of the publication 'Country-specific Effects of Neonicotinoid Pesticides on Honey Bees and Wild Bees' (Woodcock et al., 2017), which is the so far largest scale field-realistic experiment of neonics effects on bees. The study was initiated and sponsored by the agrochemical companies Bayer and Syngenta and carried out by the research Centre for Ecology and

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[23] EU (2009) Directive 2009/128/EC of the European Parliament and of the Council, establishing a framework for Community action to achieve the sustainable use of pesticides, OJ EU L309, 71–86, 24.11.2009 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1536580974138&uri=CELEX:32009L0128.

[24] 3rd party intervention by Bijenstichting 6 March 2019: "RESPONSE pursuant to Article 132 of the Rules of Procedure of the Court of Justice on behalf of stichting, DE BIJENSTICHTING IN: CASE C-499/18 P on the appeal brought on 27 July 2018 against the judgment of the General Court of 17 May 2018 in Case T-429/13 (PB C 381 van 22.10.2018) (Contested Judgment), BAYER CROPSCIENCE AG versus EUROPEAN COMMISSION

[25] Answer 7 in: https://www.europarl.europa.eu/cmsdata/152432/Answers_Jeroen_van_der_Sluijs.pdf

Hydrology (CEH). The results were published in the journal Science in 2017, and received very contradicting interpretations by both stakeholders and researchers:[26].

- **Interpretations by NGOs:** Friends of the Earth, state in their press release that 'this Landmark study confirms neonicotinoid pesticides harm bees'[27]. Similarly, Greenpeace state in their press release that the study confirms that neonics harm bees: Dr David Santillo, states that "This novel study confirms that adverse effects on individual bees and bee colonies found in high-dose laboratory studies are also observed in the fields. It shows that industry claims that neonicotinoids do not harm bees at field-relevant concentrations are baseless". [28]
- **Interpretations by industry:** Syngenta concluded that the "CEH study shows direct effects of neonicotinoids on bee health are rare"[29]**.** Bayer highlight that some positive effects were found in Germany, but also argue that the conclusions that the researchers make differs from what the data actually reveals within the report[30]. It is also argued, in a pest management journal editorial titled 'Lies, dam lies', that sensationalist interpretations of the study in media simplifies the complexity of the data (Dewar, 2017)
- **Interpretations by Expert / scientists**: An overview of comments on the study provided by Science Media Centre illustrates how also experts in the field interpret this study differently. Although most of the experts agree that the study is important, some highlight that the study shows that neonics harms bees, while other highlight the complexity of the issue.[31]

This example clearly shows how even evidence from a study published in a highly rated journal, can be interpreted in completely different manners by different stakeholders. As found by Maxim and van der Sluijs (2010), scientific uncertainty is framed and used differently by different actors.

3.4 Relevance of the PP to the case

In this case, research confirming that neonics may pose unacceptable risk to bees, has been mounting, although there still are many scientific uncertainties on the degree of the risk for different non-target species. However, the main ground for concern is that pollinator decline (especially of wild bees) is irreversible. As pollinators provide the vital ecosystem service of free pollination of crops, a significant decline of pollinators could have disastrous consequences for food production. Thereby, the seriousness and irreversibility of the risk for society and environment could justify precautionary action.

It is also interesting to note that the main controversy and public debates are focused on managed honeybees, with less attention to species that may also be vulnerable.

[26] See also https://www.nature.com/news/largest-ever-study-of-controversial-pesticides-finds-harm-to-bees-1.22229
https://science.sciencemag.org/content/356/6345/1321.full
[27] https://friendsoftheearth.uk/bees/landmark-study-confirms-neonicotinoid-pesticides-harm-bees
[28] https://www.greenpeace.org/eu-unit/issues/nature-food/1108/first-pan-european-field-study-confirms-neonicotinoid-pesticides-harm-bees/
[29] https://www.syngenta.com/site-services/ceh-study
[30] https://beecare.bayer.com/media-center/beenow/detail/controversy-over-a-large-scale-field-study-shows-why-good-science-not-sensational-headlines-should-drive-research-conclusions
[31] https://www.sciencemediacentre.org/expert-reaction-to-ceh-study-of-the-effects-of-neonics-on-honeybees-and-wild-bees/

4 Risk governance and the PP – Political and juridical dynamics

In this part, we outline risk governance processes, with particular attention to political and juridical controversies over regulative processes and the role of the PP.

4.1 Early precautionary regulations of neonics in Europe

As mentioned in the timeline in section 1.2, neonics have been available on the European market since 1991. Due to beekeeper reports and subsequent scientific risk assessments finding that neonics seemed to be a central factor in causing bee-deaths, the PP was applied to regulate neonics in several countries in Europe. The first national legal restrictions were implemented in France in 1999, where a two-year ban on the use of Gaucho (containing imidacloprid) in sunflower seed dressing was implemented (Maxim and Sluijs, 2007). In 2008, reacting to incidents of bee-deaths that were linked to the sowing of seeds coated with neonics, National authorities in Germany took precautionary steps and regulate the use of seed corn which has been treated with the active ingredients clothianidin, imidacloprid and thiamethoxam (Notification 2009/50/D)[32](Maxim and Slujs, 2013). The same year, Italian national authorities applied the precautionary principle to temporarily suspend the use of maize seeds, oilseed rape and sunflower treated with clothianidin, thiamethoxam, imidacloprid (Sgolastra et al., 2017). In Slovenia, clothianidin, thiametoxam and imidacloprid in oilseed rape and corn seed treatment have been banned, reapproved and then banned again between 2008 and 2011 (Maxim and van der Sluijs, 2013).

4.2 Legislation in the EU on plant protection products

Precautionary regulations in the EU are closely linked to changes in pesticide authorization directives. Before 2011, the Council Directive 91/414/EEC provided a procedure authorisation of plant protection products in the Member States, but the directive was not very successful in establishing a coherent framework (Bozzini, 2017, p 19). In 2009, the framework for approving plant protection products changed with the implementation of **Regulation (EC) No 1107/2009** concerning the placing of plant protection products on the market.[33] This regulation entered into force on 14 June 2011. We will here outline aspects of regulation 1107/2009 that specifically impacted on the approval and regulation of neonics.

First, it should be underlined that the regulation is underpinned by the Precautionary Principle:

> "The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment." (Regulation 1107/09 Article 1)

Further, the regulation introduced new requirements for the approval active substance. Particularly relevant for the neonic case are the requirements relating to the absence of unacceptable effects on honeybees as stated in annex II:

> "An active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test

[32]https://ec.europa.eu/growth/tools-databases/tris/en/index.cfm/search/?trisaction=search.detail&year=2009&num=50&mLang=EN
[33] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

> guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:
>
> — will result in a negligible exposure of honeybees, or
>
> — has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour."
>
> (Regulation 1107/09 Annex II, 3.8.3)

By requiring that active substances should not have 'unacceptable acute or chronic effects on colony survival and development', the protection of honeybees against pesticides was substantially strengthened compared to directive 91/414.

