Technical study to assess the need for harmonisation of sampling and analysis methods for GM material in food

Final report

Written by ICF

November 2015

EUROPEAN COMMISSION

Directorate-General for Health and Food Safety (DG SANTE)

Directorate E - Safety of the food chain

Unit E1 - Biotechnology

E-mail: SANTE-CONSULT-E3@ec.europa.eu

European Commission

B-1049 Brussels

EUROPEAN COMMISSION

Technical study to assess the need for harmonisation of sampling and analysis methods for GM material in food

Final report

Directorate-General for Health and Food Safety

November, 2015

Europe Direct is a service to help you find answers to your questions about the European Union.

Freephone number (*):

00 800 6 7 8 9 10 11

(*) The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

Luxembourg: Publications Office of the European Union, **2015**

ISBN 978-92-79-53466-9

DOI 10.2875/762184

Document Control

Document Title	Technical study to assess the need for harmonisation of sampling and analysis methods for GM material in food – Final report
Job No.	30300262
Prepared by	Main authors: Stefania Chirico (ICF), Elta Smith (ICF), Yann Verstraeten (ICF), Thanusan Gunabalasingham (ICF) and Melanie Dubuis (ICF) Country experts: Maike Rentel (Technopolis), Huib de Vriend (LIS Consult) and Győző Pintér (ICF)
Checked by	Andrew Jarvis
Date	30 November 2015

Table of Contents

Table of acronyms and abbreviations

Acronym/Abbreviation	Full name
ADM	Archer Daniels Midland
ALS	Working Group of Experts in Food Chemistry
BEUC	European Consumers' Organisation
Bt	*Bacillus thuringiensis*
CA	Competent Authority
CEN/TS	European Committee for Standardization, Technical Specification
COCERAL	European Association for the Trade in Cereals, Rice, Feedstuffs, Oilseeds, Olive Oil, Oils and Fats and Agrosupply
DG AGRI	Directorate-General for Agriculture and Rural Development
DG SANTE	Directorate-General for Health and Food Safety
DNA	Deoxyribonucleic Acid
EC	European Commission
EFSA	European Food Safety Authority
ELMA	European Lecithin Manufacturers Association
ENGL	European Network of GMO Laboratories
EU	European Union
EURL GMFF	EU Reference Laboratory for GM Food and Feed
EUVEPRO	European Vegetable Protein Industry Association
FAO	Food and Agriculture Organization of the United Nations
FEDIOL	EU Vegetable Oil and Proteinmeal Industry Association
FoEE	Friends of the Earth, Europe
FVO	EU Food and Veterinary Office
GM	Genetically Modified
GMO	Genetically Modified Organisms
HGE	Haploid Genome Equivalents
IFOAM	International Federation of Organic Agriculture Movements
IP	Identity Preserved
IPTS	JRC Institute for Prospective Technological Studies
IRMM	Institute for Reference Materials and Measurements
ISAAA	International Service for the Acquisition of Agri-biotech Applications
ISO	International Organization for Standardization
JRC	Joint Research Centre
LLP	Low-Level Presence

Acronym/Abbreviation	Full name
LOD	Limit of Detection
LOQ	Limit of Quantification
MRPL	Minimum Required Performance Limit
MS	Member State
NAEGA	North American Export Grain Association
NCA	National Competent Authority
NGO	Non-Governmental Organisation
NRL	National Reference Laboratory
NVWA	The Netherlands Food and Consumer Product Safety Authority
PCR	Polymerase Chain Reaction
PFP	Association of Primary Food Processors
RASFF	Rapid Alert System for Food and Feed
ToR	Terms of Reference
USDA	United States Department of Agriculture
VLOG	Verband Lebensmittel Ohne Gentechnik

List of definitions

Term	Definition	Source of definition
Accuracy	The closeness of the agreement between the result of a measurement and a true value of the measurand.	IUPAC (2014)
Analysis	Testing to determine whether any GMOs are present or not in food (or feed), identify which GM events are present and, if necessary, quantify the events.	Definition adopted for this study (adapted from Recommendation (EC) 787/2004[1])
Analytical sample	Homogenised laboratory sample, consisting either of the whole laboratory sample or a representative portion thereof.	Recommendation (EC) 787/2004
Asymmetric GMO	A GMO that has been authorised in countries outside the EU and for which no application for authorisation has been made in the EU. **Only obsolete and asynchronous GMOs are in the scope of this study; asymmetric GMOs are outside of the scope of this study**.	Definition adopted for this study
Asynchronous GMO	A GMO authorised in third countries while in the EU the application file has been submitted and declared valid by EFSA and the authorisation procedure is still pending. The list of GMOs that were asynchronous during the period 2009 - 2014 is provided in Annex 6, Table 40. The list of asynchronous GMOs has been updated during the timeframe for this study (2009 – 2014 in accordance with the progress of submitted applications and granted authorisations).	Definition adopted for this study
Bulk sample	Quantity of product obtained by combining and mixing the incremental samples taken from a specific lot.	Recommendation (EC) 787/2004
Incremental sample	Small equal quantity of product taken from each individual sampling point in the lot through the full depth of the lot (**static sampling**), or taken from the product stream during a stated portion of time (**dynamic sampling**).	Recommendation (EC) 787/2004
Limit of Detection (LOD)	The lowest amount or concentration of analyte in a sample, which can be reliably detected, but not necessarily quantified.	Recommendation (EC) 787/2004
Limit of Quantification (LOQ)	The lowest amount or concentration of analyte in a sample that can be reliably quantified with an acceptable level of trueness and precision.	Recommendation (EC) 787/2004

[1] Commission Recommendation of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003.

