

Precautionary approach or cautionary tale?

An evaluation of the European Regulatory Framework for Crop Protection Products and Agricultural Biotechnology Traits



Report

June 2021 Project No.: 0559610



Signature Page

June 2021

Precautionary approach or cautionary tale?

An evaluation of the European Regulatory Framework for Crop Protection Products and Agricultural Biotechnology Traits

Report

n

Euros Jones Partner, Belgium Carolyn Thomas Partner, UK

ERM

Cantersteen 47

1000 Brussels

Belgium

© Copyright 2021 by ERM Worldwide Group Ltd and/or its affiliates ("ERM"). All rights reserved. No part of this work may be reproduced or transmitted in any form, or by any means, without the prior written permission of ERM.

CONTENTS

EXEC	UTIVE	SUMMARY 1	
1.	INTRO 1.1 1.2 1.3	DUCTION 5 Methodology 5 Literature review 5 Linguistic differences – crop names 5	5
2.	2.1 2.2 2.3 2.4	EXT AND BACKGROUND 6 Background to European Crop Protection Legislation 6 The impact of the Green political movement in Europe 8 Green deal and Farm-to-Fork 9 Political Drivers in Europe – and the impact on the regulatory processes 10	3
3.	THE EU	IROPEAN DEBATE ON BIOTECHNOLOGY LEGISLATION12	2
4.	4.1 4.2 4.3 4.4	STUDIES IN CROP PROTECTION 15 Crop protection politics and policies in France 15 Development of EU criteria for endocrine disruption 18 EU re-evaluation of Glyphosate 20 Restriction on neonicotinoid seed treatments 23	53
5.	IMPAC 5.1 5.2 5.3 5.4	TS26Yield development in European Agriculture26Evolution in use of crop protection products29Impact on third country trade – MRL setting30Impact on environment and biodiversity315.4.1Scope of assessment5.4.2GHG emissions31315.4.3Land Use5.4.4Data5.4.5Results: GHG Emission36365.4.6Results: Land Use5.4.7Results – Summary	5901114655
6.	CONCI	USIONS AND COMMENTARY	
•••			
7.	KEFEH	ENCES	J

APPENDIX A ACTIVE SUBSTANCES NON-APPROVED IN EU; 2010-2020

List of Tables

Table 1: Regional focus of active substances introduced and in development	.8
Table 2: Yield development comparisons - 2000 - 2018; 5 year averages (mt/ha)2	27
Table 3: Environmental impacts assessed with justification	31
Table 4: Life cycle stages assessed and method for calculation	31
Table 5: Data sources for data used in modelling	35
Table 6: Comparisons of 5 year averages for GHG emissions, yield and total nitrogen (N) input for	
rapeseed in Canada and France	37
Table 7: Comparisons of 5-year averages for GHG emissions, yield and total nitrogen (N) input for	
maize in Canada and France	39
Table 8: Comparisons of 5 year averages for GHG emissions, yield and total nitrogen (N) input for	
wheat in Canada and France4	41

Table 9: Average annual change in SOC and GHG emissions/removals from cropland in Canada and
France
Table 10: Average annual change in SOC with no-till under different durations of experimental period
in Eastern and Western Canada (adapted from (B.C. Liang, et. al., 2020))43

List of Figures

12
13
15
16
20
24
25
26
) ,
28
29
37
38
for
39
for
40
ו
42
45
46

EXECUTIVE SUMMARY

Introduction

- The purpose of the report is to review the political and regulatory drivers in Europe and understand how and why the legislative framework has evolved as well as understanding how EU policies are having an impact outside its own borders. The report also provides food for thought on the role of stakeholders in influencing the regulatory frameworks that impact food safety and agricultural productivity policies.
- A number of high profile food safety issues in the European Union, including BSE (mad cow disease) in the mid-1990s, have caused a long-term effect at the EU level. The increased public awareness put the spotlight on food safety in the European Union resulting in the introduction of new legislation and the formation of the European Food Safety Authority (EFSA) as a lead advisory body. While the formation of EFSA was meant to ensure the provision of independent expert advice, its role and its perceived lack of independence has been questioned by many NGOs.
- Despite the stricter legislation and the growing role of EFSA in the EU process, this has not reduced the NGO and political focus on food issues. In the last two decades, changes to the EU's food safety legislation have become increasingly conservative and precautionary. This can be linked to a growing antagonism to new technology in the agricultural sector, in particular for chemical crop protection and agricultural biotechnology. While the EU looks to drive further harmonisation within its own borders, there is limited engagement from the EU in ensuring harmonisation at the global level. This trend is expected to have a continued negative impact on global harmonisation.
- The EU is looking to further change its own policy direction and, as part of the launch of their 'Green Deal', the European Commission published their Farm to Fork and Biodiversity strategies in May 2020. The launch was accompanied by a report on the implementation of the EU's pesticide regulatory framework, and includes a commitment to reduce the overall use and risk of chemical pesticides by 50% by 2030. While the Green Deal also looks to promote an agenda to make the EU the world's first climate neutral continent by 2050, the continued reduction in the number of tools available to farmers will make it increasingly difficult for agriculture to contribute to their climate neutral commitment.

Commentary and key considerations

- The impact of implementing EU standards While the EU's gradual implementation of common food safety policies has resulted in significant benefits in reducing the administrative burden of trade, the legislation has become more conservative particularly in respect to the use of chemicals and new technologies where we see increased questioning and restricting. The EU's unpredictable approach increases uncertainty for trading partners and this has been demonstrated especially in the case of the approval of biotechnology traits and is being increasingly seen in the rules that apply to pesticides and the setting of restrictive Maximum Residue Levels (MRLs).
- While the EU promotes an argument that European production standards are based on the strictest globally, the actual carbon footprint from crop production in Canada compares very favourably with European production, with lower greenhouse gas emissions per ton of production on average.
- The need for a range of solutions The data in this report on production and on the environmental footprint of agriculture also highlight that there is no 'one size fits all', and a range of available technologies and techniques are vital to support efficient production systems. The loss of solution at the European level does have an impact on yields and cropping patterns; but this will also limit the European farmers' ability to deal with new challenges and this has to be a concern.
- The use of no-till is one agricultural practice that can have significant benefits in terms of higher yields, greater soil protection and reduced greenhouse gas emissions. However, those benefits do not appear to apply in all agronomic conditions and maintaining a wide range cropping techniques and crop protection solutions will help the farmer to optimise their cropping systems based on the

agronomic conditions they face. It is therefore vital that the voice of the farmer is heard in order to highlight the need for a range of solutions on order to maximise sustainability in agriculture production.

- The voice of the European farmer While European farmers clearly have an interest in ensuring productivity and profitability for their own businesses as well as maintaining a range of crop protection tools, their political advocacy work fails to look at gaining better access to technologies themselves, but rather fixates on imposing EU production restrictions on third country imports.
- The reasons for the position taken by European farmers and their leaders is partly influenced by the fact that they have only little or no influence in the authorisation process and they see a situation where Europe is restricting substances that will remain on the market in third countries. With Europe being a significant importer of agricultural commodities, European farmers are looking to ensure that third country producers face the same conditions in their production.
- A policy of promoting the 'lowest common denominator' in terms of agricultural technology use should be a major concern for Canadian farmers, who would be badly served in taking such a position given the role of technology to support productivity and continued commodity exports.

Political Drivers in Europe and their impact on the regulatory landscape

The influence of stakeholders and civil society organisations has grown at the European level and they have played a role in shaping EU regulations that have become more restrictive for crop protection products and for biotechnology. The paper looks at a number of case studies that have significantly impacted the tools available to European farmers while also impacting trade with third countries.

- Biotechnology legislation The EU's antagonistic approach to new technology in the agricultural sector is perhaps most notable in the implementation of its biotechnology legislation. With no discussions on the approval of traits in the EU, the decision-making framework purely focuses on import approvals. This process is however slow, with delays at both the evaluation stage and during the final political level decision-making process. With the delays, the EU approvals process is significantly influencing farmers' planting decisions in major exporting countries, therefore preventing farmers from choosing the most recent seed varieties if the EU is a major customer. While the EU's regulatory review process should only take twelve months, the reality is that the approval of biotechnology events take an average of six years compared to an average 2-year approval process in Canada, Brazil and the United States.
- Crop protection politics and policies in France Since 2008, France have put in place national plans to increase controls and reduce use of pesticides at the national level. The first 'EcoPhyto' plan was established in 2008, with the principle objective being to reduce the use of plant protection products by 50% in 10 years. A further reduction plan was published in 2020 with a specific phase out target for glyphosate. The French media have been particularly active in questioning the independence of experts involved in the evaluation process at both the French and European level; this approach has damaged the reputation of the regulatory authorities and resulted in a more restrictive regulatory process and the loss of many crop protection products.

At farmer level, the impact of the loss of crop protection tools is keenly felt in France and elsewhere in the EU. While the French farming lobby is still a formidable force, their influence in defending the need for agricultural inputs is however limited. The debate is coloured by the discussion on the Common Agricultural Policy (CAP), with the CAP payments often interpreted as a 'compensation' for the loss of crop protection tools and application of environmental conditions. As a result, the lobbying focus of farm leaders is not on gaining access to these technologies, but rather fixated on imposing these production restrictions on third country imports.

Development of EU criteria for endocrine disruption – Regulation (EC) 1107/2009 introduced a
number of controversial approaches, including the introduction of hazard based cut-off criteria in
the assessment of active substances. This has led to the loss of a significant number of substances
and is likely to impact more substances currently registered in Europe. One of the criteria that would

lead to a ban is endocrine disruption, where detailed criteria were agreed and implemented in 2018. While the issue of endocrine disruption has been on the agenda for over 20 years, the main driver for legislative change in Europe was political. The implementation of the criteria has resulted in significant uncertainty, with limited understanding in the interpretation of the results compounded by a lack of laboratories with adequate experience to provide consistency in testing.

- EU re-evaluation of Glyphosate The re-approval process for Glyphosate is an example of the challenges in the EU's regulatory process with significant political and stakeholder interventions leading to major difficulties in completing the process. With perceived differences between the opinion of EFSA and the IARC who ran a parallel evaluation on the carcinogenicity classification of glyphosate in 2015, NGOs and politicians questioned and undermined EFSA's work which lead to a highly politicised decision-making process. The final decision was a restricted 5-year approval running until December 2022. With a number of Member States having made national commitments to phase out the use of glyphosate, the next decision-making process in 2022 is again expected to be challenging and highly politicised.
- Restriction on neonicotinoid seed treatments An EU decision to restrict the use of plant protection products and treated seeds containing three of the neonicotinoids took place in 2013 and extended in 2018. While these restrictions have been agreed and implemented at the EU level, many Member States have used a derogation to allow 'emergency authorisations', where suitable crop protection alternatives are no longer available. This has also happened in France who was one of the driving forces in the initial EU level restrictions; the French Authorities have now provided a derogation in 2020 to allow neonicotinoid sugar beet seed treatment uses for up to 3 years.

Such derogations are not limited to neonicotinoids, with many short-term authorisations granted for a range of active substances no longer approved in the European Union. For third countries, the use of the short-term derogations in the EU would appear to be unfair and lead to a situation of unfair competition – especially with the EU attempting to impose restrictions on imports from countries that continue to fully approve such uses.

Legislative impact on availability of crop protection products in the EU

- A significant reduction in the number of available crop protection active substances was seen after the implementation of previous legislation (91/414), the introduction of a new hazard based assessment for active substances under Regulation (EC) 1107/2009 has continued the decline.
- In the last 10 years, approximately 80 active substances have been removed from the European market. The application of the hazard based criteria, and in particular the criteria for endocrine disruptors, could lead to the loss of many more substances in the next 5 years. There is little or no evidence to suggest an increased level of safety for consumers and the environment following evaluation based on hazard criteria. There is also limited direct evidence to suggest a significant impact on EU agricultural productivity, but the stagnation in EU crop yields in recent years can at least partly be attributed to the loss of crop protection tools. Recent non-approval decisions for a number of fungicides are potentially significant, with yield losses predicted due to expected problems in resistance management.

Impact on third country trade – MRL setting

• While there is a recognition that the EU needs to comply with WTO principles, recent pronouncements highlight that the EU will look to influence third countries to adopt the EU's regulatory framework as a *de facto* global standard. For example, in cases where an active substance is banned in the EU, MRLs and import tolerances will be re-evaluated and the limits may be reduced, ultimately making use of that substance in exporting countries challenging, if not impossible, if the importer is primarily the EU. Such MRL restrictions could have a significant impact on €70 billion worth of commodities exported annually into the EU, including the production of soybeans with an export value to the EU of €10 billion annually (Bryant Christie Inc., 2017).

While the decisions on the setting of MRLs & ITs are administrative measures, the EU's regulatory
framework requires a formal Parliamentary consultation. Since 2018, Parliament have rejected a
number of proposals to set import tolerances that would allow third country trade. This political
decision-making has the potential to significantly increase trade barriers for exporters to the EU.

Farm level changes

• Yield development - The EU saw significant yield increases from the 70's until the 90's, due largely to the new crop protection technologies and the influence of the Common Agricultural Policy which maintained high market prices in Europe. Since the beginning of the new century, the crop yields in France have stagnated and this has largely been attributed to the gradual loss of crop protection solutions. Over the same period, Canadian yields have increased significantly, a trend that can mainly be attributed to the adoption of new technology and techniques, including the use of no-till practices in rapeseed and wheat. The expectation is that the yields will continue to grow in Canada while remaining stable in France and the EU. With potential restrictions on the use of more active substances in the EU, yield levels may however fall in Europe in the coming years.

Table: Cor	able: Comparison of yields in Canada and France: Maize, rapeseed and wheat							
	C	anada		t/ha	France			
2000-2004	2014-2018	Increase (% Total			2000-2004	2014-2018	Increase (% total)	Increase (% pa)
7.20	10.03	39.4%	2.4%	Maize	8.55	9.13	6.8%	0.5%
1.42	2.21	56.3%	3.2%	Rapeseed	3.09	3.43	10.9%	0.7%
2.22	3.22	44.9%	2.7%	Wheat	7.00	6.91	-1.3%	-0.1%
	200	00-2004			2014-2018			
Canada	Fi	rance	Canada as % of France		Canada	1	France	Canada as % of France
7.20	8	3.55	84%	Maize	10.03		9.13	110%
1.42	3	3.09	46%	Rapeseed	2.21		3.43	64%
2.22	7	7.00	32%	Wheat	3.22		6.91	47%

• **Greenhouse gas emissions** – When considering greenhouse gas emission (GHG) levels from agricultural production (without considering soil organic carbon due to sequestration) emissions from the production of maize, wheat and rapeseed have fallen since the year 2000. Canada and France saw similar decreases in both maize and wheat production while a much smaller decrease was seen in Canada for rapeseed. The main driver for GHG emissions (per tonne of crop yield) is the application of nitrogen fertilisers. Comparing France and Canada for the period 2010 - 2014, average GHG emissions in Canada were lower for each of the crops evaluated: maize (-22%) rapeseed (-8%) & wheat (-7%).

Taking into account the impact of sequestration on soil organic carbon levels in the growing of the three crops, levels of greenhouse gas emissions are lower in most cases but differ between the different crops. Including sequestration for the period 2010-2014, GHG emissions in Canada remain lower than the levels seen in France: maize (-6%) rapeseed (-31%) & wheat (-31%).

Table: Comparison of greenhouse gas emissions from production of maize, rapeseed & wheat: Canada & France							
Canada kgCO2-eq/kg France							
2000-2004	2010 - 2014	% change		2000-2004	2010 - 2014	% change	
0.29	0.24 <i>(0.29)</i>	-18%	Maize	0.35	0.30 <i>(0.30)</i>	-14%	
0.75	0.74 <i>(0.56)</i>	-1%	Rapeseed	1.05	0.81 <i>(0.80)</i>	-23%	
0.46	0.43 (0.31)	-7%	Wheat	0.51	0.46 <i>(0.46)</i>	-10%	
Note: Numbers (in b	<i>rackets)</i> for 2010-2014 in	nclude impact on soil or	ganic carbon (SOC) du	e to sequestration.			
GHG compariso	ns for 2014-2018: Ca	anada and France					
	No SOC sequestration	on		Inc. SOC sequestration			
Canada	France	Canada as % of France		Canada	France	Canada as % of France	
0.24	0.30	78%	Maize	0.28	0.30	94%	
0.74	0.81	92%	Rapeseed	0.56	0.80	69%	
0.43	0.46	93%	Wheat	0.31	0.46	69%	

1. INTRODUCTION

The European Union (EU) has a significant influence on the global trade and policy frameworks that apply to food and feed products. In the current century, EU thinking in this area have become increasingly suspicious of science and scientists, and policies on the use of chemical and genetically modified technology are being increasingly driven by personal convictions instead of science.

The purpose of the report is to review the drivers in Europe and understand how and why the legislative framework has evolved as well as understanding how EU policies are having an impact outside its own borders. The report aims to provide food for thought on the role of stakeholders in the policy debate on food safety and agricultural productivity.

1.1 Methodology

The report has been developed by a team of ERM experts with many years of experience in dealing with agriculture and food policy issues in Europe, with particular expertise in dealing with crop protection legislation. The details of the report have been put together through desk-based research in order to provide a detailed overview of policy discussions, related regulatory decision-making processes and the resulting implications on market developments for agricultural inputs and production.

We would like to express our appreciation to Philipps McDougall, who have provided significant data on the crop protection market. This data is referenced throughout the document.

1.2 Literature review

As part of the desk research process, ERM have identified a number of literature resources that have been reviewed in the generation of this report. Wherever possible, the sources used are listed in the references section (section 7 of this report).

1.3 Linguistic differences – crop names

The use of the European terms 'rapeseed' (*CanEn*: canola) and 'maize' (*CanEn*: corn) have been used throughout this report.

2. CONTEXT AND BACKGROUND

2.1 Background to European Crop Protection Legislation

A number of negative reactions around the food industry and the safety of the food we consume in the European Union punctuated the late 20th and early 21st centuries. The worst of these scares were related to BSE (mad cow disease) in the UK in the mid-1990s and dioxins in animal feed in Belgium in 1999. In parallel, concerns related to GM crops that were driven by NGOs and the media and all of these developments increased public concerns about food safety in the European Union (Lezaun & Groenleer, 2006).