Articles 7 – 13 of Regulation 1107/09 specifies the risk assessment procedure for approving a pesticide. These requirements are also to be applied in reviews of already existing approvals. Recital 10 of this regulation states that, for active substances already approved prior to entry into force of the regulation, criteria harmonised by Regulation 1107/2009 are to be applied at the time of renewal or review of their approval. Further, and particularly relevant in this case, article 21 states **that an approval of active substances should be reviewed in light of new scientific knowledge:**

> "The Commission may review the approval of an active substance at any time. It shall take into account the request of a Member State to review, in the light of new scientific and technical knowledge and monitoring data, the approval of an active substance, including where, after the review of the authorisations pursuant to Article 44(1), there are indications that the achievement of the objectives established in accordance with Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of [Directive 2000/60] is compromised."
>
> (Regulation 1107/2009, article 21).

Thereby, the regulation allows for a reassessment of approved pesticides before the approval period is ended, if new risks are found and estimated to be serious. In the following sections, we will outline how these paragraphs of regulation 1107/2009 and the precautionary principle was applied, and contested, in imposing bans on neonics in the EU in 2013 and 2018.

4.3 The EC process of reassessing neonics 2012 - 2018

In 2012, a reassessment process of neonics allowed on the market in the EU was set in motion. This was triggered by that member states raised concerns about neonics risks for bees, indicated both in the monitoring studies in France, Italy, and Germany, and in the amounting number of independent studies. Particularly three studies published in peer review journals gained attention, by finding that field-realistic levels of the neonicotinoids imidacloprid (Whitehorn et al., 2012), thiamethoxam (Henry et al., 2012) and clothianidin (Schneider et al., 2012) had a significant effect on bee-colony stability and survival of honeybees and bumblebees. As these studies found 'new knowledge' indicating that the substances no longer satisfied the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009, the EC decided to follow a central aspect of precautionary action as laid down in Article 21 of this regulation, and started a re-evaluation process. EFSA was therefore requested to provide conclusions as regards the risk to bees for the uses of thiamethoxam, clothianidin, and imidacloprid, with particular attention to acute and chronic effects on colony development and the effects of sub-lethal doses on bee survival and behaviour (EFSA, 2013a).

Risk assessment process

Parallel to the requests to assess these neonics, EFSA was in an ongoing process of reviewing the 'EPPO Guidance'[34] for the assessment of risks posed by plant protection products to bees. In 2011, members of the Parliament and beekeeper associations had raised concerns on the validity and relevance of this guidance, and asked EFSA to review this with particular attention to the assessment of chronic risks to bees, exposure to low doses, exposure through guttation and the cumulative risk assessment (EFSA, 2012a). The problem with the EPPO guidance was that it ignored relevant risks assessments of neonics in the first place, as it was designed only for spray applications and not seed treated and soil-drenching chemicals, and as it assumed exposure to be restricted to the pesticide application period and to the treated crop (Sgolastra et al., 2020). In addition, the scheme was criticised for not including the views of bee experts (and instead including many representatives from agrochemical companies into the working (ICPBR) group that assessed the impact of pesticides on bees)[35]. When EFSA provided a Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (EFSA, 2012a), it was confirmed that the EPPO risk assessment guidelines had several weaknesses when applied both in field tests and lab tests. For field test, problems included "*the small size of the colonies, the very small distance between the hives and the treated field, the very low surface of the test field, leading to uncertainties concerning the real exposures of the honey bees".* (EFSA, 2012a:133). It was found that the EPPO guideline was better suited for the assessment of spray products than of seed- and soil-treatments. For lab-tests, problems included that several exposure routes of pesticides are not evaluated in laboratory conditions: the intermittent and prolonged continuous exposures of adult bees, exposure through inhalation and the exposure of larvae. Likewise, the effects of sub-lethal doses of pesticides were not evaluated in the conventional testing (EFSA, 2012a:132). In short, it became evident that the EPPO scheme for risk assessments did not account for the complexity and uncertainty of exposure and effects. Due to these limitations, the EFSA drafted a new guidance document (the so-called 'Bee Guidance document') for assessing the risks of neonics for bees (EFSA, 2013e). A preliminary version of this guidance was published for public consultation on 20 September 2012, and the amended document was published on 4 July 2013. As mentioned in section 3.3.3. on ambiguity, and as also will be discussed in the court case section, this (Bee Guidance) risk assessment scheme is one of the major grounds for controversy between stakeholders.

On the 16th of January 2013, EFSAs Panel on Plant Protection Products and their Residues (PPR Panel) presented their conclusive risk assessment reports examining the risks for bees of clothianidin (EFSA 2013b), thiamethoxam (EFSA 2013c) imidacloprid (EFSA 2013d) to the EC. In general, the conclusions estimate a high risk for some uses of neonics on cereals, maize and oilseed rape for honey bees (see detained table on e.g., clothaniadin in EFSA 2013b:38-44). A high acute risk for honeybees from exposure via dust drift as a result of the sowing was estimated (e.g. for sowing of maize and cereal seeds coated with clothianidin, imidacloprid, thiamethoxam). Additionally, a high acute risk for bees from exposure to residues in nectar and pollen for the uses in oilseed rape (clothianidin, imidacloprid) as well as cotton and sunflowers (imidacloprid), and a high acute risk from exposure to guttation for uses in maize (thiamethoxam) was estimated. However, EFSAs conclusions also underlined that uncertainty remains on many risk aspects due to shortcomings of data to a lack of a finalised risk assessment guidance document[36]. It is also highlighted that there is a knowledge gap on the risks for pollinators apart from bees. EFSAs conclusions gained some debate, and agrochemical companies disputed the conclusions and referred to studies they had funded. EC requested EFSA to review one of these field studies - Thompson et al. (2013) - that found few effects of neonics on

[34] The EPPO Guidance was drawn up by the European and Mediterranean Plant Protection Organisation (EPPO), and was first issued in 1992 and updated in 2002 and 2010.

[35] COE and BeeLife (2010) *Is the Future of Bees in the Hands of the Pesticides Lobby*?, 2010: https://docs.wixstatic.com/ugd/8e8ea4_40071cca1f974a988a6e484c5590ac07.pdf

[36] https://www.efsa.europa.eu/en/press/news/130116

bumblebees in a UK field study. However, EFSA evaluation of the filed study concluded that it contained weaknesses in design and methodology, and thus would not change any of the conclusions made in the EFSAs risk assessment (EFSA 2013d).