Term	Definition	Source of definition
Measurand	Particular quantity subject to measurement.	IUPAC (2014)
Minimum Required Performance Limit (MRPL)	The lowest amount or concentration of analyte in a sample that has to be reliably detected and confirmed by official laboratories. Currently, in the EU there is no harmonised MRPL for asynchronous and obsolete GM material in **food** (only for asynchronous and obsolete GM material in **feed**, a MRPL of 0.1 per cent has been established by Regulation (EU) No 619/2011[2]).	Regulation (EU) No 619/2011
Obsolete GMO	A GMO whose authorisation has expired in the EU due to the phasing-out/non-renewal of the authorisation. As for asynchronous GMOs, the list of obsolete GMOs has changed during the timeframe for this study. The list of GMOs is provided in Annex 6, Table 41.	Definition adopted for this study
Sampling	Selection of a food (or feed) sample from a food (or feed) lot in order to verify through analysis the presence of asynchronous and/or obsolete GM material.	Definition adopted for this study (adapted from Recommendation (EC) 787/2004[3])
Test portion (or test sample)	Sample, as prepared for testing or analysis, the whole quantity being used for analyte extraction at one time	ISO 24276:2006

[2] Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired Text with EEA relevance.

[3] Commission Recommendation of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003Text with EEA relevance.

Member State Abbreviations

Abbreviation	Country name
AT	Austria
BE	Belgium
BG	Bulgaria
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
ES	Spain
FI	Finland
FR	France
GR	Greece
HR	Croatia
HU	Hungary
IE	Ireland
IT	Italy
LT	Lithuania
LU	Luxembourg
LV	Latvia
MT	Malta
NL	Netherlands
PL	Poland
PT	Portugal
RO	Romania
SE	Sweden
SI	Slovenia
SK	Slovakia
UK	United Kingdom

Summary and key messages

- The 'zero tolerance policy' for unauthorised genetically modified organisms (GMOs) prohibits the placing on the EU market of GM material that has not been authorised in the EU. Unauthorised GMOs include those that are authorised in third countries, and for which an authorisation in the EU is pending (**asynchronous GMOs**) and GMOs with a cancelled or expired EU authorisation (**obsolete GMOs**).
- For asynchronous and obsolete GMOs in **feed**, EU legislation established harmonised sampling and analysis protocols to be used in the context of official controls (Regulation (EC) No 619/2011). This regulation also set a minimum required performance limit (MRPL) for official laboratories. For **food**, EU and international guidance on sampling and analysis is available, but these rules are not always harmonised. Additionally, no MRPL for food has been set by the EU.
- The absence of harmonised rules for **food** could have consequences on official controls undertaken by competent authorities in Member States, business operators and consumer choice and welfare. A consultation with representatives of these groups was done as part of this study to collect evidence and views of these issues.
- The consultation of **competent authorities in charge of official controls** at national and regional levels indicates that the lack of harmonised protocols for sampling and analysis and the absence of a MRPL for food has led to divergent approaches being adopted by Member States in the application of official controls for asynchronous and obsolete GMOs.
- The evidence collected regarding official controls suggests that the harmonisation of protocols for sampling could provide benefits in the form of increased reproducibility of testing results between Member States. Further harmonisation of procedures for the interpretation of results and the setting of a MRPL could improve the reproducibility of official controls and reduce the risks of divergence in compliance assessment.
- Some negative effects from harmonisation were also identified; the main issues are the increased costs and resources needed for the adoption of a MRPL. These costs would mainly arise from the need for those laboratories that use qualitative methods to detect asynchronous and obsolete GMOs in food to quantify GM content.
- **Food business operators** have decided that, whatever the sampling and analysis might be deployed, the use of controls by the supply chain is not sufficient to deal with the risks posed by asynchronous and obsolete GMOs. Operators mainly rely on risk management measures, including sourcing strategies and supply chain segregation.
- For food businesses, the current absence of harmonisation of protocols for official controls represents a source of legal uncertainty due to divergent approaches to compliance assessment.
- There have been a limited number of supply chain disruption incidents arising from the detection of asynchronous and obsolete GMOs. With increased cultivation of GMOs in source countries, the risk of occurrence of these incidents is expected to increase. The harmonisation of sampling and analysis and setting a MRPL were regarded by most consultees as a possible solution to addressing these risks.
- Limited evidence and views were provided concerning **consumer impacts**: almost half of the representatives of businesses and the civil society consulted

did not provide views on consumer impacts arising from the lack of harmonisation. Amongst those who did, industry representatives believe that higher food costs could arise from the additional testing controls required by operators. This could result in higher consumer costs in the event of trade disruption, a food recall and/or reduced availability of food products. Civil society respondents felt that there is no need to harmonise testing and sampling.

- Harmonisation would reduce existing and potential consumer food costs according to most industry representatives consulted. NGOs felt that introducing a MRPL in particular would have negative impacts in the form of reduced consumer choice because food products could be contaminated with GMOs up to the level of a MRPL.

Executive summary

Introduction

The objective of the study was to perform an *ad hoc* assessment of the need for, and feasibility of, harmonising sampling and analysis methods for official controls to detect the presence in food of GM material at European Union (EU) level. The study has focussed on official controls related to pending (asynchronous) and expired (obsolete) genetically modified organisms (GMOs). Its purpose is to help the European Commission to identify, explain and assess the issues arising from the current approach to regulation of sampling and analysis of GM material in food across the 28 EU Member States.

This report provides answers to a set of questions posed by the Commission relating to the lack of harmonised protocols for sampling and analysis and the absence of a minimum required performance limit (MRPL) for food. It considers impacts on official control activities for the sampling and analysis of asynchronous and obsolete GMOs, food business operators in the EU and consumers.

Evidence presented in the report was gathered through:

- **Online surveys** of national competent authorities (NCAs), competent authorities (CAs) at regional level and EU food business operators;
- **Semi-structured interviews** with representatives of NCAs, the civil society, third countries, food business operators and commercial laboratories;
- **A market analysis** focussed on soybean and maize; and
- **Case studies** aimed at investigating in detail the approaches to sampling and analysis in seven Member States: Austria, Belgium, France, Germany, Hungary, the Netherlands and Spain.

The conclusions are presented by reference to principal research themes, namely:

- Lack of harmonisation of methods of sampling and analysis for the **official control** of asynchronous and obsolete GMOs / setting of a MRPL;
- Impacts on **food business operators** in the EU arising from the lack of harmonisation of sampling and analysis procedures and absence of a MRPL; and
- Impacts on **consumers**.