As a reaction to the growing public concerns, the European Commission produced a white paper on food safety in January 2000 which argued that risk assessment and risk management be separated, with the risk assessment work being carried out by an independent European Food Safety Authority (European Commission, 2000). In parallel, a second white paper on the precautionary principle was developed by the European Commission and published in February 2000. While the principles of precaution set out in this white paper are clear and pragmatic, the experience over the last 20 years is that the principle has largely become a political tool to justify populist measures with limited acceptance of the science.

The White Paper on food law resulted in the development of General Food Law legislation - Regulation (EC) 178/2002 – which aimed to place science at the heart of policy on food. The legislation also set up the European Food Safety Authority (EFSA).

EFSA was, and remains, a strictly independent organisation with two of its primary objectives being scientific excellence and innovation. In a globalised world, EFSA plays a role in the discussion of risk assessment internationally and in ensuring that new developments across the globe are considered in the EU. There are however growing concerns that the EU continues to drive and put in place new measures with little or no effort to improve harmonisation at the global level.

Looking specifically at crop protection products, the EU's authorisation process is covered by three main pieces of legislation:

- Regulation (EC) 1107/2009, which governs their authorisations and marketing;
- Directive 2009/128/EC, which concerns their sustainable use; and
- Regulation 396/2005/EC, which establishes maximum residue levels of their residues in food and feed.

Regulation (EC) 1107/2009 (Official Journal of the European Union, 2009) concerning the placing of plant protection products (PPPs) on the market entered into force in June 2011, replacing the previous Directive 91/414. The Regulation aimed to streamline authorisations, using a system of zonal authorisations, and harmonised requirements across the EU whilst ensuring the protection of Human health and the environment and protecting the competitiveness of EU agriculture. Regulation (EC) 1107/2009 introduced a number of controversial approaches, not least of which was the move from a risk based to a hazard based assessment with the introduction of hazard based cut-off criteria in the assessment of active substances. Additional criteria were also put in place for the substitution of certain products based on a comparative assessment of available products on the market.

The full impact of the hazard based cut-off criteria is currently not known as many active substances are still under (re)evaluation. However, from 2010 to June 2020, approximately 80 active substances have been removed from the European market – either following a re-evaluation or based on a commercial decision not to further invest in the defence of the substance, given the significant cost and uncertainty of complying with the evolving EU regulatory system. (A full list of the non-approved active substances is provided in Annex A, together with information on those substances currently authorised and used in Canada).

Another impact of the EU renewals process is that it has resulted in greater NGO and media attention on the active substances that are being evaluated at that time. That has been seen in particular in the

re-evaluation of glyphosate and this issue is further discussed later in this report. This appears to be largely a European phenomenon and it not seen to the same extend during the re-evaluation programmes seen in other countries such as Canada.

With specific criteria for endocrine disrupting properties having been agreed and implemented in 2018, over 200 substances are currently being evaluated against these criteria. While the process of evaluating against the criteria of endocrine disruption will take a number of years, it is expected that the final decision could lead to the non-approval of many more substances in the next 5 years.

While many of the substances are being lost to the European farmers through the impact of the cut-off criteria alone, it should be noted that these substances have been previously evaluated and approved at the European level following a risk-based assessment. There is therefore no real expectation, and no evidence to suggest, an increased level of safety for consumers and the environment following a new evaluation based on hazard criteria.

There is equally limited evidence to suggest that the loss of active substances has significantly influenced European agricultural productivity, with farmers adapting to the new situation with the use of alternative plant protection products and in some cases making changes in the crop rotation patterns. It can however be concluded that the stagnation in EU crop yields in recent years can at least partly be attributed to the loss of crop protection tools. The impact may also have been negated by the use of emergency authorisations that have been granted to allow the continued application of some solutions where no alternatives are available (for further information, see <u>Section 4</u>, Figure 3 and Figure 4). The recent decisions for the non-approval of a number of important fungicides have been identified as being potentially significant. The non-approval of Chlorothalonil and Mancozeb have in particularly been highlighted as significant, leading to yield losses given their important roles in resistance management. It has been suggested that the loss of Chlorothalonil in the UK would have a significant impact on yields and could increase production costs by 8 - 12% (NFU, 2019).

EU harmonisation of crop protection legislation

Within the European Union, greater harmonisation of the regulatory process has been achieved through the application of common European data requirements and technical guidance. However, the level of uncertainty around the outcome of the regulatory process in the EU has increased dramatically. The increasing complexity and conservatism of new guidance documents remains problematic, as does the increasing uncertainty given the length of time required to complete the regulatory review process.

At product authorisation level, harmonisation is proving to be very challenging. A zonal authorisation system is in place under Regulation 1107/2009, with the EU being divided into three climatic zones (North, Central, South). While many Member States (MS) agree that further harmonisation is required, many continue to insist on applying their own specific national requirements. This approach leads to difficulties in work sharing and full harmonisation, leading to significant delays in the approval process, increased registration costs for the applicant and the ultimate loss of products or restrictions in the label of use.

While the EU legislation looks to drive further harmonisation internally, the many changes in the decision-making criteria are leading to a situation where the level of global harmonisation is reducing significantly. In the latter part of the 20th Century, the EU was a significant contributor to the harmonisation discussions within the OECD; this situation has however changed with the EU focused on developing their own standards with little or no willingness to develop common standards at the global level.

Introduction of new chemistry

While a stated aim of the EU legislation is to encourage further innovation in the crop protection sector, it can be argued that this has not been achieved in particular when considering chemical crop protection. The investment required to discover, develop and register a new active substance is extremely high and is estimated to take 8 - 10 years with an investment of \$280m per compound. The increasing complexity of the regulatory regime and the longer timelines for market entry increase the time to

achieve a breakeven return on investment. Coupled with the evolving criteria and the uncertainty in the increasingly conservative evaluation process, R&D companies are deterred from introducing products based on new active substances into the European market. They are instead developing new products for initial market introduction in other parts of the world.

The impact on innovation can be seen in the table below, which highlights the evolution of development and introduction of new active substances globally. While Europe was seen as the main market for the development of 1 in 3 new active substances in the 1980s, the situation has evolved with only 1 in 6 substances being developed with Europe as the key market (see table below). While this development can partially be attributed to the increasing importance of growing markets such as Latin America, the key driver for this change appears to be the significant uncertainty linked to the EU legislation.

Region	1980–1989	1990–1999	2005–2014
Worldwide	123	128	73
Europe	41	40	12
Share Europe (%)	33.3	31.3	16.4

Source: (Phillips McDougall, 2013)

The reduction in the number of new solutions has been in particular seen since 2011 and the introduction of Regulation 1107/2009. In the 9-year period until 2020, there have been applications for the approval of 22 new chemical active substances – at a rate of approximately 2.5 new substances per year. This is significantly lower than the rate seen between 1980-2005 where, on average, over 10 new submissions were submitted annually.

2.2 The impact of the Green political movement in Europe

The green agenda is a powerful global phenomenon. The evolution of the green lobby at the European level has seen a significant focus on agricultural and food issues.

The green focus on food started in the mid-1990s and is illustrated by the stance taken by the EU on the approval of GM technology. The green party, which was in coalition with the ruling government in Germany from 1998-2005, had a significant influence of shifting the debate on GM crops, in particular through their agricultural Minister Renate Kunast (e.g. EU legislation which took effect in April 2004 where food and animal feed products which contain more than 0.9% of GM materials must be labelled).

The legislation on General Food Law in 2000 was aimed at increasing confidence in the EU's management of food safety issues; it can be considered that this has largely been achieved from a consumer confidence perspective. However, stricter legislation and the growing role of EFSA has not reduced the NGO and political focus on food issues. Indeed, it can be argued that the political focus on plant biotechnology and plant protection products (in particular glyphosate) has been driven by the NGOs – with an expectation that the regulators take action to meet the requirements of activist stakeholders and politicians. This has in particularly been seen in the discussions on the application of the precautionary principle and concerns raised regarding the independence of scientists within the regulatory process.

Precautionary principle

The precautionary principle has been set out to deal with situations of uncertainty, with the burden of proof being with the notifiers or the risk evaluators to prove that there are no negative ecological and environmental consequences (Bourguignon, Didier, 2015). Whilst there are arguments for and against

the principle the 'green agenda' adopted by the Commission and the Parliament can result in a level of conservatism that is significantly higher than in other regulated industries - and leading to the loss of substances that can be used safely when following safe use practices.

One such example is the EFSA guideline on bee risk assessment. The level of conservatism within this guideline would lead to the initial failure for virtually all active substances and the need to conduct complex and costly higher tier testing. This is clearly impractical, particularly when considering the scale of testing that would be required.

Scientific independence

In the implementation of the EU regulatory system, questions have been raised about the independence of the experts involved in the process. The independence of EFSA has in particular been questioned by many NGOs, and this has led to a situation where many recognised experts who have worked with industry have subsequently been excluded from participating in EFSA's work on specific projects. One such example was in the development of the bee guidance document, where NGOs have raised concerns about the independence of the scientists involved in the process of developing the previous guidance in place. As a reaction, EFSA excluded a large number of experts who were considered to have a conflict of interest given their involvement either with industry or in the development of previous guidance. This has resulted in a perverse situation where the large majority of recognised experts have been excluded from the process - and many of the scientists that have been involved have an academic understanding of the issue but little or no understanding how that science can be translated into a regulatory system. EFSA's bee guidance document was initially agreed in 2013, see (European Food Safety Authority, 2013); however, due to uncertainties about some of the assumptions included in the guidance document and concerns about its application, it has not been formally integrated in the EU's regulatory framework. A process has been formally initiated in 2020 to review and update the guidance to better support regulatory decision making. Further information on the bee guidance document and the impact on insecticide seed treatment authorisation is set out in section 3.4.

2.3 Green deal and Farm-to-Fork

The most recent development in the European Union is the latest policy proclamation. The EU's Green Deal has a broader environmental protection aim but with agriculture and land use being key elements within the strategy. Within the Green Deal, the specific Farm to Fork strategy is focused on agriculture and food with a particular focus on crop protection.

The new European Commission was appointed in late 2019 and will remain in office for 5 years under the leadership of German Commission President Ursula von der Leyen. One of the initial focus areas for the von der Leyen Commission was on agricultural policy with a particular focus on pesticide legislation. The initial concepts of the European Green Deal were set out in December 2019 and while the Covid-19 situation did have an impact on the development of specific strategies, the Commission pushed ahead and published their Farm to Fork and Biodiversity strategies in May 2020. Indeed, the European Commission references Covid-19 as one of their justifications for legislation with European Commission Vice-President Frans Timmermans highlighting that:

"The coronavirus crisis has shown how vulnerable we all are, and how important it is to restore the balance between human activity and nature. At the heart of the Green Deal the Biodiversity and Farm to Fork strategies point to a new and better balance of nature, food systems and biodiversity; to protect our people's health and well-being, and at the same time to increase the EU's competitiveness and resilience. These strategies are a crucial part of the great transition we are embarking upon."

The launch of the Farm to Fork and Biodiversity strategies were also accompanied by a report on the implementation of the EU's pesticide regulatory framework. Moreover, many of the policy-making commitments made by the Commission were related to the future approval and use of pesticides. The following sets out some of the key measures in the strategy documents:

- The Commission will take additional action to reduce the overall use and risk of chemical pesticides by 50% and the use of more hazardous pesticides by 50% by 2030.
- Make the best use of nature-based, technological, digital, and space-based solutions to deliver better climate and environmental results, increase climate resilience while also reducing and optimising the use of inputs (e.g. pesticides, fertilisers).
- The Commission will also facilitate the placing on the market of pesticides containing biological active substances and reinforce the environmental risk assessment of pesticides. It will act to reduce the length of the pesticide authorisation process by Member States.
- It will revise the Sustainable Use of Pesticides Directive, enhance provisions on integrated pest management (IPM) and promote greater use of safe alternative ways of protecting harvests from pests and diseases.

Looking at the strategy documents, it is clear that the focus of the European Commission's communication has shifted, being significantly more negative on the use of pesticides and giving limited recognition to their importance in agricultural production. While the report recognises that pesticides are used with the aim of optimising food production, the focus of the message is on the "…urgent need to reduce dependency on pesticides and antimicrobials, reduce excess fertilisation, increase organic farming, improve animal welfare, and reverse biodiversity loss."

The European Commission Communication also looks at the impact of its policies on global agricultural production. The Commission states in its communications that:

A more sustainable EU food system also requires increasingly sustainable practices by our trading partners. In order to promote a gradual move towards the use of safer plant protection products, the EU will consider, in compliance with WTO rules and following a risk assessment, to review import tolerances for substances meeting the "cut-off criteria" and presenting a high level of risk for human health The EU will engage actively with trading partners, especially with developing countries, to accompany the transition towards the more sustainable use of pesticides to avoid disruptions in trade and promote alternative plant protection products and methods.

This communication has triggered a negative reaction from a number of third countries who see that the European agenda is being imposed on them with little or no opportunity for a global discussion on the potential implications. The specific reference to the cut-off criteria is in particular a concern for many non-EU countries, as the EU's hazard based criteria has been developed at a political level with little scientific justification - and moving away from the risk assessment based system in place. While reference is made to the need to avoid disruptions in trade, this will lead to significant challenges for the sustainable agricultural production and trading opportunities for many countries.

Implementation of the Farm to Fork strategy

With the publication of the initial EU strategy documents in May 2020, this is now the start of a long policy process at the EU level. The Commission have made commitments to come forward with a number of policy changes and legislative proposals. The first of these proposals are likely to be published in 2021 and this will lead to significant discussions with stakeholders and policy makers – final legislative texts will probably be agreed in 2022 and 2023 – and with staged implementation, the direct impacts of any new legislation are likely to be felt from 2025 onwards.

2.4 Political Drivers in Europe – and the impact on the regulatory processes

According to research commissioned by the European Parliament, public perception of plant protection products in Europe have been heavily influenced by the media, through tactics such as repetition and an unwillingness to change existing attitudes and even reinforce entrenched behaviours. The study goes on to not only questioning the objectivity but also the accuracy and sourcing of some of the material shared. The report also references a study from 1999 which showed that 40-60% of consumers tended

to trust NGO messaging on food safety, more than the 29-49% of consumers who would trust scientists, and far higher than those who would trust authorities (9-27%) and least of all, industry (Keulemans, et al., 2019).

The influence of civil society organisations and their political campaigns since the 1990's should also not be underestimated, as they too have played a role in shaping regulations that have become more restrictive for crop protection products and for biotechnology in the EU.

Consumer perceptions can be considered a part of what drives legislative change in Europe, especially where the visibility of an issue triggers a level of politicisation that exposes the European Commission to potential reputational damage. This is exemplified in the case of Glyphosate, which showed how the Commission can shift from what can be usually considered a technocratic decision-making style to one that is responsive to public perceptions and aimed at assuaging public interest (Bazzan & Migliorati, 2020).

The political influence on the authorities responsible for regulatory assessments and decision-making in the European Union also needs to be considered closely as a source of uncertainty, which has likely contributed to the increased politicisation of food safety issues. Since the 1990s, many European countries have promoted a regulatory evaluation process where the risk assessment and the risk management (authorisation decisions) are taken by separate bodies. While many policy makers view this split of responsibilities (along with greater independence of risk assessors) as a European success story, it is questionable if this is the case. It is in particular interesting to note that the highest level of efficiency and public trust exist in those countries where a single body is responsible for the regulatory evaluation process. The single body concept works efficiently in countries such as the UK, Ireland and Austria – while much greater complexity and politicisation occurs in countries where multiple bodies are involved in the process (such as France, Germany and Spain).

To better understand the impact that various political drivers have on the regulatory process in Europe, the next two chapters provide information on relevant case studies. <u>Chapter 3</u> looks at the European debate on biotechnology and the impact on the implementation of the legislative process. <u>Chapter 4</u> evaluates specific case studies in the European crop protection sector, looking specifically at [1] the politics and policies in France, [2] the development of criteria for endocrine disruptors, [3] the re-evaluation process of glyphosate, and [4] the restriction of neonicotinoid seed treatments.

3. THE EUROPEAN DEBATE ON BIOTECHNOLOGY LEGISLATION

The political landscape has had a significant impact on the approval of biotech traits in Europe. With the political fallout that resulted from the mad cow disease (BSE) crisis, the EU has developed an approach that is particularly precautionary and antagonistic to new technology in the agricultural sector. While this has applied across numerous sectors, genetically engineered (GE) crops have been the most significant victim of this antagonism.

The EU's complex and lengthy policy framework for biotechnology creates a challenging environment for research and limits access to innovative tools for EU farmers. While importing large amounts of GE crops, commercial cultivation of GE crops is 1.5% of EU's maize area - (130,000 hectares of GE maize in Spain and Portugal). The single variety authorized for cultivation is banned in nineteen Member States (MS), with that ban being introduced over a number of years (for example, it was implemented in France in 2008) (USDA Foreign Agricultural Service, 2018). The EU imports more than 30 million metric tons (MT) of soybean products, 10 - 15 million MT of maize products, and 2.5 - 4.5 million MT of rapeseed products per year. The current situation of the EU, with very little cultivation of GE plants and high imports, is not expected to change significantly in the medium term.

The EU's policy framework for biotechnology creates a situation that is complex from a regulatory perspective and does not take into account recent scientific knowledge. This unfavourable environment has adverse impacts such as restricting public and private research in biotechnology, impeding commercial production of biotech plants, and creating trade disruptions. The interest of industry in developing varieties of GE plants suitable for cultivation in the EU has waned. There is furthermore a perceived threat of destruction by activists, as well as challenging marketing conditions that also serve to discourage the cultivation of GE crops in the EU.

Consumer perception issues

For nearly two decades, European consumers have been exposed to consistent negative messaging from anti-biotech groups purporting that GE crops are harmful. As a result, attitudes towards GE products are mostly negative, with concerns about the potential risks from cultivation and consumption being a highly contentious and politicized issue.

The level of acceptance varies significant between countries and this has been evaluated by the USDA FAS (see figure below).