Risk management 2013 – EC implements restrictions
As the risk assessment were provided, the risk management process was initiated. After reviewing EFSAs risk assessments reports, the EC proposed to adopt a ban on these three substances (regulation 485/2013) and asked the Member States to vote over the regulation. The main reasons for proposing to apply the PP seemed to be the seriousness of the risk. In a speech by the Commissioner responsible at the Council's 'Agriculture and Fisheries' meeting on 28 January 2013, the urgency of the matter is highlighted after reviewing EFSAs conclusions:

> "In its conclusions, EFSA has identified a number of concerns and [has] Confirmed serious risks linked with the use of the three neonicotinoids used on several important crops grown across the [European Union]. These concerns call for swift and decisive action! The time is now ripe to act to ensure an equally high level of protection of bees across the [European Union]. The Commission will propose a set of ambitious but proportionate legislative measures to be presented for first discussion at the meeting of the [Standing Committee] that will take place on Thursday of this week. There is one particular point I want to be clear: Our proposal will call for EU harmonised and legally binding measures, inspired by the precautionary principle, but also by the principle of proportionality! In fact, a number of safe uses of these substances as regards bees have been identified by EFSA. A total ban would not therefore be justified.'"
> (Cited in Judgment in cases T-429/13 and T-451/13, para 427)[37]

It should be noted that this quote not only suggests applying the PP in relation to the seriousness of the risk, but also in reference to proportionality. In line with this, the proposed regulation suggested to ban most uses of imidacloprid, clothianidin and thiamethoxam, but to still allow some as the probability of effects on bees seemed lower. This was the case for indoor use (in greenhouses) and for winter crops. Consequently, it could be argued that some measure of proportionality, in terms of 'tailoring measures to the chosen level of protection', was taken.

On the 15 March 2013, the Member States voted over proposed regulation 485/2013, but the voting resulted in a stalemate (13 voted in favor of ban while 9 opposed the ban (McGrath, 2014:3)). Hence, another round of voting was requested. The interim period between the first and second voting was marked by an intense period of political lobbying in different member states, where it seems that industry stakeholders and/or NGOs/associations (lobbyism) may have affected outcomes in the risk management phase (McGrath 2014, Patterson and McLean, 2019, Boyd, 2018). In the UK, it seemed the industry lobby influenced government opinion in the first phase (Boyd 2018), although government's approach changed towards a more precautionary stance (Patterson and McLean, 2019).

On 29th of April 2013, the second round of voting was held, and 15 countries voted for the ban, eight against, and four countries abstained (EC press release 2013A). Following the absence of an agreement (qualified majority) between Member States, the Commission announced that it would proceed with the process, basing its decision on the evidence presented in the EFSA reviews (ibid). On the 24th of May, the Commission implemented **Regulation (EU) No 485/2013[38], banning all outdoor use of 3 of the 6 neonicotinoids** that are marketed in Europe in crops attractive to bees (EC press release

[37]For full reference and link to the judgement, see the reference section.
[38]Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances https://eur-lex.europa.eu/eli/reg_impl/2013/485/oj

2013B). For acetamiprid, EFSA established a low risk to bees, and restrictions of this substance were therefore considered inappropriate[39]. Also, Member States could apply for exceptions, and several Member States have repeatedly granted emergency authorisations for some of the restricted uses (including Romania, Bulgaria, Lithuania, Hungary, Finland, Latvia and Estonia)[40].

After imposing restrictions, EC also commissioned EFSA to assess foliar spray and all uses other than seed treatments of the 3 neonicotinoids Conclusions were submitted in 2015 (EFSA 2015a; 2015b; 2015c).

The implementation of regulation 485/2013 was followed by highly polarized debates. The restrictions were endorsed by many NGOs and institutions, including the European Environmental Agency[41], and contested by the agrochemical industry, who following a series of field studies argued that these products were safe under field conditions (Campbell, 2013). Some of these controversies will be further elaborated in the section on the court cases below.

2018 Reassessments

For the reassessment, the EC requested EFSA to apply the bee guidance risk assessment scheme (EFSA 2013e). Further, as foreseen in recital 16 of Implementing Regulation (EU) No 485/2013, the Commission initiated a review of new scientific information in 2015 by mandating EFSA to organise an open call for data (EFSA 2015d). This open call represented a significant procedural change in the evaluations, as it provided all interested parties, like NGOs, beekeeper organizations and agrochemical companies, with an opportunity to contribute. In earlier evaluations, this process was entirely based on data provided by agrochemical companies (Auteri et al., 2017: 970). As result, 376 contribution from 48 different sources were submitted and reviewed. Thereby, stakeholders had several possibilities to influence the decision-making process especially in the risk assessment stage, due to the arrangements of open calls. Stakeholders were also involved in funding, encouraging or producing risk assessments that had to be considered, such as e.g. Thompson's (2013) field study. The degree of influence the involved parties had in the final decision-making process is hard to estimate, but other studies have indicated that stakeholder interactions / lobbyism did play a role in national policy formulations on neonics the UK (Boyd, 2018; McGrath, 2014) and in France (Maxim and Sluijs, 2013).

In February 2018, EFSAs updated risk assessments of clothianidin, imidacloprid and thiamethoxam (EFSA, 2018a, 2018b and 2018c) were presented to the EC and the Member States, who were to consider potential amendments to the 2013 restrictions[42]. These assessments found that "for all the outdoor uses of these substances, there was at least one aspect of the assessment indicating a high risk, leading to the conclusion that overall, these neonicotinoids represent a risk to bees" (EFSA, 2018e). It is highlighted that the risks vary due to factors such as bee species, the intended use of the pesticide and the route of exposure, but that taken as a whole, the conclusions confirm that neonicotinoids pose a risk to bees.

After examining EFSAs conclusions, the Commission maintained the proposals to completely ban the outdoor uses of the three active substances. This was supported by a qualified majority of Member States[43] in the Regulatory Committee on 27 April 2018[44]. On

[39] https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en
[40] https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en
[41] https://www.eea.europa.eu/highlights/neonicotinoid-pesticides-are-a-huge
[42] http://www.efsa.europa.eu/en/press/news/180228
[43] In the voting 16 countries (Germany, France, UK, Spain, Italy, The Netherlands, Sweden, Greece, Cyprus, Austria, Portugal, Ireland, etc), voted in favour, while Romania, Denmark, Czech Republic, Hungary) opposed the ban, and 13 countries abstained (including Poland, Belgium, Finland)
[44] https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en

the 29th of May 2018, the Commission implemented **Regulations (EU) 2018/783, 2018/784 and 2018/785)**[45] limiting the marketing authorizations for PPP containing imidacloprid, clothianidin and thiamethoxam[46] with exception for the following uses: insecticide on crop staying within a permanent greenhouse during its entire life cycle or seed treatment to be used only in permanent greenhouses. Several EU member states notified emergency exemptions, as farmers complained that the ban would lead to a severe loss of production of e.g. sugar beet.[47]

4.4 Court cases – Agrochemical companies against the EC

Following the implementation of the restrictions in 2013, three of the major Agrochemical companies filed court cases against the European Commission seeking to annul Regulation 485/2013 (Case T-429/13 by Bayer Crop Science, Case T-451/13 by Syngenta Crop Protection AG, and Case T-584/13 by BASF Agro BV[48]). On May 27, 2018, the court dismissed the actions brought by Bayer and Syngenta in relation to the neonicotinoids clothianidin, thiamethoxam and imidacloprid. Two months later, Bayer CropScience made an appeal (Case C-499/18) against the judgment of the General Court in Case T-429/13.