Lack of harmonisation of methods of sampling and analysis for the official control of asynchronous and obsolete GMOs and setting of a MRPL

The consultation with NCAs and CAs indicates that there is no consensus on whether the lack of harmonisation of food sampling procedures has an impact on the reproducibility of test results. According to 17 respondents in 14 Member States, the lack of harmonised sampling procedures affects the reproducibility of test results between and/or within Member States. Fifteen respondents in 13 Member States reported no impacts. The lack of harmonisation in the interpretation of test results gives rise to different approaches to compliance assessment.

The majority of consultees expect the harmonisation of protocols for sampling and analysis to provide benefits in the form of increased comparability of results and accuracy of testing. Those who identified negative effects from harmonisation cited the increased costs and lack of flexibility arising from the introduction of new mandatory protocols that differentiate between official controls for asynchronous/obsolete GMOs and other GMOs. If harmonised protocols are introduced it would be appropriate to consider their consistency with the protocols already applied for official controls for all GMOs.

Views on the potential benefits and drawbacks of setting a MRPL are more mixed. Of the 62 NCA and CA consultees, 38 respondents in 22 Member States foresee benefits in improved comparability of results. Furthermore, consultees referred to a possible increase in accuracy[4] of results. There is, however, some concern about the financial implications: 26 respondents in 15 Member States suggesting that a harmonised MRPL would increase analysis costs. In that context a possible assessment of whether policy action is needed to set a harmonised MRPL could usefully be informed by an analysis of the associated costs and their implications.

Conclusions for the study questions that relate to official controls are provided below.

Study question	Conclusions
A.1. How many official food samples are tested annually for presence of asynchronous and obsolete GM material in the Member States?	Complete data on the number of official food samples tested for presence of asynchronous and obsolete GM material in the Member States are not available but the study provides a measure of the scale of such activity. Twenty-five Member States tested for the presence of asynchronous and obsolete GM events between 2009 and 2014. Authorities in 14 Member States provided specific data on the number of samples tested annually: the numbers ranged from an average of one sample per year or less (in Cyprus and Estonia) to more than a thousand (in Germany). NCAs and CAs in other Member States were not able to provide detailed data on the number of samples collected: NCAs and CAs do not always collect data on sampling that is specific to asynchronous and obsolete GMOs.
Which asynchronous and obsolete GMO events are tested?	The types of asynchronous and obsolete GM events tested vary. They include: LLRICE 62, Soy A5547-127, DP356043, DP 305423, MIR604, MON88017 and MON89034.
A.2. What sampling procedures are implemented for the presence of asynchronous and obsolete GM material in food in the Member States?	There is variation in the sampling procedures adopted by Member State NCAs and CAs for both bulk commodities and for packaged food products. For bulk commodities the sampling procedures established by Recommendation 787/2004 are most commonly used. Authorities most commonly use their own domestic standards when sampling packaged foods. Samples are collected from different stages of the supply chain, including at border inspection posts, wholesalers and retail premises.
A.3. Does the lack of harmonisation of sampling procedures have any impact on the reproducibility of test results (within and between Member States)?	Competent authorities are split on whether the lack of harmonisation of food sampling procedures has an impact on the reproducibility of test results. Of the 37 NCAs and CAs consulted on issues arising from the lack of harmonisation of sampling procedures, 17 respondents in 14 countries indicated that this did have an impact on reproducibility of results between or within Member States[5]. Fifteen respondents in 13 countries indicated that there are no impacts. The remaining five consultees did not respond. Respondents in five Member States had practical experiences of impacts on the reproducibility of test results between or within

[4] Accuracy is defined as the closeness of the agreement between the result of a measurement and a true value of the measurand (IUPAC, 2014). In this study we report the terms used by consultees, while noting that it is unclear how the setting of an MPRL can result in increased accuracy.

[5] Multiple options could be selected by respondents.

Study question	Conclusions
Have Member States ever had practical experience on that?	Member States. The lack of harmonisation of protocols for static and dynamic sampling of bulk agricultural commodities was the factor most often cited as having an impact on the reproducibility of test results.
A.4. What test procedures are implemented in the Member States regarding the control of the presence of asynchronous and obsolete GM material in food (qualitative, quantitative, MRPLs)?	There are differences in the screening procedures applied to control of asynchronous and obsolete GM material in the Member States, although some common aspects were identified (such as the types of elements and constructs used for screening). Event-specific methods are largely harmonised (EURL GMFF methods are widely adopted) but there is variation in the limits applied. To identify GM events 28 laboratories (in 19 Member States) use qualitative PCR methods while 21 laboratories (in 15 Member States) use quantitative PCR methods. Seventeen laboratories (in 12 Member States) used both qualitative and quantitative PCR methods. Limits of detection range from 0.01 to 0.5 per cent, and limits of quantification are at or below 0.16 per cent.
A.5. Does the lack of harmonisation in the interpretation of test results have an impact on compliance assessment (within and between Member States)? *Have Member States ever had practical experience on that?*	The lack of harmonisation in the interpretation of test results gives rise to different approaches to compliance assessment: NCAs in two countries assess compliance based on whether asynchronous or obsolete GM material exceeds a specific limit (0.1 per cent in both cases), while in other cases no limits are applied. The majority of NCAs and regional CAs (30 respondents in 17 Member States) considered the lack of harmonisation of analysis protocols to have an impact on compliance assessment between or within Member States. Most respondents who believed that the lack of harmonisation in the interpretation of test results has an impact on compliance assessment also reported practical experiences of these impacts. The adoption of different criteria and limits to assess whether a testing result is positive or negative was cited as an example.
A.6. Would the definition of a Minimum Required Performance Limit affect protocols of testing?	Half of respondents (31 out of 62, covering 17 Member States) believed that the definition of a MRPL for food would affect protocols for testing. The most cited consequence was the need to perform quantification of GM content for those laboratories that use qualitative methods to detect asynchronous and obsolete GMOs in food. According to respondents, the setting of a MRPL would require additional work and resources due to the need to implement quantitative methods.
A.7. Are there any beneficial or negative effects deriving from the harmonisation of sampling and analysis and the introduction of a Minimum Required Performance Limit for food as it already exists for feed? What are these effects?	The beneficial effects from the harmonisation of sampling methods include increased comparability of sampling results and fewer disputes between Member States. Most respondents (36 NCAs and regional CAs across 20 Member States) also believed that there would be benefits from the harmonisation of analytical methods, including greater comparability of results. A majority also expect that setting a MRPL would result in beneficial effects that include improved comparability of results. Most respondents did not foresee negative effects from the harmonisation of sampling and analysis, but 26 respondents in about half of the Member States expected adverse effects from setting a MRPL, such as greater burden of work and costs of