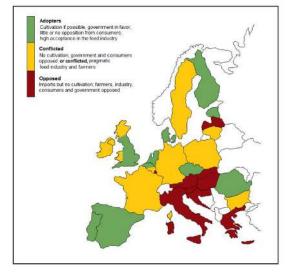
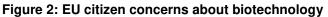


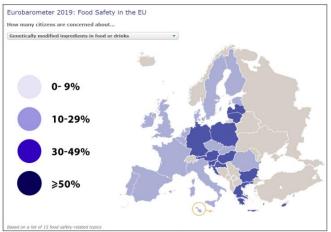
Figure 1: Acceptance of Agricultural Biotechnology by Member State (2018)

Source: (USDA Foreign Agricultural Service, 2018)

In European countries that grow GE crops (Spain and Portugal), perception is less negative. The position of some countries is conflicted due to a position that is significantly different between scientists

and the food industry on the one side, and consumers, NGOs and governments on the other side. Some countries are seen as particularly negative with a broad coalition of the major stakeholders being antagonistic to the growing and importing of GE crops. The level of consumer concerns in Europe is also worth noting with over 30% of consumers being concerned in some countries, with Germany and Poland being the most significant members of this group.





Source: 2019 Eurobarometer on Food Safety in the EU

Market entry delays for new biotechnology traits

While new GE crops are entering the global marketplace at an increasingly rapid rate, the EU regulatory procedures take significantly longer than those in the supplier countries, and thus delays the market entry of new technology. With the authorisation process in supplier countries being significantly quicker than the import approval process in the EU, this results in trade disruption in the affected commodities and related processed products. European feed manufacturers and cereals and feedstuffs traders have repeatedly criticized the length of the EU authorization process, as the delays result in trade disruptions and price increases for protein-rich products, which the EU needs for its animal feed sector. Shipments of agricultural commodities destined for the EU have been rejected when traces of such events have been detected at the point of entry.

The EU approvals process is significantly influencing farmers' planting decisions in major exporting countries, with the EU delays preventing farmers from choosing the most recent seed varieties. While the EU's regulatory review process should only take twelve months (six months for safety assessment by EFSA and six months for the European Commission to approve), the reality is that the approval of GE events take an average of six years – compared to an average 2-year approval process in Canada, Brazil and the United States.

According to the US's Foreign Agricultural Service, the main bottleneck of the EU's lengthy approval process lies with the EFSA process, as they require almost five years to deliver the required safety assessments. While the delays can partly be attributed to inefficiencies in the system, it also has to be recognised that the political pressures on EFSA do lead to a more conservative evaluation with the request for significant additional information, and this leads to delays in the process.

Recent court judgements have significant impact

There was initially hope that the trend of innovative biotechnologies could help revive plant biotechnology in the EU. However, in July 2018, the Court of Justice of the European Union (CJEU) issued a judgement that organisms created through certain mutagenesis techniques must be subject to the regulations relating to genetically modified organisms (GMOs). The judgement impacts *in vitro* mutagenesis techniques, which it decrees should be considered as genetically modified – and would therefore subject to the EU's complex and politicised legislative framework for GM. The new legal interpretation is seen to have a particular impact on the legislative process that would apply to Clearfield

rapeseed varieties. There is however also a high level of concern in the market as such techniques have been used in the historical breeding background of many types of marketed seeds, and it is unclear if and how the judgement could impact on such seeds that may be on the market today.

Scientists and the main farming organizations warn that this judgment could harm research and agriculture in the EU. EU trading partners have also identified that this judgment also has potential to create trade disruptions in the future (USDA Foreign Agricultural Service, 2018).

It is worth noting that the original court action in France was initiated by a group of 9 different stakeholders, including Friends of the Earth, the *Confédération paysanne* (one of the three main farmers' organisations in France) as well as a number of other environmental and anti-GM NGOs (Conseil d'État (France), 2020), (Confédération paysanne, 2017).

Role of farmers' organisations in the biotechnology debate

The role of farmers and their organisations in the biotechnology debate, in particular at the European level, has been challenging with different views being expressed by various groups. There is a strong anti-GMO view expressed by a number of farmers' organisations, which can be seen as a protectionist viewpoint and a rally cry against imports. It is also worth noting that this often arises in those countries with numerous different farmers' organisations, such as France and Italy, and where the opinions of the different organisations are often polarised on the subject. Significant differences also exist between specific producer groups depending on their competitive interest – with the animal sector being largely supportive of imports, and the crop sector showing some opposition to competing imports.

Given the conflicting interests and the numerous different farmer groups, the European farmer voice is not particularly influential in the debate and is not able to influence the debate, with most politicians and the public remaining antagonistic to these technological developments.

4. CASE STUDIES IN CROP PROTECTION

4.1 Crop protection politics and policies in France

Background and market situation

The French national view on the role of crop protection products has evolved significantly in the last 15 - 20 years. While France was seen as the main supporter for productive agriculture in the 1990's, we now see a situation where there is a strongly negative view of both pesticides and plant biotechnology.

The total crop protection market has been trending downwards for more than a decade and the data in figure 3 shows a significant reduction from 2014 - 2019. Over that five-year period, average French sales fell on average by 7.3% per annum, with sales of US\$2,019 in the year 2019. In the same timeframe, the market in the rest of Europe also fell - by an average of 2.7% per annum. While the overall fall in the market can be attributed to lower commodity prices, the larger fall in France is also significantly impacted by national policy measures.

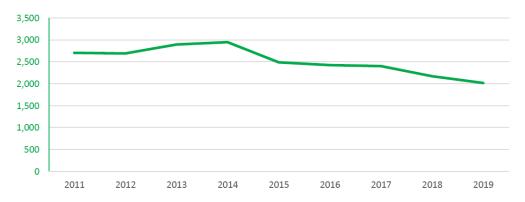


Figure 3: Total Crop Protection Sales; France 2011-2019 ('000 USD)

Over the same period 2014 - 2019, there has been a significant growth in the market for biological plant protection products. Sales were estimated to have grown by about 7% annually over the period 2014 - 2019, with the French market believed to have surpassed the \$200 million dollar bar for the first time in 2018 or 2019 and now representing around 10% of the total market (Sources: Various).

Public perception in France

The general perception is that the population is more and more concerned with environmental issues and impacts on human health related to agriculture, food and chemicals in general (including pesticides). Organic agriculture is becoming increasingly attractive and a reassuring option for consumers.

It is also interesting to note the results of a 2019 Eurobarometer report on food safety, which sets out the level of trust that the French public have in the information provided on food risks. The results are revealing in showing a high level of trust in consumer organisations and to a certain extent NGOs, with the level of trust in authorities being much lower – with very little trust in the food industry as a whole. This is especially the case when compared to the levels of public trust in other European countries.

Note: Data courtesy of IHS Markit Phillips McDougall (<u>www.phillipsmcdougall.com/</u>)

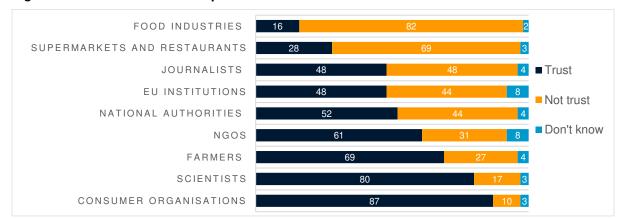


Figure 4: Who does the French public trust for information on food risks

Source: (European Food Safety Authority, 2019)

Public and media influence

Within France, a lot of pressure stems from the media, across all sources from traditional press to social networks and TV, as well as from NGOs such as *Générations Futures*, which is linked and seen as the French affiliate of Pesticides Action Network.

The media have a very strong influence on public opinion and on citizen's levels confidence in industry, agriculture and the Competent Authorities. The media and social networks disseminate a large amount of information about pesticides and their uses. With the origin and scientific relevance of the information not always being fully verified, the majority of the information is negative towards agriculture and the crop protection industry.

Similar to the situation with the European Food Safety Authority, there is a particular focus in France on the independence of Authority experts. The newspaper Le Monde has been particularly vocal on this issue at both the French and European level – especially questioning EFSA's glyphosate evaluation, and setting out what they see as the flaws in the process following glyphosate's re-approval (Le Monde, 2017).

A similar pressure applies to experts working at ANSES (*Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail*) and it is generally concluded that "experts" have conflicts of interest given their work with industry. The formal requirement for the publication of expert 'declarations of interest' appear to fan the fires and give rise to further challenges by activist stakeholders. One negative result from this pressure is that the opportunities for a scientific dialogue between industry and regulators on a particular authorisation application is severely limited.

With public pressure on the system, the French authorities are also criticized for their lack of transparency towards industry (for example regarding the assessment methodology and procedures), with their procedures leading to significant delays in the evaluation process for plant protection products. It should be pointed out that the limitations for such dialogue in ANSES apply specifically for pesticides dossiers, as other sectors under ANSES's responsibility, such as veterinary medicines, have significant opportunities to dialogue directly with the evaluators.

The French Ecophyto plans and their impact

Since 2008, France have put in place a number of national plans to increase the controls and reduce the use of pesticides at the national level. The first of their 'EcoPhyto' plans were established as part of the National Environmental Action Plan ("Grenelle de l'environnement") of 2008 with the action plan covering 2009 - 2014 and aiming to reduce the use, risks and impacts of plant protection products. The Ecophyto plan also implements the European Directive on the Sustainable Use of Pesticides. The main objective set out in the first EcoPhyto was to reduce the use of plant protection products by 50% in 10 years.

Taking into account the actions implemented in the first phase, Ecophyto II (covering 2015 - 2020), the main objectives of the updated plan continue to be linked to the reduction of use, risks and impacts of plant protection products. The use reduction targets were however adapted with reductions of 25% by 2020 and 50% by 2025 being promoted. The plan also looks at alternative solutions and recognises that such alternatives are not widely available. It therefore strongly focuses its objectives on the dissemination of information and training for agricultural professionals and farmers.

The Ecophyto II+ Plan of 2020 provides new measures to achieve the objective of reducing the use of plant protection products by 50% by 2025, with a specific phase out target for the use of glyphosate – with the main uses to be phased out by 2020 and all other uses to be phased out by 2022 at the latest. The plan also aims to promote biocontrol products and natural preparations of low concern, as well as focusing on reducing human exposure to pesticides in general.

The Ecophyto plans have been promoted at the political level and have increased uncertainty for the crop protection sector. However, the impact on use of products has been more limited than that targeted at the political level, given the continued pest pressures and clear agronomic needs. The political pressure against the use of chemical crop protection is however expected to continue with a focus on a populist dialogue.

Role of farmers in the French dialogue

While the French farming lobby is still a formidable force, their influence has waned in recent years and their role in defending the need for agricultural inputs is limited. The FNSEA is historically the leading federation for French farmers; their position has been challenged in recent years by newer associations including the *Coordination rurale* and in particular the *Confédération paysanne*. The *Confédération paysanne* is seen as an association that challenge the role of 'big business' and the use of agricultural inputs - and are in favour of very small farmers who rely on environmental subsidy payments for survival.

With such a division in the political representation of French farmers, the farming community can be very critical of the crop protection sector – and often unwilling to stand up and speak out on the need for crop protection solutions. This dislike can partly be attributed to an anti-big business viewpoint in communities of small farmers. The author however believes that this unwillingness to speak up on the need for crop protection can largely be attributed to parallel discussions on the CAP, with the CAP payments often being presented as a 'compensation' for the loss of solutions (crop protection and biotechnology), and the less productive farming that results.

While the voice of the French farmers is not always heard on agricultural inputs, there are certain situations where they do continue to have an influence. This can in particular be seen in the sugar sector where the French authorities have granted national emergency authorisations in 2020 for the use of neonicotinoid seed treatments (see section 4.4 for further detail). This is however not seen as a policy shift but rather a one-off solution to a particularly challenging situation. Nevertheless, with the loss of more and more crop protection active substances, the number of 'one-off situations' may well increase in the coming years (Les Echos, 2020).

4.2 Development of EU criteria for endocrine disruption

Discussions on the impact of endocrine disrupting substances have influenced EU policy thinking since the late 1990s and have now been translated into specific criteria that impact the authorisation process for plant protection products.

One of the initial steps took place in 1996 when the Commission sponsored an international meeting to address the potential impacts of endocrine disruption on the health of humans and wildlife and to establish an agreed integrated plan for future research and monitoring activities in this field ('<u>The</u> <u>Weybridge Report</u>' (European Commission, 1996). While the scientific dialogue had been initiated, the policy dialogue at the EU level moved quickly with political pressure to introduce new legislation moving ahead of any scientific developments.

For plant protection products, the European Commission reacted to requests, in particular from the European Parliament, to include criteria for endocrine disruption in the pesticide legislation and this was included in the amended regulatory framework agreed in Regulation 1107/2009.

While the initial framework was set out in 2009, the legislation required that detailed criteria should be developed and implemented by December 2013. The development of the criteria was however significantly delayed with significant differences of position between stakeholders, as well as between the different services of the European Commission. Both EFSA and the European Chemicals Agency (ECHA) played an important role in the development of the criteria. An initial Scientific Opinion was published by EFSA in March 2013 and this resulted in significant political discussions – including a court case taken by the European Parliament against the European Commission for failing to comply with the legal deadlines for the implementation of final criteria.

The criteria were finally agreed in December 2017, and from November 2018, they apply in the evaluation of all new and ongoing applications for plant protection products.

During the policy discussion on the criteria for endocrine disruptors criteria, much of the discussion focused around the likely impact of the final criteria. Many of the key policy makers, in particular in the European Commission, claimed that the impact would be limited. While industry concerns highlighted that the final impact could be significant and would substantially reduce the availability of plant protection products, this viewpoint was largely dismissed as industry scaremongering.

Initial impact of the endocrine disruption criteria on substance approvals

From initial evaluations of plant protection active substances, the numbers of substances to be classed as endocrine disruptors (and therefore removed from the market) is likely to be in line with the predictions that were made by industry. From an initial review by EFSA, 7 of 43 active substances have been identified as endocrine disruptors and are likely to be removed from the market once the regulatory process has been completed. However, the evaluation process has been extended for the majority of substances under evaluation to allow the submission of additional data being requested to complete the review. Additional data has been requested in 80% of cases and the first results of those evaluations will likely be seen in 2021 and 2022.

Potential impact on trade

The discussion on the endocrine disruption criteria has also led to a significant debate related to the setting of import tolerances to allow international trade. Where the active substances are banned in the EU having been identified as endocrine disruptors, it is possible that all MRLs and import tolerances for those substances will be removed in the EU. While the European Commission have indicated that the re-evaluation (and possible amendment of MRL levels) will be based on a substance specific, case-by-case, evaluation, the political pressure in this area will be high. The Commission however has recently stated that they will be pushing forward and "...will consider, in compliance with WTO rules and following a risk assessment, to review import tolerances for substances meeting the "cut-off criteria" and presenting a high level of risk for human health".

What does this mean going forward?

The EU's regulatory process for developing criteria for endocrine disruption provides an interesting case study in the development of new legislation in a scientific domain.

While the issue of endocrine disruption has been on the agenda for over 20 years, the EU has followed a process that is distinct from the process implemented in other countries. The main driver for legislative change in Europe was not based on significant scientific concerns but rather on a political drive to introduce new legislation – and to show the European public that Europe is driving forward new legislation in areas where public and political concerns exist.

Compared to other OECD countries, the EU system is not driven by a single authority with responsibility for evaluations, authorisations and market monitoring. This leads to more political consideration in driving forward the legislation.

This is not only seen in the development of the primary legislation; it also impacts the implementation of the secondary legislation in particular in the setting of additional data requirements. While specific data requirements and test methods have been in development in recent years, the requirement to provide such studies within a tight timeframe poses a number of problems, in particular:

- While the test methods have been developed, there is some uncertainty in the interpretation of the results. There are significant concerns that decisions in the European system will be precautionary and based on the interpretation of the individual study; the process does not allow an opportunity to review a significant body of evidence on a range of substances, which would allow a more developed understanding and interpretation of the data.
- For the complex new study test methods that have been developed, only a limited number of laboratories have been able to develop the necessary capabilities to carry out the studies. With pressure to meet regulatory deadlines, there is limited resource to carry out the work – with some of the available laboratory resources having inadequate experience to provide the required quality and consistency in carrying out the studies.

For a robust evolution of the regulatory process, lessons can be learnt from the EU's experience with endocrine disruption. Considerations include ensuring that changes in the regulatory process are based on a robust process with the required scientific knowledge to back it up and support a clear decision making process.

4.3 EU re-evaluation of Glyphosate

The EU's regulatory process for crop protection products requires a regular re-evaluation of all approved active substances. The re-approval process for Glyphosate is one clear example of the challenges faced in the EU's regulatory process with significant political and stakeholder interventions leading to major difficulties in completing the process.

Glyphosate was initially approved at the EU level for a 10-year period running until June 2012, and an initial extension was granted until December 2015 to allow time for the re-evaluation process. The EU evaluation process was initiated in 2012 with the evaluation being carried out by Germany as the nominated 'rapporteur Member States' (RMS) and submitted in December 2013 for a peer review by EFSA. During the EFSA review process, the evaluation on the potential carcinogenic properties of glyphosate was running in parallel in the International Agency for Research on Cancer (IARC) with the conclusions of IARC being communicated in March 2015 and the final monograph published in July 2015.

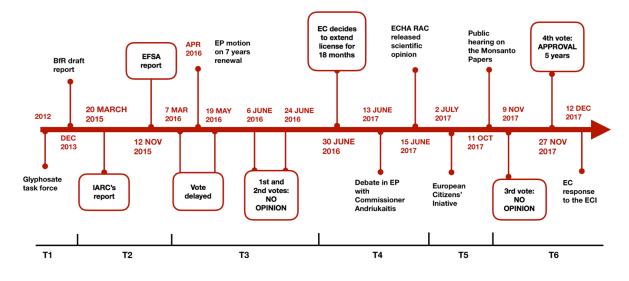


Figure 5: Timelines for the EU process for the re-evaluation of glyphosate

Source: (Bazzan & Migliorati, 2020)

Following a request of the European Commission that EFSA take into consideration the IARC monograph, the final EFSA conclusion was published November 2015. EFSA's conclusion did not identify any specific concerns and highlighted that glyphosate is unlikely to pose a carcinogenic hazard to humans.