The main complaints of Bayer CropScience and Syngenta are grounded in their understanding that neonics, when used properly, does not affect bees. However, many of the complains also argue that the Precautionary Principle had been misused and misinterpreted. As summarised by the judgment of the court cases, the companies complained that the criteria for the PP was not met because "purely hypothetical risks were taken into account, that there was no adequate scientific assessment or cost/benefit analysis, and that the measures taken were disproportionate" (Judgment in cases T-429/13 and T-451/13, para 335). John Atkin, Syngenta's chief operating officer, stated in a press release, that "In suspending the product, [the European Commission] breached EU pesticide legislation and incorrectly applied the precautionary principle,".[49] In the following sections, the complaints and the courts responses on the arguments relating to the PP will be examined.

First, many of the complaints relate to EFSAs **risk assessment** process and alleged that "EFSA's Conclusions are not based on as thorough a scientific assessment as possible or on the best available data, and that EFSA took **a purely hypothetical approach** to the risk" (Judgment in cases T-429/13 and T-451/13, para 342). According to the complaints, the risk assessments that inspired the ban were invalid and not sufficiently scientifically verified. Bayer CropScience states, in the last of their six pleas:

> "Sixth plea in law, alleging that that the adoption of the Contested Measure breaches the precautionary principle, because:
> — inter alia, it involved the Commission, as risk manager, taking a purely hypothetical approach to risk, which was founded on mere conjecture and which was not scientifically verified (a result, in large part of the risk assessments not constituting a thorough scientific assessment), and it involved the Commission refusing to conduct any analysis of the potential benefits and costs of its actions."

[45] Official Journal of the European Union L132, (30 May 2018) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2018:132:FULL&from=DA
[46] As specified in Article 1, the following restrictions were implemented for the three neonics:
- prohibition of any non-professional use, indoors or outdoors;
– prohibition of uses for seed treatment or soil treatment on the following cereals when these are to be sown from January to June: barley, millet, oats, rice, rye, sorghum, triticale, wheat;
– prohibition of foliar treatments for the following cereals: barley, millet, oats, rice, rye, sorghum, triticale, wheat;
– prohibition of uses as seed treatment, soil treatment or foliar application for around 100 crops, including rapeseed, soya, sunflowers and maize, with the exception of uses in greenhouses and of foliar treatment after flowering.
[47] https://www.reuters.com/article/us-eu-sugar-neonics/insecticide-ban-to-hit-eu-sugar-beet-crops-farmers-say-idUSKBN1I41FI
[48] For links to the court documents, see 'court case documents' under references in chapter 8, p 48.
[49] https://www.sciencemag.org/news/2013/08/pesticidemakers-challenge-eu-neonicotinoid-ban-court

(Case T-429/13, plea 6)

The complains about the EFSAs risk assessments are detailed and relate to the uncertainties as outlined in section 2. Some concerns are raised about estimated rates of exposure in experiments, and about how the effects of different exposure rates are measured. As example, one complaint is that the high risk on exposure via guttation for maize was based on unrealistic assumptions (Judgment in cases T-429/13 and T-451/13, para 408). In the judgment of the case, the complaint about different details on risk assessment process were considered. In conclusion, the complaint alleging a purely hypothetical approach to risk was entirety rejected and EFSAs risk assessments were considered comprehensive and realistic (ibid, para 415).

In relation to this, it is interesting to note that in some of the complaints on the risk assessment procedures, it seems to be indicated that the risk assessment was too comprehensive. Particularly, the use of the Bee-Guidance document instead of the EPPO Guidance is criticised. As stated by Bayer complaint in 2018, if the EPPO Guidance had been applied:

> "(i) monitoring studies would have been considered "decisive", rather than "of limited use"; (ii) "data gaps" would only have been concluded where there were previous data requirements; (iii) only risks in relation to honeybees would have been considered; (iv) only risks of relevance at the colony level would have been considered; and (v) risk mitigation measures would have been taken into account where they gave rise to differences in the normal use of a product"
> (Case C-499/18, para 126).

Point (i) and (v) suggest that the assessment should have been added on different kinds of research, specifically monitoring studies and risk mitigation. Regarding the monitoring studies, the Court finds that EFSA did consult them but did not included in the assessment because they could not provide valid conclusions on correlations between cause and effects (Judgment in cases T-429/13 and T-451/13, para 208, 209 and 380). The point on including risk mitigation studies overlaps with the point on the proportionality argument (see section below). Point number (ii), (iii) and (iv) indicates that the if EPPO guidance had been used, there would have been less consideration of the complexities of bee behaviour and of other species than honeybees. In other words, the risk assessment had been much more limited if the EPPO guidelines would have been applied.

A second set of arguments relate more to the **risk management** process and the relation between the Precautionary Principle and the **principle of proportionality.** The principle of Proportionality implies that measures adopted should not exceed the limits of what is appropriate and necessary. The agrochemical companies alleged that the PP had been misused or misinterpreted by not taking proportionality into account. As example, Syngenta states, in the second of their three pleas:

> Second plea in law, alleging that the Contested Regulation imposed disproportionate and discriminatory restrictions on TMX, based on purely hypothetical risk, without conducting a thorough scientific assessment or any impact assessment at all, in violation of the precautionary principle and the principle of proportionality.
> (Case T-451/13, plea 2)

Here, it is indicated that proportionality was neglected because a formal impact assessment (in the form of a cost-benefit analysis) was lacking. It is referred to that carrying out an impact assessment is mentioned in the 'Communication on the Precautionary Principle' (EC 2000). Indeed, the Commission did not mandate a formal impact assessment or cost-benefit analysis to evaluate the economic consequences of Regulation No 485/2013 before its adoption (Bozzini and Stokes, 2018). However, in the judgment, the Court underlines that Communication on the PP (EC 2000) point 6.3.4 states that cost-benefit analysis can be included where appropriate and feasible, and that the scope and format of such an analysis is not defined (Judgment in cases T-429/13 and T-451/13, para 458). Further, while the Communication specifies that an economic cost-benefit analysis could be carried out where appropriate and feasible, it also underlines that an assessment "cannot be reduced to an economic cost-benefit analysis. It is wider in scope and includes non-economic considerations" (ibid, para 458). In the case of neonics, it was found that a cost-benefit analysis was not appropriate, nor feasible, because long term economic and ecological effect are very difficult to measure. Therefore, it was concluded that it was sufficient that the Commission was informed about different impacts of a restriction, and that the requirements of the Communication on the PP thereby were satisfied. Specifically, it is stated that it was sufficient that the commission had "acquainted itself with the effects, positive and negative, economic and otherwise, to which the proposed action, as well as the failure to act, may lead, and has taken that into account in its decision." (Judgement in cases T-429/13 and T-451/13, para 406). It is further underlined that it was not necessary to estimate these effects precisely, because "such precise calculations will in most cases be impossible to make, given that, in the context of the application of the precautionary principle, their results depend on different variables which are, by definition unknown" (ibid, para 460). Interestingly, a paper evaluating this process highlights that the process may have been different if the updated 'Better Regulation package' had been applied, as it interprets the PP different from the earlier Communication (Bozzini and Stokes, 2018). The Better Regulation package mentions that all acts based on the precautionary principle should be based on a formal impact assessment, instead of a general balancing of issues. What such a formal impact assessment of neonics should look like is however not specified, and it would probably contain many uncertainties connected to the measurement and prediction of different developments. Further, as outlined in section 2 and 5.1 in this paper, there is already much uncertainty and ambiguity around the research on economic aspects of neonics (and their restrictions).