Study question	Conclusions
	laboratory analysis.

Impacts on food business operators and on the market

Operators mainly rely on risk management measures, including sourcing strategies and supply chain segregation, to exclude asynchronous and obsolete GMOs from their products.

The lack of harmonised protocols for official controls is a source of legal uncertainty due to divergent approaches to compliance assessment that then arise.

There are some examples of the detection of asynchronous and obsolete GMOs leading to supply chain disruption. With increased cultivation of GMOs in source countries, the risk of such incidents occurring is expected to increase.

The harmonisation of sampling and analysis and setting of a MRPL were regarded by most consultees as a possible means of addressing these risks. Conclusions for study questions relating to impacts on food business operators are provided below.

Study question	Conclusions
B.1. What are the sampling, analysis and risk management strategies and protocols applied by food business operators regarding asynchronous and obsolete GMOs?	Most industry respondents do not apply sampling and analysis protocols for asynchronous and obsolete GMOs. Operators use risk management strategies that rely primarily on avoiding the possibility of contamination at source in producer countries and segregation of conventional and GM products throughout the supply chain. If asynchronous or obsolete GMOs are detected, companies consider options that will generally include diverting imports of non-compliant commodities to non-EU countries and downgrading[6] food products to feed status. Food samples are generally taken when the risk management approach indicates there may be contamination and so the number of samples taken rises and falls according to the associated risk.
How many and what kind of samples are taken and what types of tests are performed on an annual basis in the framework of the own check controls?	Respondents did not provide information on the number of samples taken for asynchronous and obsolete GM analyses, but indicated the total numbers of samples tested for GMO analyses. These ranged from zero to about 7,000 samples per year. One consultee provided information on the type of tests performed, which concerned contamination between different plant species.
B.2. For food business operators also involved in feed activities (i.e. crop growers and traders, crushers), what are the strategies and measures adopted and implemented to manage the two products flows for which different sampling and analysis procedures apply?	The supply chains for food and feed are highly interconnected. Businesses involved in food and feed activities reported that the same strict control strategies and measures are applied to both food and feed and that these are stricter than would be required under the rules for feed because of the legal uncertainty surrounding compliance results for food.

[6] In the context of this study and based on the information provided by business associations, the term 'downgrading' refers to modifying the status of a product initially intended to be sold as food with the aim to sell it as feed or as another product not intended for human consumption.

Study question	Conclusions
B.3. Does the lack of harmonisation of sampling and analysis for official controls for the presence of asynchronous and obsolete GM material affect food business operators at EU level? *If so, what are these impacts?*	About half of stakeholders consulted, including business associations covering most stages of the food supply chain, believe that the lack of harmonised protocols for sampling and analysis for official controls has impacts on food business operators at EU level. The absence of harmonisation creates legal uncertainty for operators relying on imports of raw commodities from third countries. There is an increasing risk of supply disruption and serious financial losses arising from the detection of traces of asynchronous or obsolete GMOs in imported food.
B.4. What would be the potential consequences for food business operators under a scenario where the current lack of harmonisation of sampling and analysis for official controls would remain unchanged? How would this affect their risk management strategies?	In the absence of harmonisation, consultees believed that the impacts are expected to become more significant. The risks of trade disruption and financial losses are expected to increase in a context where GMO cultivation is increasing worldwide. The position of the business representatives that responded was that risk management strategies are already stringent and suggested that the implementation of still more stringent strategies would not be feasible. If faced with recurring losses due to the absence of a MRPL, operators may be forced to temporarily or permanently cease crushing activities in the EU.
B.5. What would be the expected impact of harmonisation of sampling and analysis and the definition of a MRPL for food tests as regards asynchronous and obsolete GM material?	Most of the consultees who commented on expected impacts believed that the harmonisation of sampling and analysis and the setting of a MRPL would provide benefits to food business operators in the EU. These benefits would include reduced legal uncertainty and increased reliability of the compliance assessment across the EU.

Impacts on consumers

Food business operators and NGOs had different perspectives on the impacts on consumers of harmonisation. Food business operators suggested that it would reduce costs and risks in the food chain, and that this would benefit consumers. NGO respondents were concerned that introduction of a MRPL would lead to a reduction in consumer choice because GMO presence up to the limit would be allowed. The answer to questions relating to impact on consumers are provided below.

Study question	Conclusions
B.6. Does the harmonisation of testing and sampling, or the lack of harmonisation thereof, affect consumers in the EU? If so, how?	Almost half of the stakeholders consulted did not provide views on consumer impacts arising from the lack of harmonisation. Of those who did, industry representatives stated that the lack of harmonisation results in higher food costs due to the additional testing controls required by operators and could result in higher costs in the event of trade disruption or a food recall and/or reduced availability of food products. The industry respondents see harmonisation as a means to reduce current existing and potential costs, to the benefit of consumers. NGO respondents, by contrast, suggested that there is no need to harmonise testing and sampling. They stated that introducing a MRPL would have negative impacts in the form of reduced consumer choice because food products could be contaminated with GMOs up to the level of a MRPL.