While EFSA's conclusion was clear and positive, the IARC position created a significant political opportunity for NGOs and many at the political level. The perceived differences of opinion led in particular to significant discussions in the European Parliament, with a number of hearings where EFSA and IARC representatives were asked to clarify their differences of opinion on carcinogenicity. The regular exchanges between EFSA and IARC served to significantly undermine the position of EFSA in the eyes of NGOs and many of the Members of the European Parliament (MEPs) who took a close interest in the issue. Much of the focus of the discussion was on a perceived lack of independence of EFSA.

With a continuous challenge to EFSA's position, EFSA's reaction was to restrict and tighten its internal procedures (stricter declarations of interest for existing and new experts, exclusion of experts with industry experience, etc.). This however had little or no impact on those that were challenging its

position, and it can be considered that the additional measures by EFSA provided additional impetus for the NGOs to continue to push for further tightening of the procedures.

With the perceived difference of opinion between EFSA and the IARC, NGOs and politicians continued taking to the media to undermine the work being done by EFSA, and in particular to challenge their independence. Indeed, the main focus of the discussion was related to EFSA's independence. The additional measures put in place only appeared to confirm the NGO viewpoint that EFSA's ways of working had been inadequate.

The negative media about EFSA's role was also supplemented by additional NGO and media opportunities, focusing in particular on the finding of glyphosate in beer, wine and in the urine of Members of the European Parliament (MEPs)! See e.g. (Deutsche Welle, 2016) and (The Greens/EFA, 2016).

In spite of the scientific evidence gathered by EFSA against carcinogenicity, the debate over Glyphosate escalated, and a European Citizens' Initiative (ECI) was launched in January 2017, requesting a ban on the use of glyphosate in the EU. The EU-wide initiative was widely supported by NGOs and, with a high level of public support in several countries, the target of one million EU citizen signatures was achieved in July. By reaching 1 million signatures, this triggered a requirement for the European Commission to take specific action – and also provided further media opportunities.

The challenges to EFSA reached their peak in September 2017 when a number of European media outlets published articles questioning the integrity of the EFSA risk assessment of Glyphosate. It was highlighted that the EFSA evaluation included information copied from the initial dossier provided by the Glyphosate Task Force application; despite the fact that this is the recognised way of working in the EU evaluation process. This resulted in a European Parliament public hearing on the 'Monsanto Papers' in October 2017, and the Parliament subsequently called on the Commission to phase out the use of Glyphosate by 2022.

While the decision making process in this case should have been a standard comitology decisionmaking procedure (with decisions being taken by the Ministries of the EU Member States), the issue moved into an increasingly politicised process. With the Commission looking to manage the decision making process, more time was initially assigned to EFSA to review the carcinogenicity evaluation, taking into account the IARC monograph. However, with public mobilisation leading to a formal European Citizens' Initiative, the voting positions of Member States became less unclear.

The voting positions of France, Italy and Germany were all key in the process and with the escalation of the discussion reaching unprecedented levels, the national discussion included statements by the French President and the German Chancellor. Due to significant media and political pressure at the national level, all three countries indicated an unwillingness to support an approval at different stages of the process. The final decision for a restricted 5-year approval was eventually voted in November 2017, with the support of Germany but with nine of the 28 EU countries voting against the approval proposal. The decision in Germany however resulted in significant political fall-out within the coalition government, with the two parties having taken opposite position on the re-approval.

The process of reauthorisation of glyphosate has triggered the most acute policy crisis in EU food governance over the last decade, with many commentators believing that it significantly undermined the role of the European Commission. The amount and extent of societal, political and scientific input (or interference depending on your point of view) is unprecedented. While the European Commission was struggling to have its draft implementing regulation approved by Member States' (MS) representatives in the standing committee on Plants, Animals, Food and Feed (ScoPAFF), a variety of new initiatives have resulted in further reviews and changes to the EU regulatory process.

The European Citizens Initiative (ECI), which had a number of requests including a ban of glyphosate in Europe, has resulted in significant changes in the EU's General Food law legislation, which impose a number of new measures that will increase the cost and complexity of complying with the EU's pesticide legislation. While it did not achieve its main aim of banning glyphosate, it can be concluded that the initiative contributed to the restricted approval that was finally granted.

Also as a reaction to the European Citizens Initiative (ECI), the European Parliament established a special committee on EU authorisation procedure for pesticides (PEST Committee) to review the whole pesticides authorisation procedure in light of the glyphosate process. The published conclusions of the PEST Committee have been one of the inputs that has influenced the policy proposals in the EU's recent Farm to Fork initiative.

Next phase in the glyphosate evaluation process

It should be recognised that the political and NGO focus on glyphosate was not triggered by any new scientific development – but was rather an opportunistic exercise by NGOs at the time of the timed reevaluation of glyphosate. Much of the opposition originated in the anti-biotechnology arena, but the renewal process provided a perfect opportunity to challenge the approval of glyphosate.

The role of IARC and the timing of their evaluation has also been questioned. It is however very clear that the publication of the IARC opinion resulted in a significant shift in the decision-making process – and the repercussions are significant in triggering new transparency legislation and a deep review of the pesticide legislation.

With the 5-year approval of glyphosate running until December 2022, the review process has also already been initiated. With significant pressure on the German authorities (including personalised attacks on their individual experts) in the initial glyphosate evaluation, the current review is being managed by four Member States, with a peer review to be managed by EFSA expected to start in the second half of 2021.

Given the significant NGO and political pressure at the time of the initial review, the expectation is that similar levels of activities will take place in 2022. With a number of Member States having already made national commitments to phase out the use of glyphosate, the final decision making process will surely be politicised and will put extreme pressure on the European Commission. The final decision will also impact third countries and non-EU agricultural stakeholders will need to be aware of the opportunities to input into this process.

Market implications of the EU's glyphosate review: Italian pasta

In addition to the political and regulatory consequences of the glyphosate evaluation, there have been significant commercial implications, with the market reacting to public and consumer concerns, and raising questions in particular about third country imports. Farmers' groups have also been key drivers in this discussion in some countries, including in Italy with one of the main farmers' organisations *'Coldiretti'* questioning the increasing imports of durum wheat and challenging the pasta producing countries to use nationally produced durum wheat in their products "...where the use of glyphosate in pre-harvest is prohibited, unlike what happens in Canada and other countries." (Coldiretti, 2018)

As a response to the pressure in the market, some of the pasta producers reacted at that time, with Barilla in particular stating that their pasta products on Italian market were to be produced using 100% Italian wheat (Barilla Group, n.d.). It should however be noted that this commitment was limited to the Italian market and did not apply to other European markets.

In addition to the discussion on glyphosate, negative publicity has also been linked to the CETA free trade agreement, with *Coldiretti* in particular lobbying against CETA and Canadian wheat imports, arguing against a 'seven-fold increase in durum wheat input since CETA was implemented' with 'increased and unfair competition putting farmers' jobs in Italy at risk'. While there is no consistent view in Italy between the different farmers' organisations, it is clear that some consumer and farmer groups will continue to raise concerns around glyphosate and CETA – and link those concerns to Canadian durum wheat imports (Agrifoodtoday, 2019), (II Salvagente, 2020).

Given the potential challenges to imported products, the discussion on the sustainability of different production methods will become increasingly important. Section 4 .4 of this paper looks in more detail at the sustainability of different production models; it will be important to ensure that the data on sustainability is an important part of the on-going dialogue in Europe.

4.4 Restriction on neonicotinoid seed treatments

Until 2013, five neonicotinoid insecticides were approved as active substances in the EU for the use in plant protection products, namely clothianidin, imidacloprid, thiamethoxam, acetamiprid and thiacloprid.

However, based on a risk assessment carried out by EFSA in 2012, the Commission took a decision in 2013 to severely restrict the use of plant protection products and treated seeds containing three of the neonicotinoids - clothianidin, imidacloprid and thiamethoxam. The review of the approval of the three active substances came about following a number of concerns raised by Member States; this was in particular linked to a number of cases in 2011 where dust from treated seed led to the poisoning and loss of numerous bee hives. It is however widely recognized that the problem was related to poor seed treatment application methods, which resulted in the release of the dust (University of Utrecht, 2011).

The initial measure prohibited the use of the three neonicotinoids in bee-attractive crops (including maize, oilseed rape and sunflower) and required the submission of further data to confirm the safety of the remaining uses. Following the assessment of additional information by EFSA, the Commission proposed a complete ban on the outdoor uses of the three active substances from 2018.

The discussion on neonicotinoids led to a significant interest from environmental NGOs, and many of the concerns around these class of chemicals was linked to the publication of a number of papers in 'Science' in early 2012 (Henry, 2012), (Whitehorn, 2012).

The aims of the papers published in Science have however been questioned by some commentators. Claims that the development of the scientific papers were a result of a political campaign to undermine the uses of neonicotinoids, and where the concerned scientists had decided in advance to seek evidence supporting a ban on the chemicals and persuade regulators to take regulatory action (The Times, 2014), (Genetic Literacy Project, 2014).

With a clear environmental and political interest in the issue of neonicotinoids, the bee poisoning cases that took place in 2011 increased the media and public interest in the issue and provided a well-framed backdrop to promote the papers published in Science. In addition to the activity of the environmental NGOs, there was also a high level of activity of beekeeper representatives, many of which were closely aligned with the NGOs.

While historically the beekeepers' political representation had been closely aligned with the farmers' associations, the discussion on insecticidal seed treatment led to many beekeepers questioning that alliance, and resulted in a much closer alliance with environmental NGOs. As an example, The European Beekeeping Coordination (BeeLife) was set up as a formal entity in 2013; while representing European beekeepers, it presents itself as a *"European NGO working for a brighter future for bees and pollinators, improving their protection and their collaboration in our agricultural system"* (BeeLife, 2020).

In addition to the alliance between environmental NGOs, scientists and beekeepers, it should also be noted that other campaign groups played an important role during the discussions on insecticide seed treatments and bee health. Actors included the campaign group Corporate Europe Observatory (CEO), who challenged the role of lobby groups in EU policy making. CEO in particular challenged the industry's 'furious lobbying campaign' with the European Commission (Corporate Europe Observatory, 2013).

With the pressure from multiple groups, the agricultural lobby in this discussion found it particularly challenging to be influential in the discussion. From informal discussions with farmers' representatives, it was clear that they faced 'internal' challenges in trying to agree a common viewpoint between cropping farmers and beekeepers. They also faced a situation where their usual allies in agricultural Ministries were also very careful in the positions that they took, especially given the public support for the small beekeeping sector.

Much of the discussion related to insecticide seed treatments has been linked to significant losses in beehives in the European Union. While it is recognized in the expert community that beekeeping practices, including varroa control, are the most important issues in protecting beehives, the general belief at the public and political level is that crop protection products are the main problem. It is also interesting to note that, while there is a general viewpoint communicated in Europe regarding a

significant reduction in beehive numbers, the reality is quite different, with the total number of beehives having increased by nearly 60% between 2004 and 2019.

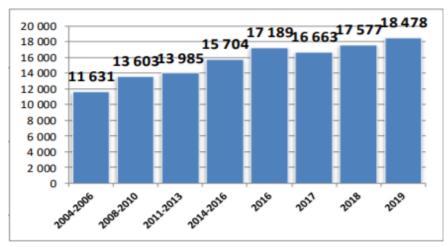


Figure 6: Number of hives in European Union (2004-2019)

Source: (European Commission, 2020)

With such an increase in beehive numbers, it is maybe surprising that this has not influenced the public and political discussion on the perceived bee losses and the role of plant protection products. There however appears to be very limited interest amongst beekeepers and policy makers to change this narrative. Linking the narrative to pesticide use appears to be part of the Commission's focus. This can be seen in a recent response to a question from a Member of the European Parliament; while the question related to general concerns about bee health, the Commission's response was focused on *'halting the biodiversity loss'*, by *'taking actions to reduce the overall use and risk of chemical pesticides by 50% and the use of more hazardous pesticides by 50% by 2030'* (European Commission, 2020).

Seed treatment emergency authorisations in the EU Member States

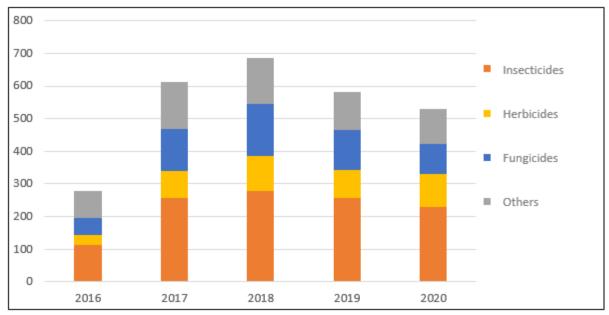
Following the restrictions on the three neonicotinoids in 2013, several Member States have used a derogation possibility that exists in the European Union to allow 'emergency authorisations' for some of the restricted uses. In particular, Romania, Bulgaria, Lithuania, Hungary, Finland, Latvia and Estonia applied for multiple derogations on major crops since the entry into force of the restrictions of use.

These derogations have been applied in particular for uses in maize, oilseed rape and for sugar beet, where the Member State authorities have recognized that there are no realistic alternatives to the use of neonicotinoid seed treatments. The regular use of such derogations has however been challenged by the European Commission and this has resulted in regulatory decisions against Romania and Lithuania in 2020, requiring that they stop granting neonicotinoid emergency authorisations for future seasons.

The situation in France should also be highlighted, given that the French Authorities were particularly supportive of taking regulatory action to ban the neonicotinoids. In addition to the EU restriction, France had implemented its own legislation in 2016, which banned the uses of neonicotinoids from 2018 onwards. Having implemented those measures, the French Authorities agreed in August 2020 to provide a derogation and allow seed treatment uses for up to 3 years. In making the decision, the French Agricultural Ministry highlighted that a failure to act would have had very serious consequences with possible yield losses of 30 to 50% with farmers moving away from sugarbeet production – with major economic impact on 25,000 farmers and an estimated 46,000 jobs (Les Echos, 2020). Similar derogations for uses in sugar beet have also been implemented in a number of other countries including in Belgium, Austria and Poland (RTBF, 2020).

Emergency authorisations - General use in Europe

The use of such derogations is not limited to neonicotinoids, with many Member States granting shortterm authorisations for a range of active substances that are no longer authorised in the European Union. The following table provides further information on the number of derogations granted by the Member States of the European Union in the period 2016-2020.





Source: (European Commission, n.d.)

Emergency authorisations - impact on third countries

For third countries looking at the situation in Europe, the use of the short-term derogations would appear to be unfair, leading to situations of unfair competition. According to the European legislation, the derogations can be granted to deal with situations where such uses are *"necessary because of a danger which cannot be contained by any other reasonable means"*. However, this situation cannot apply to a third country where particular uses are essential tools to control particular pests – but where exports to the EU may in future no longer be possible where an MRL trading standard would no longer be in place.

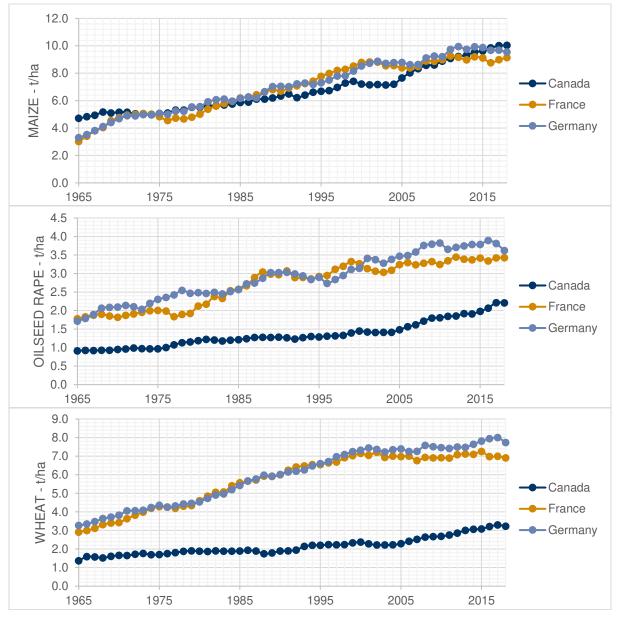
5. IMPACTS

5.1 Yield development in European Agriculture

The legislative changes introduced in Europe over the last 20 years have required significant changes in practices at the farm level while also having an impact on the availability of certain technologies. While the European policy discussions are largely focused on environmental and health protection, considerations around agricultural productivity have been much more limited.

Looking at the historical development in crop yields, the following graphs show the yield evolution (based on the average yields of five previous years). While the actual yield levels vary significantly, in particular for rapeseed and wheat, it is interesting to look at the trend in the yield growth.

Figure 8: 5-year yield averages for maize, rapeseed & wheat; Data for France, Germany & Canada (1965 – 2018)



Data source: FAO (Graphs: ERM)

From the data, it can be seen that European producers saw significant yield increases form the mid-70's until the mid-90's, while yield increases in Canada were significantly lower during that period. The European yield increases at that time can largely be attributed to two main factors:

- 1. The EU's Common Agricultural Policy provided price support for production in Europe and this encouraged additional intensification
- 2. This period saw the development of a large number of new crop protection active substances that entered into the European market. The development of newer classes of fungicides with improved properties in particular positively impacted European yields, given the wetter climate faced by European producers.

From the late 1990's, the yield situation has significantly changed as shown in Figure 8. The very slow increase in European yields can be partly attributed to changes in the Common Agricultural Policy. However, much of the impact after 2005 can be attributed to changes in the availability of crop protection products, with fewer new solutions coming to market together with the loss of a significant number of active substances.

Since the beginning of the new century, the percentage yield increases in Europe have been much lower that has been seen historically and are also significantly lower than what was seen in Canada. The data in the table below compares the yield evolution between France and Canada between 2000 – 2018. Comparing the 5-year averages, the data indicates limited yield increases for maize and oilseed in France of approximately 0.5% per annum with the wheat yields actually decreasing slightly. Over the same period, Canadian yields have increased by between 2.4 - 3.2% annually.

French yields remain significantly higher for rapeseed and wheat, and this can be largely attributed to higher rainfall in the main growing areas, when compared with the growing areas in Canada. The evolution in maize yields should however be noted: while Canadian yields were on average 19% lower than in France in the period 2000 - 2004, the situation has changed significantly in the period 2014 - 2018 with Canadian yields surpassing that of their French counterparts by an average of 9%.