Another aspect of proportionality is related to the complexity of neonics and their use, as some applications contain lower risk than others. Bayer Crop Sciences claimed in their fifth plea, that the regulation breaches the principle of proportionality as the "contested Measure goes beyond what is appropriate to the achievement of its legitimate objectives and may even undermine them, and the Commission failed to consider less restrictive options for regulation that were available to it" (Case 429/13, plea 5). The objections concern e.g. the use of foliar sprays and the prohibition of non-professional uses outdoors and indoors, uses that were considered to give less exposure to bees.

In replying to this, the Commission denies that the contested measure was adopted in a rushed manner and that risk mitigation measures were not considered (Judgment in cases T-429/13 and T-451/13, para 418). Further, it is pointed out that the uses of neonics that the Commission restricted, correspond largely with those that EFSA had either identified an acute risk, or had been unable to rule out a risk because the necessary data were unavailable (ibid, para 422). As stated in the last part of that paragraph, the uses of neonics that were deemed inconclusive because there was a lack of data, were also restricted. In the judgment, EC's Communication on the PP (EC 2000) is referred to, where it is mentioned that

> "when the available data are inadequate or non-conclusive, a prudent and cautious approach to environmental protection, health or safety could be to opt for the worst-case hypothesis. When such hypotheses are accumulated, this will lead to an exaggeration of the real risk but gives a certain assurance that it will not be underestimated."
> (Judgment in cases T-429/13 and T-451/13, para 114).

Thereby, it is underlined that the PP allows for a cautious approach when knowledge is uncertain. This points to that there are different understandings of the role of **scientific uncertainty** in the application of the precautionary principle. The applicants (Bayer and Syngenta) often refer to the fact that EFSA's 2013 conclusions identified several uncertainties where further research was needed, and problematised that the risks were 'inconclusive'. Thereby, they insinuate that there should have been a higher degree of scientific certainty on the actual risks before the PP could be applied. This focus on scientific uncertainty reappear in Bayer's appeal in 2018, where it eg. is argued that an "appropriate level of scientific certainty" was not set (Case 499/18). Again, it was argued that EFSAs assessments were rushed and insufficient, that the standards of proof to adopt precautionary measures were misinterpreted, and that the PP therefore was wrongly applied.

In the judgment of the case in 2018, a different interpretation of the role of scientific uncertainty is found. As example, it is stated that the PP specifically implies that scientific uncertainty allows for protective measures to be taken:

> "Where there is scientific uncertainty as to the existence or extent of risks to human health or to the environment, the precautionary principle allows the institutions to take protective measures without having to wait until the reality and seriousness of those risks become fully apparent or until the adverse health effects materialise"
> (Judgment in cases T-429/13 and T-451/13, para 110)

This underscores that the PP should be applied when there is scientific uncertainty if the risks towards humans or nature are estimated to be highly serious. Further, it is emphasised that a fully complete and conclusive scientific risk assessment may be impossible due a lack of scientific data, but that preventive measures may be taken if the risk assessment is adequately backed up by the scientific data available at the time when the measure was taken (ibid, para 117-120). The context of application of the PP is one of uncertainty, and the Court notes that "if all the consequences of inaction and of action were known, it would not be necessary to resort to the precautionary principle; it would be possible to decide on the basis of certainties" (ibid, para 460). In such cases of certainties, the **prevention principle** applies rather than the precautionary principle[50]. A good illustration can be found in Patterson and McLean's (2019) analysis of the UK government's decision on neonics, where the approach changed from a 'sound science approach', to a 'precautionary approach' allowing regulations when scientific uncertainty prevails. Again, this underlines that scientific uncertainty is at the core of the PP.

In sum, the court case documents highlight the different understandings of the role of scientific uncertainty and different kinds of assessments when considering the PP. Besides this, it seems that Bayer puts more emphasis on the innovation argument in the appeal in 2018. In the introduction of the appeal, it is argued that "the Court of Justice's task is to guard against the precautionary principle becoming a universal incantation to block innovation" (Case C-499/18). It is further pointed out that since the ban created uncertainty in the legal framework regarding the possibilities for maintaining approvals for the period of validity, the industry is reluctant to introduce new active substances, and this contradicts the Commission emphasis on the importance of innovation in this sector. In the following sections we will discuss some takes on the balancing of the PP and innovation based on a broad review of relevant literature in addition to stakeholders' public announcements.

5 The precautionary principle and its future

5.1 Reflection on the PP in the literature

In the case of restricting neonics, we have identified two major reflections/discussions regarding the application of the PP.

The first theme is related to different aspects of proportionality; adapting different restrictions more proportionate to the different uses of neonics, and that the process of applying the PP should include an impact analysis. Here, it should be noted that most of

[50] In risk management based on the Prevention Principle, risks are managed by agreeing on an acceptable risk level for the activity and putting enough measures in place to keep the risk below that level. This approach is meant for risks that are well known and quantifiable in a credible way. The Precautionary Principle however has been introduced to cope with risks with poorly known outcomes and poorly known probabilities, making the prevention principle approach problematic (Van der Sluijs and Turkenburg, 2006)