1 Introduction

1.1 Purpose

This is the final report for a technical study to assess the need for harmonisation of sampling and analysis methods for genetically modified (GM) material in food. The project was delivered by a team led by ICF International for the Directorate-General for Health and Food Safety (DG SANTE) of the European Commission. ICF worked with the support of Technopolis and LIS Consult.

The objective of the study is to perform an *ad hoc* assessment of the need for, and feasibility of, harmonising sampling and analysis methods for official controls to detect the presence in food of GM material at European Union (EU) level. The study focusses on official controls related to pending (asynchronous) and expired (obsolete) genetically modified organisms (GMOs).[7] Its purpose is to help DG SANTE to identify, explain and assess the issues arising from the current approach to regulation of sampling and analysis of pending and expired GM material in food across the 28 EU Member States.

1.2 Context

The 'zero tolerance policy' for unauthorised GMOs prohibits the placing on the EU market of GM material that has not been authorised in the EU.[8] There are four types of unauthorised GMOs (André, 2014; Van Broeckhoven et al., 2013):

- GMOs that are authorised in third countries, and for which an authorisation in the EU is pending (**asynchronous authorisation**);
- GMOs with a cancelled or expired EU authorisation (**obsolete authorisation**);
- GMOs that are authorised in third countries, but no application for authorisation has been made in the EU (**asymmetric authorisation**); and
- GMOs that are not authorised in any country.

This study focusses on official controls regarding asynchronous and obsolete GMOs in **food**.

For asynchronous and obsolete GMOs in **feed**, Regulation (EC) No 619/2011 established harmonised sampling and analysis protocols to be used in the context of official controls. This regulation also set a minimum required performance limit (MRPL) [9] for official

[7] The following definitions apply for this study:

- Asynchronous GMO: A GMO authorised in one or more third countries while in the EU the application file has been submitted and declared valid by the European Food Safety Authority (EFSA) and the authorisation procedure is still pending. The list of GMOs that were asynchronous during the period from 2009 until the launch of this consultation is provided in Annex 6, Table 40. The list of asynchronous GMOs has been updated during the timeframe for this study (2009 – 2014).
- Obsolete GMO: A GMO whose authorisation has expired in the EU due to the phasing-out or non-renewal of the authorisation. As for asynchronous GMOs, the list of obsolete GMOs has changed during the timeframe for this study. The list of obsolete GMOs is provided in Annex 6, Table 41.

The definitions of asynchronous and obsolete GMOs to be applied for this study have been developed by the European Commission in cooperation with the study team and have been adapted based on feedback received by national competent authorities through the piloting of survey questionnaires and interview topic guides.

[8] Directive 2001/18/EC requires Member States to implement appropriate measures to avoid negative impacts on human health and the environment, which might arise from the deliberate release or the placing on the market of GMOs. Additionally, Regulation (EC) No 1829/2003 on genetically modified food and feed requires that only GMOs that are authorised in the EU can be placed on the EU market for food and feed.

[9] Regulation (EC) No 619/2011 defines the MRPL as the lowest amount or concentration of analyte in a sample that has to be reliably detected and confirmed by official laboratories. In absence of a harmonised MRPL,

laboratories. For **food**, EU and international guidance on sampling and analysis is available[10], but these rules are not always harmonised. Additionally, no MRPL for food has been set by the European Union.

The absence of harmonised rules for food could have the following consequences:

- there may be divergence within/between Member States in the analytical results and the interpretation of those results;
- there may be divergence in the enforcement decisions that are taken;
- there may be a lack of legal certainty for food business operators caused by the current situation; and
- there may be consequences on consumer choice and welfare.

The information available on the impacts arising from the present legislative framework is disparate and, in some respects, conflicting. There is a real need therefore to bring together these sources of information (including national competent authorities (NCAs), food business operators (FBOs) and representatives of the civil society), and provide a critical analysis of the possible issues arising from the absence of harmonisation. The study findings will help the Commission determine the need for, and feasibility of, action in this area.

1.3 Research objectives

The study terms of reference (see Annex 1) require the contractor to respond to a series of questions that collectively address the problem outlined above. These questions provided the focus for the research conducted under this study and the structure of this report. They are listed in the box below.

Study questions

Lack of harmonisation of methods of sampling and analysis for the official control of asynchronous and obsolete GMOs/ Definition of a MRPL

- How many official food samples are tested annually for presence of asynchronous and obsolete GM material in the Member States? Which asynchronous and obsolete GMO events are tested?
- What sampling procedures are implemented for the presence of asynchronous and obsolete GM material in food in the Member States?
- Does the lack of harmonisation of sampling procedures have any impact on the reproducibility of testing results (within Member States and between Member States)? Have Member States ever had practical experience on that?
- What testing procedures are implemented in the Member States regarding the control of the presence of asynchronous and obsolete GM material in food

interpretation of testing results may differ between laboratories involved in official controls when the presence of GM material is at very low levels. For example, some Member States can decide that analytical results obtained below a certain level are not sufficiently reliable and reproducible between laboratories to take a decision regarding the compliance of a lot. This can result in the fact that a product is considered as compliant in one Member State and not in another.

[10] This includes, for example:

- Recommendation 2004/787/EC, providing technical guidance for sampling and detection of GMOs; and
- The reference methods for GMO analysis published by the European Union Reference Laboratory for GM Food and Feed (EURL GMFF).

(qualitative, quantitative, MRPLs,…)?

- Does the lack of harmonisation in the interpretation of testing results have an impact on compliance assessment (within Member States and between Member States)? Have Member States ever had practical experience on that?
- Would the definition of a Minimum Required Performance Limit affect protocols of testing?
- Are there any beneficial or negative effects deriving from the harmonisation of sampling and analysis and the introduction of a Minimum Required Performance Limit for food as it already exists for feed? What are these effects?