		•	•		· •	5	. ,	
Canada				t/ha	France			
2000- 2004	2014- 2018	Increase (% Total)	Increase (% pa)		2000- 2004	2014- 2018	Increase (% Total)	Increase (% pa)
7.20	10.03	39.4%	2.4%	Maize	8.55	9.13	6.8%	0.5%
1.42	2.21	56.3%	3.2%	Rapeseed	3.09	3.43	10.9%	0.7%
2.22	3.22	44.9%	2.7%	Wheat	7.00	6.91	-1.3%	-0.1%

Table 2: Yield development comparisons - 2000 - 2018; 5 year averages (mt/ha)

Yield comparisons: Canada and France							
	2000-2004				2014-2018		
Canada t/ha	France t/ha	Canada as % of France		Canada t/ha	France t/ha	Canada as % of France	
7.20	8.55	84%	Maize	10.03	9.13	110%	
1.42	3.09	46%	Rapeseed	2.21	3.43	64%	
2.22	7.00	32%	Wheat	3.22	6.91	47%	

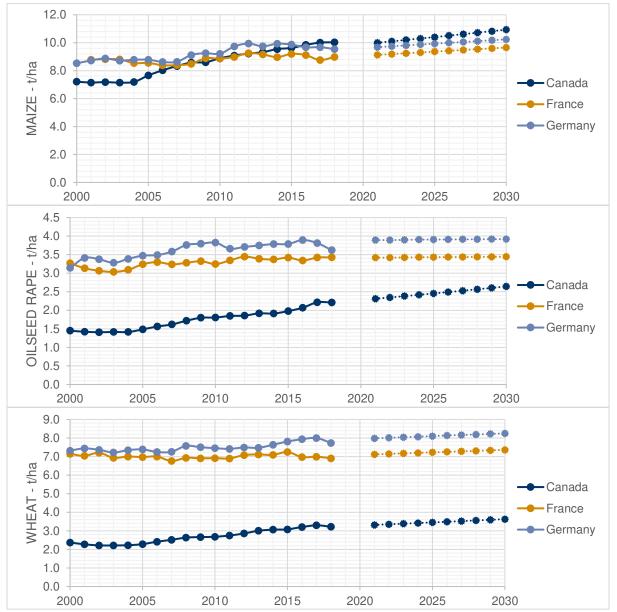
Data source: FAO (Table: ERM)

Looking forward into the next decade, the outlook data of the European Commission predict negligible yield increases in the European Union, with predicted annual yield increase in the EU-27 of 0.24% for maize, 0.03% for oilseed rape and 0.48% for wheat. The flat yields in Europe in recent years have largely been attributed to a low level of yield reductions from the loss of crop protection solutions, which is largely balanced out from seed breeding developments.

In plotting the projected yields in France and Germany to 2030 (Figure 9), an assumption is made that the small yield increases predicted in the European Union will be similar in all countries. In reality, it is expected that larger yield increases will be seen in countries in the Eastern part of the EU, with yields in Germany being flat and reducing in France due to the restrictions on the availability of crop protection solutions. While no such outlook data has been identified for Canada, it is assumed that yield increases will not be as significant as that seen since 2000, but would be expected to exceed 1% per annum for all three crops.

The projections therefore show maize yields in Canada continuing to surpass EU production, with the gap getting larger. While the Canadian yields being significantly lower for oilseed and wheat, the next decade will see some closing of the yield gap. This is especially the case for oilseed rape where Canadian yields will potentially be comparable with France within 15 - 20 years.

Figure 9: 5-year yield averages and future projections for maize, rapeseed & wheat; Data for France, Germany & Canada (2000 - 2030)

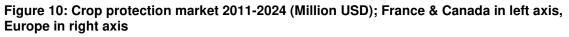


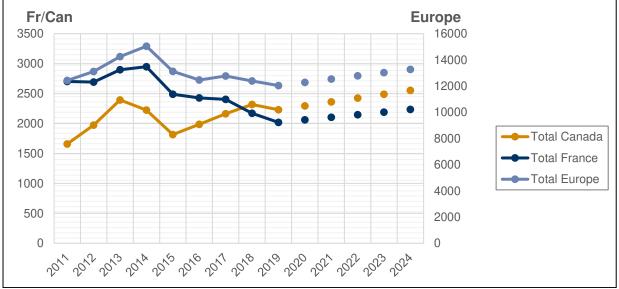
5.2 Evolution in use of crop protection products

While one of the political drivers to limit the availability of PPP is to reduce overall use, in reality there is only limited evidence that the reduction in the availability of tools is actually leading to an overall reduction, with farmers turning to the use of the remaining tools available to them.

The data in Figure 10 highlights a 25% reduction in the value of plant protection products used in France between 2011 and 2019. While there is a decrease in the value of products used, there are some reports that the actual volume of products used during that period has actually increased. This would seem to suggest the use of higher volume products – and potentially in some cases a return to older chemistry on the market (ScienceMag, 2018).

Over the same 2011–2019 period, crop protection sales in Europe have dropped by 3%, while Canadian sales have increased by a total of 35%. It should however be noted that the overall spend on crop protection products is significantly lower in Canada, when compared with France on a cost per land area basis. Based on the agricultural land area of the two countries, an average of \$13/acre was spent in 2019 in Canada, compared to \$29/acre in France.





Note: Data courtesy of IHS Markit Phillips McDougall (<u>www.phillipsmcdougall.com/</u>); (Graph: ERM)

While France and the rest of Europe have seen a fall in sales, in particular since 2014, this is partly related to climatic and market conditions and it is projected that sales value will increase in the next decade. The predicted increase in the sales value of plant protection products in France could however be significantly impacted by policy developments at both the national and EU level, including the French Ecophyto plan and the EU's Green Deal.

5.3 Impact on third country trade – MRL setting

With the European regulatory process leading to 'non-approval' decisions for a range of active substances, a significant discussion has been triggered regarding potential imports of commodities that have been treated with the banned active substances. The political decision to introduce hazard based 'cut-off criteria' as part of the 2009 legislation has raised questions about the potential for the EU to also place restrictions on third country commodities.

While the World Trade Organisation (WTO) rules require that regulatory decisions are based on a risk assessment of the substances and their residue levels, EU policy makers have questioned this way forward. While there is a recognition that the EU needs to be seen to comply with the WTO principles, the recent pronouncement within the framework of the Green Deal (see section 2.1.2) highlights that the EU will promote its internal policies and look to influence third countries to adopt the EU's regulatory framework as a *de facto* global standard.

The actual impact of restrictions on import MRLs could be significant, potentially influencing the production methods and yields of \in 70 billion worth of commodities exported annually into the European Union, including the production of soybeans with an export value to the EU of \in 10 billion annually (Bryant Christie Inc., 2017).

In addition to the high-level policy pronouncements of the European Commission, the procedures to set MRLs and import tolerance (IT) levels are also being blocked on a regular basis by the European Parliament. While the decisions on the setting of MRLs & ITs are seen as implementing measures agreed at the administrative level, the EU's regulatory framework for MRLs requires a formal Parliamentary consultation. Since 2018, a number of situations have arisen where the Parliament have refused to accept MRL setting decision by the European Commission, which were based on EFSA assessments.

Case study: MRL setting process blocked at political level

An application for the setting of an EU import tolerance for the use of clothianidin in potatoes has been evaluated by Germany and by EFSA, who published its <u>reasoned opinion</u> in September 2018. The application for an import tolerance was particularly related to uses in Canada.

EFSA proposed to raise the MRL from 0.03 mg/kg to 0.3 mg/kg and this was supported by the EU Member States in the regulatory committee (ScoPAFF-pesticide residues). For EU decisions on pesticides residues, the European Parliament has a formal role. Given concerns at the political level regarding neonicotinoid substances, linked to the restrictions that had already been put place in the EU, the Parliament passed a motion in February 2019 against the setting of an import tolerance for clothianidin.

While Member States have raised concerns with the Parliament action, they have not been able to agree to the setting of the import tolerance and the process remains unresolved in March 2021 – with a potential impact on the export of potatoes from Canada to the EU.

The Parliamentary decisions are largely driven by the argumentation that MRLs/ITs should not be granted for substances that are no longer authorised in Europe. While this political process is clearly not in line with the risk assessment principles of the WTO, the position agreed by the European Parliament has not been challenged.

Third countries clearly have concerns with the EU's decision-making framework. However, changing the EU's position is seen as challenging, given the internal perception that the measures taken are precautionary and maintain Europe's food safety standards.

5.4 Impact on environment and biodiversity

5.4.1 Scope of assessment

ERM have assessed the effect of the differing approaches to agriculture, implemented in Europe and Canada, on selected environmental impacts at a national level, with a particular focus on comparing Canada and France.

Table 3 shows the environmental impacts assessed for the period 2000 – 2018:

Environmental Impact	Unit of measurement	Justification
Greenhouse gas (GHG) emissions	kgCO2-eq / kg	This is an indicator for climate change impacts from crop production and is an important driver for all industries, including agriculture, to reduce their impact.
Land use	ha / tonne	Increased land use by crops may be linked to the destruction of natural habitats, which impacts on biodiversity.

The crops assessed represent key agricultural products produced in Canada:

- rapeseed;
- wheat; and
- maize.

These three crops represent approximately 65% of crop production in Canada (FAO, 2020) over the period 2000 - 2018. France is a good comparator to Canada as it has been the largest producer of rapeseed, wheat and maize in the EU over the period 2000 - 2018 (FAO, 2020).

5.4.2 GHG emissions

GHG emissions were calculated using a streamlined "cradle to farm gate" life cycle approach, based on the principles of the GHG Protocol *Product Life Cycle Accounting and Reporting Standard* (WRI; WBCSD, 2011). This considers emissions of all greenhouses gases from extraction, production and use of all raw materials used in cultivation of the crops and direct emissions from agriculture, such as machinery operations, N₂O emissions from nitrogen application and the decompositions of residues. Sequestration of biogenic carbon (i.e. long-term storage of carbon from biological sources, for example in the soil) is also considered in the assessment but is reported separately (See Section 5.4.2.2).

The specific lifecycle stages assessed in the GHG assessment are shown in Table 4 with the method applied. All calculations were done on a per hectare basis for each year and then reported per kg of crop produced.

Life cycle stage	Method
Seed production	Assess average amounts of seed required and impacts from seed production based on published literature. This stage typically represents a small proportion of the total GHG emissions.
Farm operations	GHG emissions from key agricultural practices (i.e. tilling, sowing, chemical/manure applications, harvesting and transport of inputs and crops) based on published LCI data, using estimates at field level. The percentage of land under no-till agriculture, conservation or conventional agriculture is used to calculate the GHG emissions for each activity, as no-till typically requires less mechanical interventions and fuel.
Crop protection chemical production	Assess average amounts used based on FAO national data for total use of herbicides, fungicides and insecticides in each year and GHG emission intensity for

Table 4: Life cycle stages assessed and method for calculation

	production of crop protection products based on published LCI data. This stage typically represents a small proportion of the of the total GHG emissions.
Inorganic fertiliser production	Amounts of N, P_2O_5 and K_2O nutrients applied annually assessed on a per crop basis for years in which data are available. Types of fertilisers used were estimated for each country based on FAO data for the period 2012 – 2017.
Direct emissions from fertiliser use	Direct emissions from inorganic use (e.g. N_2O emission) were assessed based on IPCC Tier 1 calculation methods (IPPC, 2006)
Organic fertiliser (e.g. Manure)	Impacts from the use of organic fertilisers were calculated per hectare of agricultural land using FAO national data for total nitrogen applied and total N_2O emissions (based on IPCC Tier 1 calculation methods (IPPC, 2006)). Organic fertilisers are assumed to have no GHG emissions from production as this is borne by the system that produced it.
Crop residues	GHG emissions from crop residues calculated following IPCC Tier 1 (IPPC, 2006) using FAO national data.
Biogenic carbon sequestration (reported separately in line with GHGP guidance)	 Only changes in soil organic carbon are considered, based on: Canada: Regional averages for all cropland (no crop specific data available), based on modelling used for national GHG inventory reporting, covering the period 2001 – 2011 (AAFC, 2016). France: EU soil monitoring programme, based on an EU wide sampling network and modelling, providing national averages for all cropland (no crop specific data available) only the change between 2009 and 2015 (Panagos et al, 2020).

5.4.2.2 Biogenic carbon sequestration

Biogenic carbon in crop

Biogenic carbon, is carbon contained in biological sources such as plants, trees, and soils, and represents a net removal of carbon dioxide from the atmosphere. For crops which are harvested and subsequently removed from the land, the net change of carbon dioxide in the atmosphere for carbon contained in the harvested crop can be considered to be zero, as the carbon is returned to the atmosphere when the crop it is consumed or combusted.

In contrast, biogenic carbon sequestration refers to the long-term removal of carbon from the atmosphere, for example in trees and soils.

Land management / field practices

Land management techniques such as the use of no-till¹ and conservation tillage² practices have the potential to preserve and increase soil organic matter (SOM) storage in the soil and thus increase soil organic carbon, resulting in a net uptake of carbon from the atmosphere over the long term. Over time, SOM builds up in the soil until a steady-state level of soil organic carbon (SOC) is reached. At this point, new organic carbon additions to the soil are balanced by losses of organic carbon because of decomposition and erosion, and there is no further significant net uptake of carbon to the soil (McConkey et. al., 2017).

Over the past 30 years, substantial increases of SOC have been identified on cropland in Canada through the adoption of no-till practices, particularly in the Prairies region³. These increases are attributed to the fact that those soils were degraded due to frequent bare fallow and intensive tillage during most of the 20th Century, which have been restored though the use of no-till practices (McConkey et. al., 2017). The increased uptake of no-till has been made possible by the availability of effective crop protection products, to remove weeds and disease, and planting equipment that can

¹ No-till: Procedure by which a crop is planted directly into the soil using a special planter, with no primary or secondary tillage after harvest of the previous crop.

² Conservation tillage: Any tillage sequence designed to minimize or reduce the loss of soil and water; operationally, a tillage or tillage and planting system that leaves 30% or more crop residue cover on the soil surface.

³ Alberta, Saskatchewan and Manitoba.

effectively seed through crop residue on the soil surface (Agriculture and Agri-Food Canada (AAFC), 2016).

However, there are several key factors which can determine how SOC in cropland soils change with the adoption of no-till practices. This means there can be significant uncertainty in assessing the magnitude of biogenic carbon sequestration as SOC at a national level. These key factors include:

- Soil depth: Assessments of SOC in agricultural soils have tended to focus on top 30 cm of the soil profile. No-till agriculture increases SOC in shallow soil horizons compared to conventional tillage systems. However, conventional systems may have larger stores of SOC in deeper soil horizons than with no-till systems, such that increases in SOC seen in shallow horizons under no-till can be reduced or negated when the whole soil profile is considered (Ogle, S.M., Alsaker, C., Baldock, J. et al., 2019), (Haddaway, N.R., Hedlund, K., Jackson, L.E. et al., 2018).
- Climate: Changes in SOC in soils under no-till are variable in different climates. In many wet and cool climates, no increase in SOC is observed when no-till is adopted in the place of conventional tillage systems, with only differences in SOC distribution in the soil profile observed (B.C. Liang, et. al., 2020).
- Soil type: Changes in SOC are variable with soil type, with coarse / sandy soils showing larger increases in the Prairie provinces in Canada (B.C. Liang, et. al., 2020). However, in wider studies, finer soils have been shown to have greater increases in SOC, depending on the climate conditions (Ogle et al, 2019).
- Duration: As organic carbon accumulates in the soil, the rate of net accumulation will slow as it approaches a new equilibrium. The time taken for this to occur can vary significantly depending on the type and condition of the soil, but time periods between 20 50 years are not uncommon (Liang et al, 2020).
- N₂O emissions from soil: Increases in SOM, by adding more carbon and nitrogen to the soil, may impact nitrification / denitrification processes, potentially leading to changes in N₂O emissions from the soil (Guenet et al, 2020). However even with a small increase in N₂O emissions, given the higher global warming potential of N₂O, this has the potential to reduce or negate the net effect on global warming that would otherwise be achieved with increased SOC. the increase flux of greenhouse gases. These N₂O emissions will however also be influenced by factors such as soil type and climate; in a recent Canadian study, little or no change is seen in N₂O emission in well aerated soils, while higher emission levels are seen when no-till practices are used in humid and poorly aerated soils (B.C. Liang, et. al., 2020).

It should however also be noted other recent studies show that no-till agriculture does have the potential to lower N₂O emissions in some conditions. Plaza-Bonilla et. al., (2018) showed that in Mediterranean rain-fed conditions, data over an 18 year period showed that no-till practices increased barley grain yields compared to conventional tillage; while Moreover, soil N₂O emissions (per unit grain yield) for the same period were 2.8 to 3.3 times lower under no-till compared to conventional tillage.

From the data available, there is a clear indication that no-till practices do have an impact on carbon sequestration in soils, and that impact can be both negative and positive, depending on the agronomic and climatic factors. Further research in this area may be helpful to fully understand the implications and maximise the use of no-till in those climatic regions where a positive benefit can be seen.

It should however also be noted that, no-till and conservation tillage practices can provide other potential benefits, other than the accumulation of SOC for the soil and these benefits also need to be taken into account. These include; improved infiltration, water-holding capacity, erosion reduction, nutrient cycling and soil biodiversity. These can increase yields and provide other environmental benefits.

5.4.2.3 Direct land use change (dLUC)

The impact from direct land use change (dLUC), where carbon is released to the atmosphere from long term storage in soil and biomass of non-agricultural land (such as forests or grasslands) when the land is converted to agricultural land, have not been assessed in the calculation. FAO data for the change in cropland areas between 1980 and 2018, in both France and Canada show that the total area cultivated has remained relatively stable over the period and GHG emissions from dLUC for specific crops are likely to be minimal.

Additionally, for this study, the principal aim is to compare how the difference in the use of crop protection chemicals and genetically modified crops between Canada and the EU may impact the sustainability of crop production. Therefore, including GHG emissions associated with direct land use change would not provide as clear a comparison between the regulatory regimes for crop protection technologies between the EU and Canada.