the articles that criticise the restrictions on neonics implemented in the EU are not directly discussing the PP. Rather, they are more directly criticising aspect of EFSAs risk assessment process, and/or highlighting production or economic consequences of the restrictions of neonics. Many of these articles, that often refer to each other, can be found in the journal 'Pest Science Management[51]' and the news journal 'Outlook on Pest Management', (including Walters, 2013; Kathage et al., 2018; Campbell, 2013; Dewar, 2017; Dewar, 2019; Hurley and Mitchell, 2017; Blake, 2018) while others come in the form of reports by institutes (including e.g. Nicholls, 2013, Noleppa & Hahn, 2013; Noleppa, 2017). It is argued that unforeseen consequences of the ban were that other pesticides were applied with possibly other unintended side effects, that some pests were returning and that some crops were damaged causing economic losses. Some similar critiques are also found in the field of risk research, a proportionality-related critique can be found in problematising the issue of "risk-risk trade-off": that decreasing one particular risk in one area leads to another risk appearing elsewhere which was not originally considered (Löfstedt and Schlang, 2017). Alemanno (2013) argues that the application of the PP for regulating neonics can lead to a tunnel vision, ignoring possible trade-offs between risks, and that a detailed risk-risk analysis should have been conducted before the decision on the restrictions were made. Dewar (2019) argues that for many uses (e.g. for the protection of oilseed rape against flea beetles), there are no good alternatives to the use of neonics, and that the restrictions of neonics, a large proportion of farmers started using other pesticides like pyrethroids. This argument, that the ban of neonics would have damaging effects on the environment as older and less targeted pesticides would be used instead, was also noted in the judgment of the court case of Bayer and Syngeta (Judgment in cases T-429/13 and T-451/13, para 509). Replying to this, the Commission referred to that that the Member States that suspended certain uses of neonics for several years (Germany, France, Italy and Slovenia) never reported any such adverse effects on the environment (ibid, para 514).

A different set of arguments related to the PP in this case, is that the PP measures came too late and have been too weak. This critique is not only posed by e.g. NGOs, but also by the European Parliament. In a report on the Union's authorisation procedure for pesticides, the EP strongly criticises the current practice of pesticide authorisation for failing to sufficiently apply the precautionary principle (European Parliament 2018). Different researchers also argue that the PP should have been applied earlier and that risks connected to neonics should have been detected earlier, before they entered the market in the 1990s (Boivin and Poulsen, 2017, Sgolastra et al., 2020, Shafer et al., 2019). Related to this, it is suggested that the regulation of pesticides should be modelled on the regulation of pharmaceuticals, implying that instead of letting pesticides pass a once-off test, they should undergo a long-term monitoring of adverse effects throughout the lifetime of a product (Milner and Boyd (2017).

5.2 Effect of the PP on innovation pathways

In the context of food security, where industrial agriculture to a high degree depend on pesticides while pests increasingly become pesticide resistant, there is a constant need for innovative solutions. Main innovations in this context would be new and more effective products, and with this perspective, regulations are hindering innovations. Specifically, the pesticide regulation regime in the EU has been criticised for being too strict and cumbersome, especially with the change from a risk to a hazard-based approach when implementing Regulation 1107/2009 (Chapman, 2014; Bozzini, 2017). It is argued, that with the escalating costs of putting new products on the market due to increasing data requirements and test guidelines*,* innovation of PPPs has moved from Europe to other

[51] This journal is peer-reviewed, and it is part of the SCI (Society of Chemical Industry), which is 'international forum where science meets business on independent, impartial ground'

markets. The restrictions on neonics implemented by the EC regulations in 2013 and 2018 were met similar kinds of arguments by agrochemical companies. As highlighted by a spokesperson for Bayer, it is important for the firm's investment decisions to have guidance and clarity regarding the European Union's regulatory framework.[52] Bayer also noted in the court case appeal that the ban on neonics would have "severe consequences for innovation in the crop protection sector in Europe." (Bayer appeal C-499/18, para 2)[53]. It is argued that because neonics were banned before their approval application was up for review (enabled by article 21 of regulation 1107/2009 allowed the commission to revaluate the approval of neonics approval before the approval period had ended), producers of plant protection products became reluctant to invest in applying for approval for new products. It seems plausible that regulatory stability is valuable for innovation processes in large agrochemical companies. However, in the following sections, we will take a broader view on innovation and illustrate some different innovation pathways for pest management that have appeared/are foreseen under the condition of the restrictions of neonics in the EU.

Firstly, history has shown that innovations of new pesticides do appear under restrictions, because new crop protection practices (including new pesticides) are often created as a consequence of other practices being banned. The most evident case is how the banning of DDT (partly banned in Europe in 1978 and totally banned for agricultural use in Europe in 1983[54]) resulted in innovations of other pesticides (Bouwman et al., 2013). In this case, as DDT was not patented, banning this toxic substance was actually good news for companies who could introduce new patented pesticides[55](Davis, 2019).

Secondly, Milner and Boyd (2017) mention that, if not done too abruptly, the withdrawal of pesticides can incentivise innovations, not only of new types of pesticides but also of cultivation methods. This opens up for a broader perspective on innovation, not only seeing innovation as developing new types of plant protection products. Different innovations may take place within strategies for 'Integrated Pest Management' (IPM) which is promoted in the EU through the 2009 sustainable use directive[56], aiming to reduce the use of pesticides through several innovative multi-faceted methods.

Regarding the application of neonics, some **mitigative innovations** have taken place for reducing the emissions of neonics. Particularly, there has been improvements of technical means of treatment recipe, improvements to the quality of seed treatment formulations, and modifications to planting equipment using deflector techniques that reduce emission of dust during sowing of seeds coated with neonics (Foster, 2011; Bonmantin et al., 2015). Spraying technology has also innovated such that spray-drift to outside the fields is reduced and more of the spray lands on the targeted crop and less on the soil (see e.g. Liu et al., 2005). There are also innovative ways of applying neonics to seeds by pelleted seeds (the common way of applying imidacloprid to sugar beets, where the poison not on the outside of a pellet around the seed. In pelleted beet seed, the insecticide is not on the surface but underneath the outermost layer of the beet seed pellet, with a high resistance to abrasion and thus a lower risk for dust emission[57]. However, the dust emissions are not the only concern: only a small fraction (between 1.6 and 20%) of the neonics in the seed coating is absorbed by the plant, meaning that 80 to 98.4% of the pesticide ends up as pollution in soil and water (Van der Sluijs et al., 2013). Therefore, and also due to the complexity of the usage of neonics (on different crops, using different methods), and the uncertainty around levels of residues (especially in soil and water), it is difficult to estimate how effective these mitigation efforts are. Furthermore, seed coating implies a prophylactic

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52 https://www.sciencemag.org/news/2013/08/pesticidemakers-challenge-eu-neonicotinoid-ban-court
53 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62018CN0499
54 https://ec.europa.eu/commission/presscorner/detail/en/MEMO_03_219
55 E.g parathion, malathion andnchlorprifos
56 EU (2009) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, OJ EU L309, 71–86, 24.11.2009
57 See document by CIBE on The case for neonicotinoids in pelleted sugar beet seeds: https://www.cibe-europe.eu/img/user/058-18%20CIBE%20The%20case%20for%20neonicotinoids%20in%20pelleted%20sugar%20beet%20seeds%20April%202018.pdf

use, which does not fit well with the IPM approach of reducing the need of pesticides to a minimum and using them only as a last resort, as implemented in directive 2009/128/EC on the sustainable use of pesticides[58](see explanation of IPM in section 3.3.3). Thereby, it could be argued that the use of seed coated systemic insecticides closes possibilities for other kinds of innovations.