Impacts on operators and on the market

- What are the sampling, analysis and risk management strategies and protocols applied by food business operators regarding asynchronous and obsolete GMOs? How many and what kind of samples are taken and what types of tests are performed on an annual basis in the framework of the own check controls?
- For food business operators also involved in feed activities (i.e. crops growers and traders, crushers), what are the strategies and measures adopted and implemented to manage the two products flows for which different sampling and analysis procedures apply?
- Does the lack of harmonisation of sampling and analysis for official controls for the presence of asynchronous and obsolete GM material affect food business operators at EU level? If so, what are these impacts?
- What would be the potential consequences for food business operators under a scenario where the current lack of harmonisation of sampling and analysis for official controls would remain unchanged? How would this affect their risk management strategies?
- What would be the expected impact of harmonisation of sampling and the definition of a MRPL for food tests as regards asynchronous and obsolete GM material?

Impacts on consumers

- Does the harmonisation of testing and sampling, or the lack of harmonisation thereof, affect consumers in the EU? If so, how?

In addition to the study questions outlined above, this study also aimed at providing a description of market's and supply chain's specifications and trends for the main products identified as being impacted by the presence of asynchronous and obsolete GMOs. The main issues addressed by this market analysis were as follows:

- What are the most relevant food sectors and products with regards to the presence of obsolete and asynchronous GM material in traded commodities?
- What are the sizes (values and volumes) of the EU and global markets for the main food products identified?
- What are the temporal evolution (past, present, future), structures and functioning of supply chains from fields to consumers, in the EU and worldwide, for the main food products identified?
- What are the main factors influencing variations in supply and demand of the main food products identified?

1.4 Structure

This final report presents the study findings and conclusions. It begins with a brief description of the method (section 1) before presenting the research findings in section 3. The conclusions, providing answers to the study questions are given in section 4. Section 4 also includes possible recommendations.

Annexes provide the following information:

- Annex 1 contains the study terms of reference;
- Annex 2 presents the evaluation matrix;
- Annex 3 provides details on the research methods adopted and stakeholders consulted;
- Annex 4 illustrates the results of the market analysis conducted by the study team;
- Annex 5 presents aggregated data collected through stakeholder consultations;
- Annex 6 includes the detailed list of GM events considered asynchronous or obsolete for the purposes of this study; and
- Annex 7 provides the list of references.

2 Study method

2.1 Introduction

This section provides a summary of the study method, limitations and challenges faced by the study team. A more detailed description is provided in Annex 3.

2.2 Method

The report provides evidence gathered through:

- **Online surveys** of NCAs, competent authorities (CAs) at regional level and EU food business operators;
- **Semi-structured interviews** with representatives of NCAs, the civil society, third countries, food business operators and commercial laboratories;
- **A market analysis** focussed on soybean and maize; and
- **Case studies** aimed at investigating in detail the approaches to sampling and analysis in seven Member States: Austria, Belgium, France, Germany, Hungary, the Netherlands and Spain.

The online surveys targeted the following categories of stakeholders:

- NCAs involved in GMO sampling and analysis: in total, 62 respondents took part in the survey, covering all 28 Member States.
- EU business associations: representatives of FBOs involved in both food and feed activities were targeted by the survey. In total, six EU business associations responded[11], representing various stages of the food and feed chains: trade of raw commodities, processing, manufacturing and retailing (details on respondents are provided in Table 2).
- Individual businesses and business associations at national level: EU business associations were asked to forward the request to take part in the survey to their national members. Responses were received from a food company operating in an EU Member State, a national business association and a multinational company.

Interviews targeted the following stakeholder groups:

- NCAs and FBOs in the seven case study countries: NCAs in all case study countries were consulted. Three national businesses associations (two in the Netherlands and one Spain) and three multinational food companies took part in interviews.
- Commercial laboratories undertaking testing on behalf of the EU food industry: representatives of two leading laboratories were consulted.
- Representatives of the civil society: representatives of three non-governmental organisations (NGOs) involved in consumer and environmental protection were interviewed.
- EU business associations: scoping interviews were completed with three EU business associations[12].

[11] Federation of the European vegetable oil and proteinmeal industry (FEDIOL), European association representing the trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agrosupply (COCERAL), European Starch Industry Association (Starch Europe), FoodDrinkEurope, European Lecithin Manufacturers Association (ELMA) and European Vegetable Protein Federation (EUVEPRO).

[12] EUVEPRO, FEDIOL and FoodDrinkEurope.

- Third countries: representatives of the missions to the EU of the following countries were consulted: Argentina, Brazil, Canada and the US.

2.3 Limitations and challenges

The consultations faced challenges relating to the timeliness of stakeholder responses, participation rates and interviewees' engagement with the issues covered in the survey and interviews.

2.3.1 Timeliness and accuracy of responses

Delays in the consultation process occurred across the stakeholder groups:

- There were delays in the submission of survey responses and scheduling of interviews by some national competent authorities. This was due to the need for the central competent authority to gather data from regions and / or different authorities in charge of official controls.
- There were delays in the submission of survey responses by EU associations, due in part to the short period of time provided for them to collect information from their members.
- There were also some delays with the receipt of information from third country representatives who requested additional time to contribute.

Some survey responses also presented inconsistencies which required clarification. In order to ensure completeness and accuracy of data, additional time was provided by DG SANTE for the collection of missing responses and clarifications. Additional time allowed the collection of responses from all 28 Member States, all the third countries targeted by the consultation and EU business representatives covering all stages of the food and feed chains.

2.3.2 Participation

Few responses were received from individual businesses. Many of those that were contacted indicated that they preferred to respond through the relevant EU level representative association.

ICF was advised by a number of representative associations and businesses that few individual business responses should be expected because of the sensitive nature of the information and the desire not to be identified in the case studies. The study team was told that companies would be concerned that it would be easy for any business that participated to be identified due to the small number of firms active in this market.

2.3.3 Engagement with the research agenda

Two main issues arose with consultees regarding the framing of the issues in the study:

- The consultations showed that some interviewees, including NCAs, do not make the distinction between general GM presence and asynchronous/obsolete GM in their day-to-day work. Some indicated that the distinction was irrelevant (especially with regards to sampling). Some interviewees referred to GM testing in general (rather than to asynchronous/obsolete vs other GM events), and the interviewer had to move the focus back to the core research topic.
- EU business associations commented that the questionnaire for food business operators had detailed coverage of sampling and analysis issues that were not relevant and not helpful to make the case that harmonisation of sampling and analysis for food is needed. Respondents provided limited information on these aspects. Supplementary information was used by the study team to address these concerns, including EU business associations' impact assessments regarding asynchronous and obsolete GMOs.