5.4.3 Land Use

Land use should be calculated on the basis of area sown rather than area harvested, to account for the total area of land occupied by the crop and the potential that natural habitats will be lost. However, values for the sown area are not available for France and so land use for all crops has been calculated based on harvested area in both countries.

Year to year variations in the land area for a crop may not have an impact on natural habitats as they can be influenced by other factors including international prices, policies and programmes, and demand for land for other crops or purposes. However, should land area required for crops increase this may have an impact on natural habitats or limit the potential for the industries around the crop to expand and be competitive.

With increased land use requirements there is also the potential to increase GHG emissions from dLUC (see section above) in order to maintain the same level of production.

5.4.4 Data

No primary data was collected for this assessment this project. All data were taken from secondary data sources. Table 5 provides a summary of the data sources for each crop and the years covered by the data.

The key data gaps identified were crop specific data for the amount fertiliser applied in each year. The data selected for fertiliser application represent either the results of surveys or agricultural censuses or detailed modelling undertaken by organisations such as the International Fertilizer association (IFA), which are undertaken approximately every 4-5 years. Given the significance of fertiliser inputs on GHG emissions, these data have not been interpolated between available data points, so results for the GHG emissions are only shown for the year in which crop specific fertiliser data were available.

Table 5: Data sources for data used in modelling

Data	Canada	Canada			France			
Сгор	Maize	Rapeseed	Wheat	Maize	Rapeseed	Wheat		
Seeds	FAO Publicat	tion (same assumption	on for all years)	FAO Publication (same	e assumption for all ye	ears)		
Crop areas & production volumes	Statistics Car	Statistics Canada (2000 - 2017)			FAOStat (2000 - 2017)			
Farm operations:	Ecoinvent (20	Ecoinvent (2000 - 2017)			7)			
Farm operations: Area under no- till	Statistics Canada (2001, 2006, 2011 & 2016)			Agricultural census for France (2001, 2006, & 2011) - assumed no change after 2011				
Crop protection chemical use	FAOStat (2000 - 2017)		FAOStat (2000 - 2017)					
Inorganic fertiliser input (nutrients)		007, 2010 & 2014) 2005 & 2008-2009) ants (2000)	IFA (2006, 2007, 2010 & 2014) S&T Consultants (2000)	Agricultural census for France (2001, 2006, 2011 & 2017) WFM (2000,2002 - 2005 & 2007-2010)	Agricultural census for France (2001, 2006, 2011 & 2017) FertiStat (2000)	Agricultural census for France (2001, 2006, 2011 & 2017)		
Organic fertiliser nitrogen inputs	FAOStat (200	00 - 2017)		FAOStat (2000 - 2017)				
Crop residues	FAOStat (2000 - 2017)			FAOStat (2000 - 2017)				
Biogenic carbon: SOC change	AAFC, 2016			(Panagos, 2020)				

Key:

- FAO Publication: Technical Conversion Factors for Agricultural Commodities, FAO (2000)
- FAOStat: Food & Agriculture Organization of the United Nations Statistics Division FAO (2020)
- Statistics Canada: Canadian government data available from (https://www150.statcan.gc.ca/n1/en/type/data) including annual data and Agricultural census data from 2001, 2006, 2011 & 2016)
- Agricultural census for France: French government data from French Agricultural census contained in documents; Enquête sur les pratiques culturales and Pratiques culturales from 2001, 2006, 2011 and 2017.
- IFA: International Fertilizers Association total fertiliser use by crop for major countries / regions from 2006, 2007, 2010 and 2014.
- WFM: World Fertilizer Model Fertilizer Use by Crop at the Country Level (1990-2010), Rosas (2012).
- Ecoinvent: Ecoinvent version 3 Wernet et al (2016) The ecoinvent database version 3 (part I): overview and methodology. The International Journal of Life Cycle Assessment, [online] 21(9), pp.1218–1230
- S&T Consultants: Research undertaken by S&T Consultants: Lifecycle analysis canola biodiesel (2010) & Biodiesel GHG emissions using GHGenius –an Update (2005).
- Agriculture and Agri-Food Canada (AAFC) (2016) Environmental Sustainability of Canadian Agriculture: Agri-Environmental Indicators Report Series - Report 4

5.4.5 Results: GHG Emission

The results for each crop are presented in the sections below. These provide a comparison of production of the crops in each country. Absolute differences in the impact between countries for each crop are highlighted and the relative change in environmental impact for each crop over time are compared.

As the amount of fertilisers used each year, particularly nitrogen (N) fertilisers, are the key driver of the annual GHG emissions for each crop, results are only presented for year in which adequate data for fertiliser application were available (see Section 5.4.4 above). As no crop specific data for fertiliser use is available for Canada after 2014, all direct comparisons between France and Canada only cover the period 2000 – 2014.

The impact of biogenic carbon removals / emissions through the change of SOC on cropland is addressed separately in Section 5.4.5.4.

5.4.5.1 Rapeseed

Figure 11 shows the GHG emissions from the production of rapeseed split by life cycle stage for each year that crop specific fertiliser data is available over the period 2000 – 2017. The following are evident:

- GHG emissions per kg of rapeseed produced in France were larger than Canada over the period 2000 2010, with a maximum of 1.03 kgCO2-eq/kg in 2001. However, from 2011 this had reduced to 0.81 kgCO2-eq and by 2017 was 0.73 kgCO2-eq, a value similar to rapeseed produced in Canada in 2014.
- GHG emissions per kg of rapeseed produced in Canada have remained fairly constant, at approximately 0.7 kg CO₂-eq / kg, through the period 2000 -2014. However, with substantially lower values in 2005 (0.56 kgCO₂-eq/kg), 2008 (0.58 kgCO₂-eq/kg) and 2009 (0.52 kgCO₂-eq/kg). These lower values correspond to increased yields in those years compared to previous years.

The decrease in the GHG emissions for rapeseed production in France are largely driven by the increasing yields over the period, rising from an average of approximately 3100 kg/ha (2000 - 2004) to approximately 3400 kg / ha over the period (2010 - 2014).

Table 6 also shows that yields in Canada have also increased significantly over this period, from an average of approximately 1400 kg/ha (2000 - 2004) to approximately 2200 kg / ha over the period (2010 - 2014). However, during this time inputs of nitrogen fertiliser have also increased from an average of 63 kg N / ha (2000-2004) to 123 kg N / ha by 2014. This trend can be clearly seen in Figure 12, where from 2010 N-inputs in Canada increase broadly in line with increasing yields, but in France N-inputs are largely stable while yields are increasing.

For Canada, this means that reductions in the GHG emissions per kg of rapeseed produced, as a result of increased yields, are largely offset by increased application of nitrogen fertilisers, particularly inorganic nitrogen fertilisers (approximately 75% increase between 2000 and 2014). Conversely, in France, a modest percentage increase in yields (approx. 10% between 2000 and 2014) has resulted in a decrease in GHG emissions as nitrogen inputs have remained relatively stable.

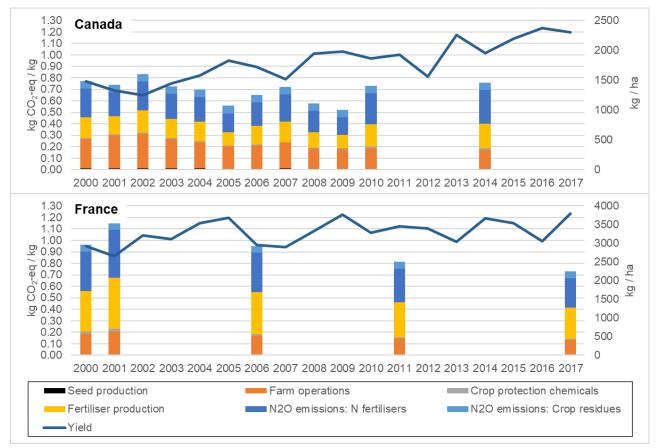


Figure 11: GHG emissions per kg of rapeseed split by life cycle stage (1° axis) with yield data (2° axis) for France and Canada over period 2000 - 2017

Table 6: Comparisons of 5 year averages for GHG emissions, yield and total nitrogen (N) input for rapeseed in Canada and France

Canada			France				
	2000- 2004	2010 - 2014	% change		2000- 2004	2010 - 2014	% change
Total N Input (kg/ha)	62	109	75%	Total N Input (kg/ha)	166	162	-2%
Yield (kg/ ha)	1420	1910	35%	Yield (kg/ ha)	3090	3370	9%
GHG emissions (kg CO ₂ -eq/kg)	0.75	0.74	-1%	GHG emissions (kg CO ₂ -eq/kg)	1.05	0.81	-23%

2010-2014 – comparison of Canada and France						
	Canada France Canada (as % of France)					
Total N Input (kg/ha)	109	162	67%			
Yield (kg/ ha)	1910	3370	57%			
GHG emissions (kg CO2-eq/kg)	0.74	0.81	91%			

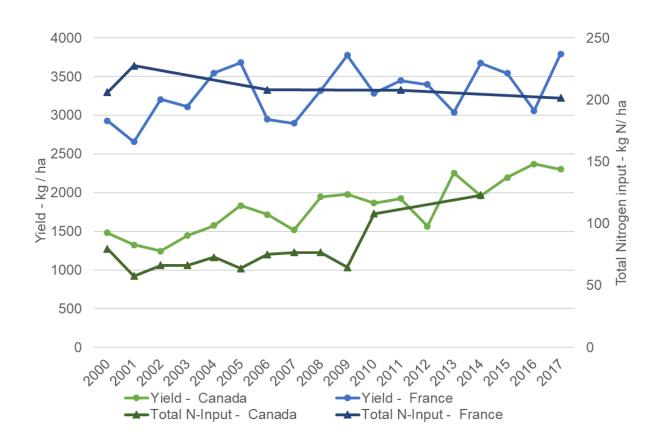


Figure 12: Total nitrogen inputs and yield of rapeseed for France and Canada: 2000 - 2017

5.4.5.2 Maize

Figure 13 shows the GHG emissions from the production of maize split by life cycle stage for each year that crop specific fertiliser data is available for over the period 2000 – 2017. The following are evident:

- GHG emissions per kg of maize produced in France were larger than Canada over the whole period studied, ranging from 0.4 kgCO₂-eq/kg in 2003 to 0.28 kgCO₂-eq/kg in 2011 and 2017.
- In Canada GHG emissions per kg of maize ranged from 0.32 kgCO₂-eq/kg in 2000 to a low of 0.20 kgCO₂-eq/kg in 2008.
- Yields of maize have increased significantly in Canada from 6,280 kg/ha in 2000 to 10,000 kg/ha in 2017, while yields in France have generally increased more gradually to consistently average approximately 9,000 kg/ha, with a maximum of 10,100 kg/ha achieved in 2017.
- Production of fertilisers and N₂O emissions from application of nitrogen in fertilisers account for approximately 65% of the GHG emissions for maize produced in both Canada and France. This proportion is approximately across all years calculated from 2000 – 2017.

Table 7 shows that the 5 year average annual GHG emissions for maize production decreased between 2000 and 2014 by a similar proportion in both Canada (-18%) and France (-14%). In Canada, this decrease was a result of increasing yields (+30%) with inputs of N increasing too (+15%). In France, there were lower increases in yields (+8%) and total N inputs were reduced by approximately 5%, resulting in a decrease in the GHG emissions from maize production in France of a similar magnitude to Canada.

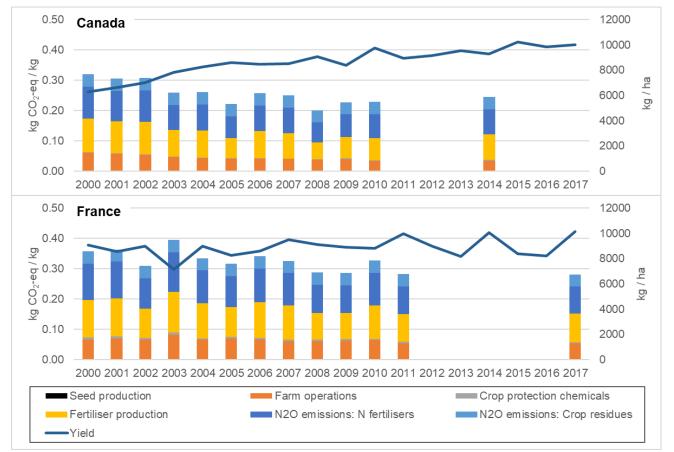


Figure 13: GHG emissions per kg of maize split by life cycle stage (1° axis) with yield data (2° axis) for France and Canada over period 2000 - 2017

Table 7: Comparisons of 5-year averages for GHG emissions, yield and total nitrogen (N) input for maize in Canada and France

Canada			France				
	2000 - 2004	2010 - 2014	% change		2000 - 2004	2010 - 2014	% change
Total N Input (kg/ha)	146	167	15%	Total N Input (kg/ha)	200	189	-5%
Yield (kg/ ha)	7195	9336	30%	Yield (kg/ ha)	8553	9202	8%
GHG emissions (kg CO ₂ -eq/kg)	0.29	0.24	-18%	GHG emissions (kg CO ₂ -eq/kg)	0.35	0.30	-14%

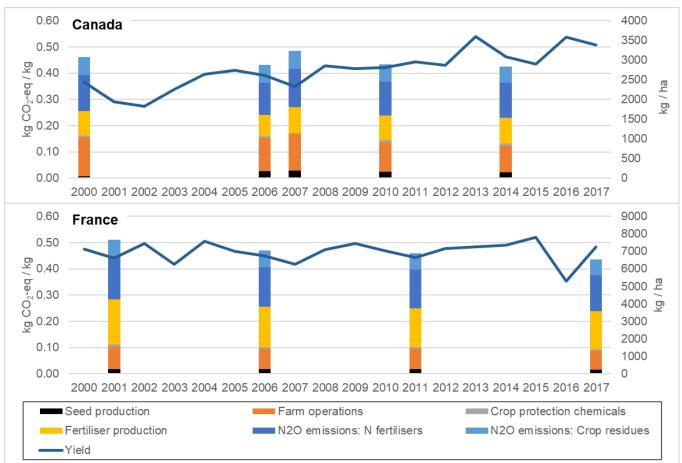
2010-2014 – comparison of Canada and France						
	Canada France Canada (as % of France)					
Total N Input (kg/ha)	167	189	88%			
Yield (kg/ ha)	9336	9202	101%			
GHG emissions (kg CO2-eq/kg)	0.24	0.30	80%			

5.4.5.3 Wheat

Figure 14 shows the GHG emissions from the production of wheat split by life cycle stage for each year that crop specific fertiliser data is available for over the period 2000 - 2017. The following are evident:

- Only limited crop specific annual data for fertiliser use for wheat in Canada (5 years) and France (4 years) were available for the period studied.
- GHG emissions per kg of wheat produced in France were similar but typically larger than Canada over the whole period studied, ranging from 0.51 kgCO₂-eq/kg in 2001 to 0.44 kgCO₂-eq/kg in 2017.
- In Canada GHG emissions per kg of maize ranged from a maximum of 0.49 kgCO₂-eq/kg in 2007 to a low of 0.43 kgCO₂-eq/kg in 2010.
- Yields of wheat have increased significantly in Canada from 2,240 kg/ha in 2000 to 3,380 kg/ha in 2017, while yields in France have remained relatively stable at approximately 7,000 kg/ha.
- Production of fertilisers and N₂O emissions from application of nitrogen in fertilisers account for approximately 50% of the annual GHG emissions for wheat produced in Canada and 65% France. These proportions are approximately constant in each country across all years calculated from 2000 – 2017.

Figure 14: GHG emissions per kg of wheat split by life cycle stage (1° axis) with yield data (2° axis) for France and Canada over period 2000 - 2017



Canada			France				
	2000 - 2004	2010 - 2014	% change		2000 - 2004	2010 - 2014	% change
Total N Input (kg/ha)	72	82	15%	Total N Input (kg/ha)	224	200	-11%
Yield (kg/ ha)	2224	3064	38%	Yield (kg/ ha)	7002	7093	1%
GHG emissions (kg CO ₂ -eq/kg)	0.46	0.43	-7%	GHG emissions (kg CO ₂ -eq/kg)	0.51	0.46	-10%

Table 8: Comparisons of 5 year averages for GHG emissions, yield and total nitrogen (N) input for wheat in Canada and France

2010-2014 – comparison of Canada and France						
	Canada France Canada (as % of France)					
Total N Input (kg/ha)	82	200	41%			
Yield (kg/ ha)	3064	7093	43%			
GHG emissions (kg CO2-eq/kg)	0.43	0.46	93%			

Table 8 shows that the 5 year average annual GHG emissions for wheat production decreased between 2000 and 2014 in by a similar proportion in both Canada (-7%) and France (-10%). In Canada, this decrease was a result of increasing yields (+38%) with inputs of N also increasing (+15%). In France, yields were broadly stable but there was a decrease in total N inputs (-11%) and so the decrease in the GHG emissions from wheat production in France was of a similar magnitude to Canada.

5.4.5.4 Biogenic carbon: Impact of changes in soil organic carbon (SOC)

As discussed in Section 5.4.2.2, the change from conventional tillage to no-till and conservation tillage practices is credited with increasing SOC in cropland soils in Canada, particularly in the prairie regions. These practices have been widely adopted due to the favourable climate conditions and the need to address soil degradation due to frequent bare fallow and intensive tillage during most of the 20th Century.

Tillage practices

Figure 15 presents the change in distribution of cropland under conventional, conservation or no-till at a national level for Canada and France (national level data unavailable for France in 2001 and 2006). Further to this, data is available at a provincial / regional level for Canada and on a crop specific basis for France. In this study, data for the Prairie provinces has been used to represent methods used for wheat and rapeseed cultivation in Canada, and the Central provinces has been used to represent production of maize. This is because 95% of those crops are produced in these areas.

Figure 15 shows that that no-till and conservation tillage are much more prevalent in Canada than France and the area under no-till in Canada has increased substantially from 31% in 2001 to 61% in 2016. This increase is largely driven by the adoption of no-till practices in the Prairies provinces. In France conventional tillage practices dominate and the use of no-till agriculture is limited, only rising to approx. 6% of cultivated land by 2016. However, conservation tillage techniques are used on approximately 40% - 45% of cultivated land. No-till practices rely on the use of crop protection products, the use of which has increased in Canada over the period 2000 - 2018, while it has remained largely stable in France.