Another innovation pathway is to look towards the development of **new plant protection technologies** that could be promising for having the benefits of plant protection with less collateral damage to the environment and human health include nano-pesticides (Kah et al., 2018) and RNA interference (RNAi) (Rodrigues and Figueira, 2016; Price and Gatehouse, 2008; Yu et al., 2013). The aims of nano-pesticide formulations are generally (a) to increase the apparent solubility of poorly soluble active ingredients or (b) to release the active ingredient in a slow/targeted manner and/or protect the active ingredient against premature degradation, which all could contribute to reduction of the amount of active ingredient needed to effectively protect plants. RNA interference is a gene silencing mechanism triggered by providing double-stranded RNA (dsRNA), that when ingested into insects can lead to death or affect the viability of the target pest. The advantage is that is highly specific to the target pest and has in theory almost no impact on non-target organisms. It can target insect specific genes. When target sequences are chosen that are unique to the pest insect, it can only kill the target pest insect, so in theory high selectivity is possible. It can also be used in transgenic plants, or it can be applied to non-GMO crops (Price and Gatehouse, 2008; Rodrigues and Figueira, 2015).

However, there are also **innovations of non-chemical alternatives to neonics** for pest management. The argument that there are no alternatives to neonics has been contested, and several non-chemical methods are found in different studies (Jactel et al., 2019; Furlan and Kreutzweiser, 2015; Lundin et al., 2020; Veres et al., 2020). Furlan and Kreutzweiser (2015) outline examples from management of three insect pests in maize crops and an invasive insect pest in forests, including diversifying crop rotations, altering the timing of planting, tillage and irrigation, using less sensitive crops in infested areas, applying biological control agents, and turning to alternative reduced risk insecticides. Jactel et al's (2019) review found eight categories of potential alternative methods to neonics (including synthetic or natural chemical insecticides, biological control with microorganisms or macroorgamisms, biological control through farming practices (e.g. intercropping) etc.), and that in 78% of cases, at least one non-chemical alternative method could replace neonicotinoids. When acknowledging such alternatives, it can be argued that the prophylactic use of neonics may hinder innovation and experimentation with alternative pest management and non-chemical alternatives (Furlan et al., 2017; Veres el al., 2020). The complexity of crops that need protection and the complexity of pests indicates that much more research is needed, and innovations of e.g. prognosis tools for pests may also be relevant in this regard (Lundin et al., 2020).

Lastly, the IPM framework also includes the possibility of **social innovations**. Furlan et al. (2017) describes a large-scale example of this, where mutual funds and IPM increased profits for maize crop farmers in Italy, reducing the use of pesticides without negative impact on average yields and at the same time avoiding environmental impacts. Importantly, the farmers started an economic insurance initiative that insured them from large economic losses in bad years, without having to use insecticides.

5.3 Innovation Principle

In this case, we have only found one direct mention of the 'Innovation Principle' directly in relation to neonics. In an article in the Agrochemical magazine 'Outlooks on Pest Management, Robin Blake (a Senior Consultant for Compliance Services International

[58]EU (2009) Directive 2009/128/EC of the European Parliament and of the Council, establishing a framework for Community action to achieve the sustainable use of pesticides, OJ EU L309, 71–86, 24.11.2009 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1536580974138&uri=CELEX:32009L0128.

(CSI), chair of the Agrisciences committee for the Society of Chemical Industry and Associate Editor for the journal Pest Management Science), argues that the application of the PP in the case of neonics is *at odds with the desire to innovate and the* "Innovation principle" – whenever policy or regulatory decisions are under consideration the impact on innovation as a driver for jobs and growth should be assessed and addressed. He further goes on to argue that the PP and IP should be complementary, recognizing the need to protect society and the environment while also protecting the EU's ability to innovate (Blake, 2018). In this paper, it is however not clear exactly how the PP and IP should be balanced, but there seem to be a focus on economic impact assessments. This raises a fundamental problem, namely that economic impact assessment belongs to the domain of the prevention principle where costs and risks can be quantified. The Precautionary Principle is introduced for uncertain risks, where one cannot weigh fundamentally unknown costs to fundamentally unknown benefits (Van der Sluijs and Turkenburg, 2006).

Nonetheless, it is likely that the IP could be brought into the controversy on neonics, as many of the agrochemical companies producing insecticides containing neonics, including Bayer, BASF and Dow AgroSciences, were engaged in the European Risk Forum and signed the letter to the Presidents of the three EU institutions proposing adoption of the Innovation Principle in 2013[59]

6 Synthesis

In synthesising this case, we will focus on the role of complexity, ambiguity and uncertainty in the risk governance that led to the bans implemented in the EU and discuss how this case illustrates the tension between innovation and precaution.

Throughout this case, it is evident that complexity and scientific uncertainty is at the heart of the controversies around the application of PP to regulate neonics. As outlined in section 3, there is a complexity of types of products containing neonics, applied to different kinds of crops with different methods, and there is much uncertainty and a lack of knowledge on residue levels. Thereby, it is also difficult to estimate a realistic level of exposure for different types of insects. The main uncertainty thereby stems from multi-causality - the complexity of interacting causes that together produce the ongoing global trend of pollinator decline. There are uncertainties regarding the sub-lethal effects on different kinds of species, and a complexity of factors (including a cocktail of pesticides) that impact different species. The scientific assessment of the relative importance of neonics in pollinator decline is highly contested. A main debate has been how to estimate and measure causes and effects, and what kinds of studies (field vs lab studies) that are valid and/or reliable. This has led to controversies around how to interpret different studies, and around different details of EFSAs risk assessments.

In 2013 and in 2018, precautionary measures were taken and uses of three neonics (imidacloprid, clothianidin and thiamethoxam) were restricted. A main background for these restrictions, was the implementation of EC Regulation 1107/2009 concerning the placing of plant protection products on the market. The regulation is underpinned by the PP, and as this regulation went into force in 2011, it enabled a reassessment of the approval of an active substance if new knowledge indicated severe risks to health or the environment. Notably, the protection of bees is particularly mentioned in this regulation. Thereby, as risk assessments increasingly found that neonics could contribute to large

[59] http://www.riskforum.eu/uploads/2/5/7/1/25710097/innovation_principle_one_pager_5_march_2015.pdf

scale bee-deaths and colony collapses, the EC requested the European Food Safety Authority (EFSA) to conduct a formal risk assessment. In 2013, after receiving EFSAs conclusions, the Commission implemented Regulation (EU) No 485/2013 - banning outdoor use of 3 of the 6 neonics that were allowed on the market (imidacloprid, clothianidin and thiamethoxam). These restrictions were reinforced in 2018 when the Commission implemented Regulations 2018/783, 2018/784 and 2018/785)[60].