2.3.4 Data availability

Market data (volumes and values) on EU production and consumption of the main food products produced with maize, soybean and their derivatives were collected by the study team. These data were obtained through desk research and consultation with food business operators. More detailed data were found for soybean, which was identified as the main commodity affected by the potential presence of asynchronous and obsolete GMOs.

2.3.5 Representativeness of responses to the consultation of NCAs

The desk research[13] and the consultations with competent authorities undertaken for this study show that the organisation of official controls varies significantly across EU Member States. While in some counties the responsibility for official controls is centralised in one national authority, other countries have several authorities at regional or local level with different sampling and analysis responsibilities. Within the same Member State there can be different authorities in charge of official controls at different stages of the supply chain, or different authorities responsible for different types of food products or different GMOs. Some countries have only one National Reference Laboratory (NRL)[14] in charge of GMO analyses, while other have a NRL and different official laboratories undertaking analyses for official controls. Finally, in some countries the same authority combines responsibilities for both sampling and analysis, while in other countries sampling and analysis tasks are undertaken by separate authorities.

The study team adapted its consultation approach to address the issue of variance in official control responsibilities:

- Two survey tools were developed: a survey for authorities responsible for sampling and a survey for authorities in charge of analysis. Authorities were asked to compile the surveys according to their responsibilities.
- For each Member State, a request to submit survey responses was sent to permanent representations to the EU, NRLs and national authorities and agencies in charge of official food controls. Their representatives were asked to circulate the survey request to all other authorities responsible for sampling and analysis within their Member States, including regional authorities. National and regional authorities were given the possibility to submit separate survey responses. In Germany, for example, respondents from one national authority and eight regional authorities submitted survey responses regarding sampling, and a similar number of German respondents contributed to the survey on analysis. Details of the types of respondents for all Member States are provided in Table 9.
- Follow up phone calls were done with survey respondents to clarify the respective responsibilities regarding sampling and analysis.

Differences in arrangements for official controls were taken into account during the analysis of data and presentation of results. Individual institutional responses cannot be considered as equivalent to the national positions of Member States on sampling and analysis issues, but rather represented the perspectives of the individuals or authority that responded. When aggregate data are presented (such as the total number of responses to survey questions), these include the views of both national and regional

[13] The audit reports from the Food and Veterinary Office (FVO) provide information on Member States' organisation of official controls regarding GMOs. The list of FVO reports reviewed for this study is provided in Annex 7.

[14] Each Member State has one or more NRLs; as required by Regulation (EC) No 882/2004 on official controls, the main role of NRLs is to coordinate and provide guidance to other national laboratories involved in official controls, and to disseminate guidance established at EU level by EU Reference Laboratories.

authorities. The description of findings (section 3) notes the caveats to be considered in review of the analysis and provides details of the types of respondent in the text or in footnotes, distinguishing between national and regional institutions. The aggregate survey results presented in Annex 5 provide details of the types of respondents for the different survey questions.

3 Research findings

This section presents the findings from the stakeholder consultation and desk research conducted for this study. They are organised as follows:

- Section 3.1 focusses on official control activities for the sampling and analysis of asynchronous and obsolete GMOs and the issues and the views of national and regional competent authorities and reference laboratories on the impacts of lack of harmonisation in this area for food.
- Section 3.2 considers on the impacts on food business operators in the EU, including issues regarding trade with third countries.
- Section 3.2.1 discusses findings regarding consumer issues.

3.1 Lack of harmonisation of methods of sampling and analysis for the official control of asynchronous and obsolete GMOs and setting of a MRPL

This section presents findings from the surveys of NCAs, national reference laboratories (NRLs) and regional competent authorities (CAs) (including regional reference laboratories) responsible for the sampling and analysis of GMOs in food in the EU. It describes:

- the type and extent of sampling and analysis undertaken for official controls;
- sampling protocols for asynchronous and obsolete GM material in food;
- analysis protocols and criteria to assess compliance for asynchronous and obsolete GM material in food;
- impacts of the lack of harmonisation of protocols for sampling, analysis and interpretation of results; and
- beneficial or negative effects deriving from the harmonisation of sampling and analysis and the introduction of a Minimum Required Performance Limit (MRPL) for food.

3.1.1 Data on official controls regarding asynchronous and obsolete GM material in food

Question A.1. How many official food samples are tested annually for presence of asynchronous and obsolete GM material in the Member States? Which asynchronous and obsolete GMO events are tested?

3.1.1.1 Context

Regulation (EC) No 882/2004[15] on official controls for food and feed requires Member States to designate the competent authorities in charge of conducting official controls to ensure compliance with EU food and feed legislation, including controls regarding the 'zero tolerance policy'. The Regulation establishes the overall framework and principles to be applied by Member States regarding official controls, such as the principles that controls must be regular and proportionate to risks. It also requires Member States to establish the detailed procedures for the implementation of official controls.

[15] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Member State NCAs and CAs may take different approaches to sampling, including the number of samples taken and the focus on different types of unauthorised GMOs. This may include a sampling approach that does not differentiate between asynchronous/obsolete GMOs and other unauthorised GMOs.

3.1.1.2 Findings

Data on the number of official samples tested annually for the presence of GM material were received from NCAs and CAs in 25 Member States.[16] All of the NCAs and CAs who responded collect food samples to test for GMOs. The number of samples collected from 2009-2014 varied significantly across Member States, from around 10 each year to nearly five thousand in one Member State. Germany collected the most samples on average in this period – nearly 5,000, or five times more than the Member State with the second largest number of average samples taken (Figure 1). The inset on Figure 3.1 shows that 21 Member States collected fewer than 350 samples per annum on average. The numbers of samples taken between 2009 and 2014 as reported by each of the Member States can be found in Annex 5, Table 17.