Figure 15: Percentage of total cropland under conventional, conservation or no-till tillage practices in France (by crop) and Canada (by region) over the period 2001 - 2016

Notes:

Prairies = Alberta, Saskatchewan and Manitoba. >95% of wheat and rapeseed grown in Canada is grown in these provinces. Central = Ontario and Quebec. >95% of maize grown in Canada is grown in these provinces.

Change in SOC

Data used for the average change in SOC per year on cropland in Canada and France is shown in Table 9. The methods used to produce the data are different. Data for Canada are modelled outputs for the whole of Canada and results are available for each province. Data for France are based on field measurements taken from across France and scaled to produce a representative average for France. The change in SOC has been converted into emissions / removals of GHG per year, on a per hectare basis. These data provide estimates of the change in SOC due to all factors and not just the tillage practices used.

	ΔSOC (kg C ha ⁻¹ yr ¹)	$\Delta CO_2 - eq \ (kg \ CO_2 \ ha^{-1} \ yr^{-1})$	Period covered			
Canada Prairie provinces ⁴	97	356	0000 0011			
Canada Central provinces ⁵	-115	-422	2006 - 2011			
France ** (National data)	7.4	27	2009 - 2015			

Table 9: Average annual change in SOC and GHG emissions/removals from cropland in Canada and France

** French data based on change in SOC of 859.2 thousand tonnes over the period 2009 - 2015 and an average cropland area of 19.3 million hectares.

Table 9 shows that SOC is increasing in the Prairie provinces at a rate which is an order of magnitude greater than France. The increases calculated for the Prairie provinces are primarily a result of

⁴ Alberta, Saskatchewan and Manitoba.

⁵ Ontario and Quebec

reductions in tillage and summer fallow, with an increased use of crop protection chemicals to control weeds and disease (Agriculture and Agri-Food Canada (AAFC), 2016).

Conversely, SOC in Canada (Central provinces) is decreasing, resulting in net emissions of GHG to the atmosphere, of a similar magnitude to the to the increase in SOC in soils in the Prairie provinces. The overall losses of SOC seen in the Central provinces are primarily due to the conversion of hayland and pasture to annual crops and does not give a clear comparison of conventional tillage and no-till practices (Agriculture and Agri-Food Canada (AAFC), 2016).

Change in SOC through adoption of no-till in Canada

B.C. Liang, et. al., (2020) completed a review of studies to assess the impact of switching from conventional tillage to no-till in Canada. Their analysis suggests a clear benefit from the use of no-till practices in the Prairie provinces in Western Canada. However, it is not clear that the adoption of no-till agriculture in the cooler and wetter, Central and Eastern provinces in Canada does result in significant accumulation of SOC as it does in the Prairie provinces. No equivalent study is available for France and so this section focuses on the available data for Canada, where no-till is practiced more widely.

Table 10 presents the change in SOC after the change to no-till practices in Western and Eastern Canada for different study durations. It shows that the largest increases in SOC are in Prairie provinces up to 10 years after the change to no-till and the rate of increases slower thereafter. As discussed in Section 5.4.2.2 the increases in SOC slows over time as the soils move towards a new equilibrium state. The increases in SOC beyond 10 years are approximately twice as much in the Prairie provinces as Eastern Canada. However, Table 10 also shows a significant likelihood that SOC will reduce on cropland in Central and Eastern provinces, within the first decade of no-till being established, with and average reduction in SOC of 470 kg C ha⁻¹ yr⁻¹ (B.C. Liang, et. al., 2020).

This difference may be explained by the different tillage practices used in Prairie provinces and Eastern Canada. In Eastern Canada, full inversion tillage is typically utilised and in the wetter environment, the inversion of organic material in the soil can result in the increase of SOC at depth. This may be lost following the conversion to no-till practices at a rate which is quicker than the accumulation in the shallow soil depths. Thus, resulting in a net loss to the soil profile in the initial years after conversion.

The values for the change in SOC from studies with a duration of 20 years or more are used in the following section to assess the potential impact on GHG emissions per kg of crop produced. However, it should be noted that the number of studies included in the meta analysis is still relatively small, but this is to be expected given the resources and time required to establish such studies.

Study duration (yr)	Western Canada (Prairie provinces) ΔSOC (kg C ha ⁻¹ yr ⁻¹)	Eastern & Central Canada ΔSOC (kg C ha ⁻¹ yr ⁻¹)
3 – 10	740 (+/- 220)	-470 (+/- 410)
	n =11	n = 13
11 – 20	260 (+/- 50)	130 (+/- 120)
	n = 14	n = 15
> 20	95 (+/- 40)	40 (+/- 80)
	n = 9	n = 4

Table 10: Average annual change in SOC with no-till under different durations of experimental period in Eastern and Western Canada (adapted from (B.C. Liang, et. al., 2020))

Note: n = number of observations

Impact of SOC change on crop GHG emissions

The total change in SOC per ha observed / modelled for Canada and France and the change in SOC under no till assessed for Canada, were converted to $kgCO_2$ -eq / kg of each crop produced (based on the 2010 – 2014 averages), to show the potential impact on the net GHG emissions from long term biogenic carbon sequestration. The period 2010 – 2014 has been selected as it covers the period used in the data for Canada and France.

Figure 16 presents the 2010 - 2014 average with no change to SOC considered and the impact on GHG emissions with average SOC increases.

The following are evident:

- Based on national / regional monitoring of SOC in agricultural soils, including SOC uptake reduces GHG emissions per kg of rapeseed and wheat produced in Canada by approximately 25% compared to an approximate 1% reduction in impact for production in France. With this decrease, the impact per kg of rapeseed or wheat is 31% lower than when the crop is produced in France, compared to approximately 8% reduction when SOC change is not considered.
- Impact for maize produced in Canada increases by 19%, compared to a 1% decrease in France, when national / regional SOC data are assessed. This is attributed to the decreases in SOC estimated for the Central provinces in Canada, primarily due to the impact of land use conversion from pasture to annual crops. However, even with this increase in impact the GHG emissions per kg of maize produced are still 6% lower than production in France.
- Based on a limited number of long term studies, reductions in GHG emissions per kg of rapeseed (-24%) and wheat (-25%) produced in Canada may be achieved through SOC uptake as a result of the adoption of no-till cultivation in the Prairie provinces. These are similar to the results observed / modelled from regional analysis of SOC.
- Long-term studies of no-till agriculture in Eastern Canada show the potential for smaller increases than identified for the Prairie provinces through adoption of no-till agriculture. The impact of this is a 6.6% reduction in the GHG emissions from maize production in Eastern Canada. This suggests that other land use changes are the main driver for the reduction in SOC in cropland soils observed in the regional soil data for Eastern Canada.

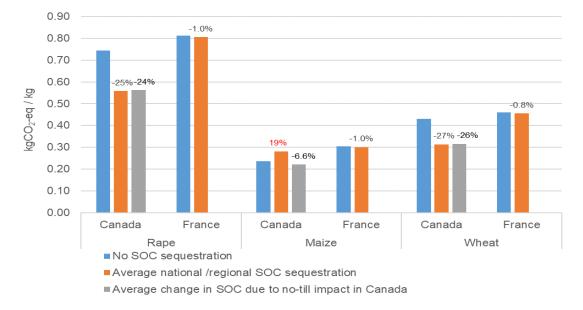
There is almost no change in the impact for crops produced in France (<1%). As the assessment of SOC for France is provided at a national level and does not identify the specific factors influencing the changes seen, such as the impact that adoption of no-till practices may have, it is possible that there are significant regional variations in SOC changes, which could result in different impacts for each of the three crops.

The uptake of herbicide tolerant crops has clearly been an important driver in the adoption of no-till practices. The lower rates of no-till agriculture seen in France may however also be due to the difference in the climate and soil conditions, compared to the Prairie provinces, which make the use no-till less favourable.

It should be noted that the climate and soil conditions in the Prairie provinces appear to favour the adoption of no-till agriculture and that this can lead to increased SOC. No-till agriculture promotes beneficial soil functions such as moisture retention, in the semi-arid climate of the Canadian Prairies, and changes in agricultural practices have been required to mitigate historic degradation of the SOC. However, increases in SOC will not increase indefinitely. The rate of increase should decrease over time until a new equilibrium is reached, subject to other changes in land management and the climate.

In addition as noted in Section 5.4.2.2, there are other uncertainties relating to the change in SOC across deeper soil horizon, the influence of increased SOC on N_2O emissions which could alter the magnitude of this impact.

Figure 16: Average GHG emissions for the production of 1 kg of crop with impact of SOC sequestration / losses and without for the period 2010-2014 (% change from including the impact of SOC changes also shown)



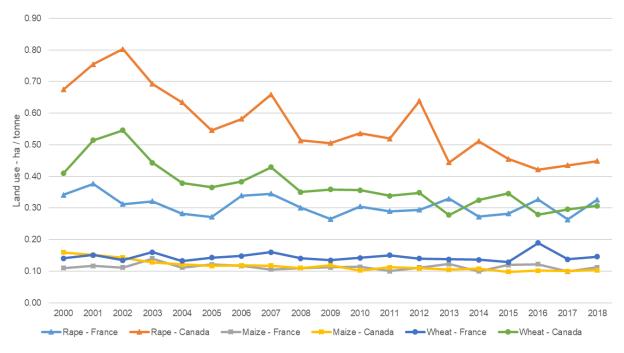
5.4.6 Results: Land Use

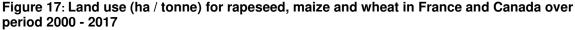
Figure 17 shows the land required to produce one tonne of rapeseed, maize and wheat in France and Canada over the period 2000 - 2018. This is the inverse of the yield and so the larger the yield the lower the land use requirement. The following are evident from Figure 17:

- The yield of rapeseed in Canada is substantially lower than in France and so land use requirement for rapeseed are greater in Canada. However, this gap has closed from a difference of approximately 0.3 ha / tonne in 2000 to approximately 0.15 ha / tonne by 2017.
- Land use for maize is very similar in Canada and France, at approximately 0.1 ha / tonne.
- In France the land use for wheat has remained stable at approximately 0.15 ha / tonne throughout the period, but in Canada it has decreased over time from 0.4 ha/tonne in 2000 to 0.3 ha / tonne in 2018.

These results show that rapeseed and wheat, almost exclusively produced in the Prairie Provinces of Canada, require significantly more land to produce the same output as in France. However, this land requirement has decreased substantially from 2000 to 2018 as a result of changes in farming practices, including increasing use of no-till practices supported by increased application of nitrogen fertilisers.

These increasing yields mean that it has been possible to increase production of rapeseed and wheat in Canada, without significantly impacting forests, grasslands and marginal lands which could be developed into natural habitats. Furthermore, by limiting the expansion of cropland, potentially significant GHG emissions from direct land use change of forest and grasslands to cropland are also avoided.





5.4.7 Results – Summary

The results of the GHG emissions assessment and land use assessment show the following general themes for the three crops in each country over the period of study:

Canada

- Yields of rapeseed, maize and wheat have been increasing consistently in Canada as a result of changes in farming practices (eg. adoption of no-till agriculture) supported by increases in fertiliser applications.
- The intensification of cultivation, with associated higher yields, has led to significant reductions in the GHG emissions per kg produced for maize (approx. -18%) and wheat (approx. -7%).
- GHG emissions from the production of rapeseed have not changed significantly over the period 2000 -2014, as the increased nitrogen fertiliser applications (+75%) have largely offset the benefit of the increased yield to reduce the impact from farm operations etc.
- When changes to SOC carbon are included, the net GHG emissions for wheat and rapeseed (predominantly produced in the Prairie provinces) is reduced by up to 25% for the period 2010
 2014. This is primarily a result of the prevalence of no-till agriculture.
- SOC has been shown to be decreasing in Central provinces cropland, primarily due to the conversion of hayland and pasture to annual crops, but the potential for increases in SOC due to no-till agriculture are also likely to be less than seen in the Prairie provinces. This decrease translates into a 19% increase in GHG emissions maize, compared to excluding SOC changes.
- Use of no-till agriculture can also have other benefits, such as; improved infiltration, waterholding capacity, erosion reduction and nutrient cycling, which can have a positive impact on yields, in areas with the appropriate climate and soil type, such as the Prairie provinces.
- Increased yields of rapeseed, maize and wheat, have reduced the land area required to
 produce a tonne of output, providing the opportunity to produce more without needing to expand

agricultural land, with associated impacts on natural habitats and potential to release carbon stored in biomass and soil to the atmosphere.

France

- In France, over the period 2000 2017, farmers producing rapeseed and maize have typically achieved higher yields (approx. 10%) while applying the same or less nitrogen fertilisers (up to 5% less) resulting in a reduction in GHG emissions per kg of production.
- Yields for wheat have been largely static over the period 2000 2018. However, applications of nitrogen fertiliser have decreased by approximately 11% and so the GHG emissions per kg of production have also decreased.
- Evidence of significant changes in SOC in cropland soils in France is limited, at a national level.

The GHG emissions from the production of all three crops in Canada were lower than production in France over the period 2000 – 2014. However, yields were also typically lower than seen in France, with associated increased land use requirement.

Yields have consistently increased in Canada over the period, with increased inputs of fertilisers and changes in farm practices, such as the adoption of no-till agriculture. Conversely, in France yields have not changed to the same extent and inputs of nitrogen fertilisers, which have historically been high, have decreased, likely due to regulatory pressures (e.g. to limit and manage nitrogen fertiliser applications which contribute to water pollution issues across the EU) and potentially financial pressures.

Higher yields can also lead to lower GHG emissions per kg of crop produced, as GHG emissions from fixed inputs, such as on farm energy use are spread more widely, even with increased fertiliser inputs, provided that other limiting factors, such as water stress, pests and disease are avoided or mitigated through appropriate farm management practices.

Further benefits of higher input farming with higher yields are the ability to produce more with the same amount of land, removing the need to expand into natural habitats or disturb other land, which may contain significant stores of carbon, such as forests, or peat land. This is a particularly important issue when the impact of direct land use change is included in the GHG emissions.

6. CONCLUSIONS AND COMMENTARY

With a population of 450 million citizens, the EU is a major trading block and its policy decisions, especially in the area of agriculture and food products, has a significant impact on trade. This impacts the production technologies that can be used, not only within the EU, but also for those in third countries exporting to the EU.

For third countries who are looking to trade agricultural products with the EU, the move to the development of common EU policies (replacing national measures in 27 countries) has resulted in significant benefits, reducing the administrative burden of trade. This has especially been seen in the setting of Maximum Residue levels for plant protection products, where common EU standards are now in place – replacing the national based system that was in place until 2005.

However, the development of food safety legislation at the EU level has also led to more conservative policies where the use of chemicals and new technologies are being questioned and restricted. The EU's approach increases uncertainty for trading partners and this is most notable in the case of the approval of biotechnology traits and increasingly in the rules that apply to pesticides and the setting of restrictive MRLs.

With the restrictive policies in place, there is an internal European belief that its agricultural production methods are safer for the consumer and better for the environment – and that third countries need to make improvements to meet the EU standard. This viewpoint needs to be challenged. This paper sets out data that favourably compares production methods in Canada with that seen in the EU, with lower GHG emissions per tonne of production. At the same time, Canadian yields continue to increase with the adoption of new techniques – while European yields are flat to decreasing, due largely to the loss of crop protection solutions. The Canadian messages can and need to be communicated in Europe to promote a balance in the discussion and promote an understanding that the environmental footprint of Canadian production is similar or often more favourable than production in Europe.

The data on environmental footprint of agriculture also highlight that there is no 'one size fits all', and a range of available technologies and techniques are vital to support efficient production systems. The use of no-till is one such agricultural practice that can have significant benefits in terms of higher yields, greater soil protection and reduced greenhouse gas emissions. But those benefits do not appear to apply in all agronomic conditions – and maintaining a wide range of cropping techniques and crop protection solutions will help the farmer to optimise their cropping systems. The voice of the farmer is therefore vital to highlight the need for a range of solutions to maximise sustainability in agriculture production.

The voice of European farmers in food safety debates is one area that is often discussed. While European farmers clearly have an interest in their own productivity and profitability, much of their political advocacy worked is focused on a level playing field in the production methods. Listening to that debate in recent years, European farm leaders seem less interested in gaining better access to technologies, and instead rather fixated with imposing EU conditions on third country imports. The reasons for the position taken by European farmers is partly due to the fact that Europe is a significant importer – Canadian farmers would be badly served in taking such a position given the importance of technology for productivity to support continued export opportunities.

With the EU's food safety policies moving from national to EU based policies, this has created significant teething problems and often leads to disagreements with policy makers in the EU Member States. With multiple EU and national scientific agencies being involved in the discussions, scientific opinions do vary significantly. The scientific views of some can be seen to undermine the position of others, and this opens the door for greater political debates and challenges to the authority of these agencies. The new European model is very different to the model in place in most Anglo-Saxon countries where a single body is in charge of evaluations, decision-making and communication. The benefits of the single

agency model needs to be recognised, in providing a high level of efficiency and predictability in decision making, while also providing a much higher level of citizen trust.

The EU's food safety policies will continue to evolve and from the most recent discussion related to their 'Green Deal', the further changes now being planned are expected to further restrict the use of agricultural technologies in Europe – coupled with an effort to export those policies to exporting third countries. It will be vital that the governments and food industries in the exporting countries take part as active stakeholders in the EU process, focusing in particular on the sustainability of agricultural production systems in their own territories.