The restrictions on neonics were contested by the agrochemical companies Bayer, Syngenta and BASF, who filed a court case against the regulation in 2013. A main critique the of the application of the PP was that the risk assessments contained scientific uncertainty. At the same time, it was also argued that an economic impact assessment was neglected. However, as argued in the court's decision, an economic impact assessment would also entail many scientific uncertainties, as many factors could impact on economic developments. Adding an economic impact assessment to the process could thereby increase complexity and uncertainty. Also, the economic impact of a significant decline of pollinators would be very challenging to assess.

Further, when considering the PP in the risk management process, scientific assessments of risks only play one part. In addition to estimations of risk, risk managers have to consider possible wider consequences for both economy and society, and consider the societal acceptability of the risks and possible consequences. In this case, the irreversibility of a possible pollinator decline and its potentially wide-ranging consequences for food production was a major ground for taking precautionary measures.

Regarding the second main theme, the balancing of the PP and the IP, it should first be underlined that IP is rarely referred to in this case, except for the reference to IP made by a researcher related to the industry (Blake, 2018). There is however a tension between precaution and innovation more generally. In our industrialised food production system, there is a constant need for innovative plant protection products, as pests continue develop resistance to established pesticides. If precautionary measures can be applied at any times, the concern is that the companies will be reluctant to invest in new innovations.

In this case, the balancing of PP and IP seem to depend a lot on the framing of innovation. If innovation is defined narrowly, in this case as innovating new plant production products, then balancing the PP with innovation concerns creating more predictability in the EU legal framework (in this case, especially considering article 21 of regulation 1107/2009), formalizing an impact analysis, and making more time for creating more certainty in risk assessments. Perhaps the issue on impact assessment could be considered when balancing the PP and IP. However, it raises the question 'what kind of impact and for whom'?. One could argue that a proper impact assessment should be broader than only economic impacts for the industry, to include impact on society more widely. That would also imply including many complexities, uncertainties, and the acknowledgement that there are fundamental limitations in assessing future impacts and that economic and statistical models contain many potential flaws and biases (Saltelli et al., 2020). A further problem is that if one aims too much towards a 'sound science approach' that suppresses uncertainty, the PP is compromised to such a large degree that one risk losing the PP and being left with the Prevention Principle. One should not forget that the Precautionary Principle was introduced for the very reason that the Prevention

[60] Official Journal of the European Union L132, (30 May 2018) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2018:132:FULL&from=DA

Principle failed repeatedly in cases characterized by high uncertainty, ambiguity and complexity.

If one opts for a broader definition of innovation, one could see more realistic possibilities for balancing the PP and the IP, more in line with the Integrated Pest Management approach and with Responsible Research and Innovation (RRI)? This could include mitigative innovations such as those that have taken place for reducing the emissions of neonics, innovations of non-chemical alternatives to neonics, innovations of e.g. technical tools such as pest prognosis tools, and social innovations such as the mutual funds (Furlan et al., 2017).

Other lessons that can be drawn from the neonics case study are:

- Key promises of the neonic innovation included: carefully targeted, high specificity. Both proved to be wrong. Neonics became the most widespread insecticide-pollutant in surface water and it seems to be the class of insecticides that has produced the most severe collateral damage on non-target invertebrates ever.

- Regulatory science and risk assessment frameworks lag systematically behind new scientific insights with huge time delays, as evident in that the Bee Guidance document, drafted in 2013, still not is fully approved and employed in regulatory assessments of new pesticides.

- There are major epistemic controversies on weight of evidence. What knowledge is relevant and whose knowledge counts (e.g. field tests vs labtests; GLP versus Academic Peer Review)? The neonic case raise questions about the current social organisation of expertise. The problem is that it leads to a practice where certain knowledge is systematically privileged (e.g. industry studies with GLP certificate) while other highly relevant knowledge is systematically excluded (e.g. peer-reviewed academic studies) from the decision making process. In this case this has led to ignoring a wide range of early warning signals and delayed action, which hampered the timely application of the PP.

7 Conclusion

This case study illustrates how the PP has been applied, and contested, in processes around regulating a specific group of insecticides. In 1999, France was the first member state that used the PP to ban a neonic (imidacloprid) in sunflower seed-dressing. Since then, many member states have taken precautionary measures and restricted various neonics. At the European level, the PP was first invoked in 2013 when the European Comission Implemented Regulation (EU) No 485/2013, where outdoor use of 3 of the 6 neonicotinoids that are marketed in Europe in crops attractive to bees were banned.[61] Referring to Article 4 of Regulation (EC) No 1107/2009, it was considered that the approved uses of clothianidin, thiamethoxam and imidacloprid no longer satisfied the approval criteria

[61]Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances https://eur-lex.europa.eu/eli/reg_impl/2013/485/oj

provided for in with respect to their impact on bees and that the high risk for bees could not be excluded except by imposing further restrictions (Regulation 485/2013 (7).

The reason for applying the PP in this case, was the risks that neonics pose to pollinators in particular. Since the introduction of neonics on the market in the 1990s, an increasing number of studies indicated risks of irreversible damage to biodiversity, especially for insects providing significant ecosystem services like pollination. It should be noted that there are also emerging concerns that continued use of neonics can cause a collapse of the entomofauna (all insects) and species that feed on insects (e.g. birds), and even affect human health. The main concern in public debates, and the main reason for applying the PP however, was the contribution of neonics to pollinator decline, which poses risks to food production and ecosystem functioning and stability. The PP is relevant here due to several scientific uncertainties. Pollinator decline has a multitude of causes and drivers and scientific assessments of the relative importance of neonics in the complexly interlinked set of causal factors is contested and plagued by uncertainty. Moreover, although neonics have been praised for being innovative, precise, and cost-effective, ambiguity has also emerged in research on the actual benefits of these insecticides.

The application of the PP was contested for several reasons. A large degree of controversy surrounds the EFSAs risk assessment process. Agrochemical companies complained that the risk assessment was inconclusive, and that the principle of proportionality was neglected due to a lack of formal economic impact assessment. But the latter belongs more to the domain of the prevention principle, not the precautionary principle, because when risks and benefits are highly uncertain, ambiguous and complex, one cannot balance fundamentally unknown costs against fundamentally unknown benefits.

Other controversies relate more to the balancing of innovation and precaution, and often centre around the legal framework (specifically article 21 of regulation 1107/2009) that enables pesticides already approved on the European market to be reassessed if new evidence on risks are found. This was one of the main arguments in the court case filed by agrochemical companies Bayer Crop Science, Syngenta and BASF (supported by industry/seed associations and different European farmers unions). It was argued that this would send negative signals to the industry, which could be more reluctant to invest if they would worry that re-evaluation procedures could occur at any time dismissing their approvals. However, with a different and broader framing of innovation, there have been several suggestions on how innovations could minimise the use of neonics. This includes mitigative innovations have taken place for reducing the emissions of neonics, innovations of non-chemical alternatives to neonics such as e.g. diversifying crop rotations, altering the timing of planting, using less sensitive crops in infested areas, applying biological control agents, and social innovations.

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