* *

7. REFERENCES

Agriculture and Agri-Food Canada (AAFC), 2016. Environmental Sustainability of Canadian Agriculture: Agri-Environmental Indicator Report Series – Report #4. [Online] Available at: https://www.agr.gc.ca/eng/agriculture-and-the-environment/agriculturalpractices/environmental-sustainability-of-canadian-agriculture-agri-environmental-indicator-reportseries-report-4/?id=1467307820931 Agrifoodtoday, 2019. Sbarchi di grano straniero, Confagricoltura contro Coldiretti: "Nessuna invasione dal Canada". [Online] Available at: https://www.agrifoodtoday.it/filiera/coldiretti-confagri-grano.html [Accessed October 2020]. B.C. Liang, et. al., 2020. Revisiting no-till's impact on soil organic carbon storage in Canada,. Soil and Tillage Research, 198(105529). Barilla Group, n.d. LA PROVENIENZA DEL GRANO DELLA PASTA BARILLA. [Online] Available at: https://www.barillagroup.com/it/la-provenienza-del-grano-della-pastabarilla#:~:text=Per%20i%20formati%20classici%20della,di%20ceneri%20(sali%20minerali). [Accessed October 2020]. Bazoche, P. et al., 2013. Willingness to pay for pesticide reduction in the EU: nothing but organic?. European Review of Agricultural Economics, 41(1), p. 87–109. Bazzan, G. & Migliorati, M., 2020. Expertise, politics and public opinion at the crossroads of the European Commission's decision-making: The case of Glyphosate. International Review of Public *Policy*, 2(1), pp. 68-89. BeeLife, 2020. BeeLife - European Beekeeping Coordination (Homepage). [Online] Available at: https://www.bee-life.eu/ [Accessed October 2020]. Bourguignon, Didier, 2015. The Precautionary Principle - Definitions, Applications and Guidance, s.l.: European Parliament. Bryant Christie Inc., 2017. Estimation of Potentially Affected Agricultural Imports Due to Hazard-Based Criteria in the EU Regulation of Plant Protection Products. [Online] Available at: ecpa.eu/sites/default/files/documents/Bryant%20Christie%20-%20Report%20-%20Estimation%20of%20Affected%20Imports%20-%20Hazard%20criteria.pdf [Accessed October 2020]. Cantley, M., 2012. European attitudes on the regulation of modern biotechnology and their consequences. GM Crops & Food, 3(1). Coldiretti, 2018. Pasta, stop Barilla al grano canadese al glifosato, s.l.: s.n. Confédération paysanne, 2017. COMMUNIQUE DE PRESSE: OGM cachés : 9 États et institutions européennes donnent leurs avis à la Cour de Justice Européenne. [Online] Available at: <u>http://www.confederationpaysanne.fr/rp_article.php?id=5769</u> [Accessed October 2020]. Conseil d'État (France), 2020. Certains organismes obtenus par mutagenèse doivent respecter la réglementation OGM. [Online] Available at: https://www.conseil-etat.fr/actualites/actualites/certains-organismes-obtenus-parmutagenese-doivent-respecter-la-reglementation-ogm [Accessed October 2020]. Corporate Europe Observatory, 2013. Pesticides against pollinators: Private letters reveal Syngenta and Bayer's furious lobbying against EU measures to save bees. [Online] Available at: https://corporateeurope.org/en/agribusiness/2013/04/pesticides-against-pollinators [Accessed October 2020]. Deutsche Welle, 2016. Glyphosate weed killer found in German beers, study finds. [Online] Available at: https://www.dw.com/en/glyphosate-weed-killer-found-in-german-beers-study-finds/a-19072785

[Accessed October 2020].

European Commission, 1996. Workshop Reports - European Workshop on the impact of endocrine disruptors on human health and wildlife, 2-4 December, 1996. [Online] [Accessed June 2020]. European Commission, 2000. White Paper on Food Safety - COM (1999) 719 final, Brussels: s.n. European Commission, 2006. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the placing of plant protection products on the market. [Online] Available at: https://eur-lex.europa.eu/legalcontent/EN/TXT/PDF/?uri=CELEX:52006PC0388&from=EN [Accessed June 2020]. European Commission, 2019. First Annual Forum on Endocrine Disruptors - Exchanging Knowledge, Identifying Challenges, Building Synergies. s.l., s.n. European Commission, 2019. The European Green Deal sets out how to make Europe the first climate-neutral continent by 2050, boosting the economy, improving people's health and quality of life, caring for nature, and leaving no one behind. [Online] Available at: https://ec.europa.eu/commission/presscorner/detail/e%20n/ip 19 6691 [Accessed June 2020]. European Commission, 2020. A European Green Deal - Timeline. [Online] Available at: https://ec.europa.eu/commission/presscorner/detail/e%20n/ip_19_6691 [Accessed June 2020]. European Commission, 2020. E-003947/2020 Answer given by Mr Wojciechowski on behalf of the European Commission. [Online] Available at: https://www.europarl.europa.eu/doceo/document/E-9-2020-003947-ASW EN.pdf [Accessed October 2020]. European Commission, 2020. Honey Market Presentation. [Online] Available at: https://ec.europa.eu/info/sites/info/files/food-farmingfisheries/animals and animal products/presentations/market-presentation-honey en.pdf [Accessed October 2020]. European Commission, 2020. Sustainable use of pesticides. [Online] Available at: https://ec.europa.eu/food/plant/pesticides/sustainable use pesticides en [Accessed 27 February 2020]. European Commission, n.d. *Emergency Authorisations*. [Online] Available at: https://ec.europa.eu/food/plant/pesticides/eu-pesticidesdatabase/ppp/pppeas/screen/home [Accessed October 2020]. European Commission, n.d. EU Pesticides database. [Online] Available at: https://ec.europa.eu/food/plant/pesticides/eu-pesticidesdatabase/public/?event=activesubstance.selection&language=EN [Accessed June 2020]. European Commission, n.d. EU Pesticides database - Search Active Substances. [Online] Available at: https://ec.europa.eu/food/plant/pesticides/eu-pesticidesdatabase/public/?event=activesubstance.selection&language=EN European Food Safety Authority, 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal, 11(7), p. 268 pp. European Food Safety Authority, 2019. Special Eurobarometer - April 2019 "Food Safety in the EU", s.l.: s.n. FAO, 2020. FAOSTAT. [Online] Available at: http://www.fao.org/faostat/en/#data Friends of the Earth Europe, 2013. Concerns About Glyphosate's Approval. [Online] Available at: https://www.foeeurope.org/sites/default/files/press releases/foee 2 concerns about glyphosate app roval.pdf [Accessed June 2020].

Gaskell, G. et al., 2010. *Europeans and Biotechnology in 2010 - Winds of Change?*, s.l.: European Commission.

Genetic Literacy Project, 2014. *EU "independent" bee task force chair plotted to blame neonicotinoids for deaths then cook research to fit PR plan, s.l.: s.n.*

Haddaway, N.R., Hedlund, K., Jackson, L.E. et al., 2018. How does tillage intensity affect soil organic carbon? A systematic review.. *Environ Evid*, 6(30).

Henry, M. e. a., 2012. A Common Pesticide Decreases Foraging Success and Survival in Honey Bees. *Science*, 336(6709), pp. 348-350.

Il Salvagente, 2020. *Torna il grano canadese nella pasta italiana (e l'incubo glifosato).* [Online] Available at: <u>https://ilsalvagente.it/2020/09/12/90775/</u>

[Accessed October 2020].

International Organization for Standardization (ISO), 2006. *ISO 14044:2006 - Environmental management — Life cycle assessment — Requirements and guidelines*. [Online]

Available at: https://www.iso.org/standard/38498.html

[Accessed June 2020].

IPPC, 2006. 2006 IPCC Guidelines for National Greenhouse Gas Inventories, Volume 4. [Online] [Accessed June 2020].

Keulemans, W., Bylemans, D. & De Coninck, B., 2019. *Farming Without Plant Protection Products - Can we grow without using herbicides, fungicides and insecticides?*, s.l.: Scientific Foresight Unit (STOA).

Kuntz, M., 2019. Has Europe lost the new biotechnology battle?. [Online]

Available at: <u>euractiv.com/section/agriculture-food/opinion/has-europe-lost-the-new-biotechnology-battle/</u>

[Accessed June 2020].

Le Monde, 2017. *Glyphosate : révélations sur les failles de l'expertise européenne*. [Online] Available at: <u>https://www.lemonde.fr/planete/article/2017/11/26/glyphosate-revelations-sur-les-failles-</u> de-l-expertise-europeenne 5220696 3244.html

[Accessed October 2020].

Les Echos, 2020. *Insecticides : le gouvernement fait marche arrière pour sauver la betterave*. [Online] Available at: <u>https://www.lesechos.fr/industrie-services/conso-distribution/le-gouvernement-reintroduit-</u>les-neonicotinoides-dans-la-culture-de-betterave-jusquen-2023-

<u>1229014#:~:text=Insecticides%20%3A%20le%20gouvernement%20fait%20marche%20arri%C3%A8r</u> <u>e%20pour%20sauver%2</u>

[Accessed October 2020].

Lezaun, J. & Groenleer, M., 2006. Food Control Emergencies and the Territorialization of the European Union. *Journal of European Integration*, 28(5), pp. 437-455.

McConkey et. al., 2017. *Monitoring, reporting, and verification of soil carbon sequestration on the cropland and grassland of Canada.* Rome, s.n.

Morvillo, M., 2020. Glyphosate Effect: Has the Glyphosate Controversy Affected the EU's Regulatory Epistemology?. *European Journal of Risk Regulation*, 1(14).

NFU, 2019. NFU's work on Chlorothalonil. [Online]

Available at: <u>https://www.nfuonline.com/cross-sector/science-and-technology/crop-protection/crop-protection/nfus-work-on-chlorothalonil/</u>

[Accessed March 2021].

Official Journal of the European Union, 2009. *REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009.* [Online]

Available at: https://eur-lex.europa.eu/legal-

<u>content/EN/TXT/HTML/?uri=CELEX:32009R1107&from=en#ntr1-L_2009309EN.01000101-E0001</u> [Accessed June 2020].

Ogle, S.M., Alsaker, C., Baldock, J. et al., 2019. Climate and Soil Characteristics Determine Where No-Till Management Can Store Carbon in Soils and Mitigate Greenhouse Gas Emissions.. *Sci Rep*, 9(11665).

Ogle, S. A. C. B. J. e. a., 2019. Climate and Soil Characteristics Determine Where No-Till Management Can Store Carbon in Soils and Mitigate Greenhouse Gas Emissions. *Sci Rep,* 9(11665). Panagos, P. B. C. S. S. B. P. L. E. a. M., 2020. *Soil related indicators to support agro-environmental policies,* s.l.: EUR 30090 EN, Publications Office of the European Union.

Phillips McDougall, 2013. *R&D trends for Chemical Crop Protection Products and the Position of the European Market - A consultancy study undertaken for ECPA*, s.l.: s.n.

Plaza-Bonilla et. al., 2018. No-tillage reduces long-term yield-scaled soil nitrous oxide emissions in rainfed Mediterranean agroecosystems: A field and modelling approach. *Agriculture Ecosystems & Environment,* Volume 262.

Punja, N., 2018. The impact of Regulation (EC) No1107/2009 on innovation and development of alternatives and new plant protection products, s.l.: European Parliament.

RTBF, 2020. Néonicotinoïdes: les betteraves belges recourent toujours à ces insecticides interdits par l'Europe. [Online]

Available at: <u>https://www.rtbf.be/info/societe/detail_neonicotinoides-les-betteraves-belges-recourent-toujours-a-ces-insecticides-interdits-par-l-europe?id=10441899</u>

[Accessed October 2020].

ScienceMag, 2018. France's decade-old effort to slash pesticide use failed. Will a new attempt succeed?, s.l.: s.n.

The Greens/EFA, 2016. WE ARE PISSED OFF! MEPs Test Positive for Glyphosate, s.l.: s.n. The Times, 2014. Scientists accused of plotting to get pesticides banned, s.l.: s.n.

University of Utrecht, 2011. *Slovenia bans neonicotinoids after massive bee deaths in Pomurje region*, s.l.: s.n.

USDA Foreign Agricultural Service, 2018. *Agricultural Biotechnology Annual - 2018 (GAIN Report Number: FR1827)*. [Online]

Available at:

https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?filename=Agricultural%20 Biotechnology%20Annual Paris EU-28 12-14-2018.pdf

[Accessed June 2020].

WeMove.EU, 2018. *Glyphosate: an emblematic failure of the EU pesticides regime.* [Online] Available at: <u>https://www.pan-europe.info/sites/pan-</u>

europe.info/files/20180411 letter pest committee.pdf

[Accessed June 2020].

Whitehorn, P. e. a., 2012. Neonicotinoid Pesticide Reduces Bumble Bee Colony Growth and Queen Production. *Science*, 336(6709), pp. 351-352.

World Health Organization - International Agency for Research on Cancer (IARC), 2015. *IARC Monographs Volume 112: Evaluation of five organophosphate insecticides and herbicides.* [Online] Available at: <u>https://www.iarc.fr/wp-content/uploads/2018/07/MonographVolume112-1.pdf</u>

[Accessed June 2020].

WRI; WBCSD, 2011. *Greenhouse Gas Protocol - Product Life Cycle Accounting and Reporting Standard.* [Online]

Available at: <u>https://ghgprotocol.org/sites/default/files/standards/Product-Life-Cycle-Accounting-Reporting-Standard_041613.pdf</u>

[Accessed June 2020].

WRI; WBCSD, 2011. *Greenhouse Gas Protocol - Product Life Cycle Accounting and Reporting Standard*, s.l.: s.n.

APPENDIX A ACTIVE SUBSTANCES NON-APPROVED IN EU; 2010-2020

Substance	Use Category	EU approval expiry	Approved in Canada	Area treated ('000 ha)
Cyclanilide	PG	2011		
Propargite	AC	2011		
Cinidon ethyl	HB	2012		
Bitertanol	FU	2013		
Didecyldimethylammonium chloride	FU	2013		
Flusilazole	FU	2013		
Carbendazim	FU	2014		
Cyfluthrin	IN, AC	2014		
Ethoxysulfuron	HB	2014		-
Fenbutatin oxide	AC HB	2014		
Molinate		2014 2014		
Oxadiargyl Warfarin (aka coumaphene)	HB			
loxynil	RO HB	2014 2015		-
Tepraloxydim	НВ	2015	YES	20
(Z)-13-Hexadecen-11-yn-1-yl acetate	AT	2015	163	20
(Z,Z,Z,Z)-7,13,16,19-Docosatetraen-1-yl isobutyrate	AT	2016		-
Amitrole (aminotriazole)	HB	2016		-
Isoproturon	НВ	2016		+
Triasulfuron	НВ	2016		
Fipronil	IN	2017		<u> </u>
Imazosulfuron	HB	2017		
Linuron	нв НВ	2017	YES	10
Maneb	FU	2017	123	10
Mecoprop	HB	2017		-
Picoxystrobin	FU	2017	YES	196
Spodoptera exigua nuclear polyhedrosis virus	IN	2017	163	190
Chloridazon (aka pyrazone)	HB	2017		
Flupyrsulfuron-methyl (DPX KE 459)	НВ	2018		
Imazaquin	PG	2018		-
Iprodione	FU, NE	2018	YES	78
Oxadiazon	HB		TES	/0
Propineb	FU	2018 2018		
Quinoclamine	AL,HB	2018		ł
Bacillus thuringiensis subsp. Tenebrionis strain NB-Others 176(TM 14 1)	IN	2018		ł
Bifenthrin	IN, AC	2019		
Chlorothalonil	FU	2019	YES	265
Chlorpropham	PG, HB	2019	123	200
Chlorsulfuron	HB	2019		
Clothianidin	IN	2019	YES	4956
Cyromazine	IN	2019	YES	n.a.
Difenacoum	RO	2019	120	11.a.
Diquat (dibromide)	HB, DE	2019		
Ethoprophos	NE, IN	2019		
Fenamidone	FU	2019	YES	86
Fenpropimorph	FU	2019	120	00
Flurtamone	HB	2019		
Glufosinate	HB	2019	YES	4646
Limestone		2019		10.70
Lufenuron	IN	2019		
Oxasulfuron	HB	2019		
Pepper dust extraction residue (PDER)	RE	2019		
Propiconazole	FU	2019	YES	1376
Pymetrozine	IN	2019	YES	n.a.
Quinoxyfen	FU	2019		
Quizalofop-P	HB	2019	YES	293
Repellents by smell of animal or plant origin/ tall oil crude	RE	2019		
Repellents by smell of animal or plant origin/ tall oil pitch	RE	2019		1
Sodium aluminium silicate	RE	2019		1
Sodium hypochlorite	BA	2019		1
Teflubenzuron	IN	2019		1
Tralkoxydim	HB	2019		1
Trimethylamine hydrochloride	AT	2019		
Benalaxyl	FU	2019		
Beta-Cyfluthrin	IN	2020	YES	n.a.
Bromoxynil	HB	2020	YES	7419
		2020	1 20	טודי

www.erm.com Version: FINAL Project No.: 0559610 Client: CropLife Canada

June 2021

\\ukldcfs01\Data\Brussels\Projects\0559610 CropLife International aisbl regu imp.EJ\Draft report\0559610_Evaluation of the European Regulatory Framework for Crop Protection Products Copy_V7.2.docx

Substance	Use Category	EU approval expiry	Approved in Canada	Area treated ('000 ha)
Chlorpyrifos	IN, AC	2020	YES	433
Chlorpyrifos-methyl	IN, AC	2020		
Denathonium benzoate	RE	2020		
Desmedipham	HB	2020		
Dimethoate	IN, AC	2020		
Epoxiconazole	FU	2020		
Ethametsulfuron-methyl	HB	2020		
Fenamiphos (aka phenamiphos)	NE	2020		
Haloxyfop-P (Haloxyfop-R)	HB	2020		
Imidacloprid	IN	2020	YES	375
Mancozeb	FU	2020	YES	1256
Methiocarb (aka mercaptodimethur)	IN, RE	2020		
Thiacloprid	IN	2020		
Thiophanate-methyl	FU	2020	YES	69
zeta-Cypermethrin	IN	2020		

Note: Data courtesy of IHS Markit Phillips McDougall (<u>www.phillipsmcdougall.com</u>/)

ERM has over 160 offices across the following countries and territories worldwide

Argentina Australia Belgium Brazil Canada Chile China Colombia France Germany Ghana Guyana Hong Kong India Indonesia Ireland Italy Japan Kazakhstan Kenya Malaysia Mexico Mozambique Myanmar

The Netherlands New Zealand Norway Panama Peru Poland Portugal Puerto Rico Romania Russia Senegal Singapore South Africa South Korea Spain Sweden Switzerland Taiwan Tanzania Thailand UAE UK US Vietnam

ERM Brussels

Cantersteen 47 1000 Brussels Belgium

www.erm.com