Twenty-five of the 28 Member States that responded test for the presence of asynchronous and obsolete GM events (see Annex 5, Table 16). Only Bulgaria, Spain and Sweden stated that they do not test for asynchronous and obsolete GM events. Authorities in 14 Member States provided specific data on the number of samples tested annually for the presence of asynchronous and obsolete GM material.[17] Authorities in four countries (Croatia, Denmark, Finland and Malta), two German Länder and one Port Health Authority in the UK[18] indicated that all of the samples collected for GM testing are analysed for asynchronous and obsolete materials.

Twenty Member States[19] specified the types of foodstuffs that they sampled for the presence of asynchronous and obsolete GM material from 2009 to 2014. The types of foodstuffs sampled varied between Member States, and included soya, maize, rice, rapeseed, linseed and flax. Respondents in eight Member States (Belgium, Germany, France, Hungary, Lithuania, Malta, Slovenia and UK) specified the asynchronous and obsolete GM events tested.[20] Where GM events were tested, these included: LLRICE 62, Soy A5547-127, DP356043, DP 305423, MIR604, MON88017 and MON89034.

[16] Spain and Latvia collected food samples for GMO analysis but did not indicate the number of samples tested.

[17] Respondents in 10 Member States (Italy, Romania, Poland, Slovakia, the Netherlands, Austria, Portugal, Belgium and Latvia) indicated that they tested for the presence of asynchronous and obsolete GM events but were unable to provide specific data on the number of samples tested. Ireland and three German Länder indicated that asynchronous and obsolete GM materials are screened as part of general GM sampling activities.

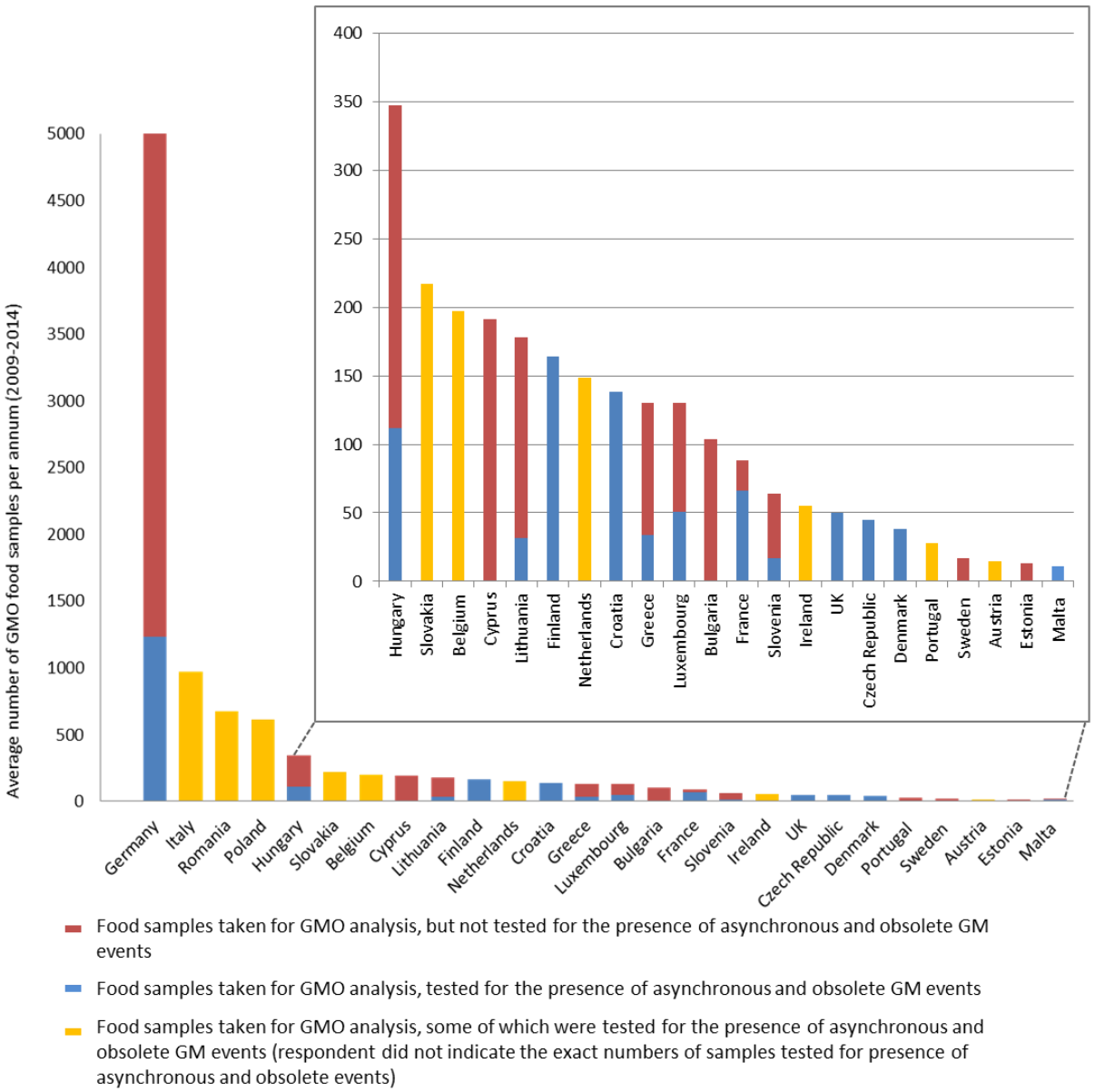
[18] GM sampling data was provided by one Port Health Authority in the UK. It is not known whether other competent authorities in the UK test for the presence of asynchronous and obsolete GM events.

[19] This included responses from one UK port Health Authority treated as national response for UK and seven German Länder, together taken as national response for Germany.

[20] This included one UK port Health Authority (treated as national response for UK); Germany did not provide unified national response, although four German Länder detailed specific asynchronous and obsolete GM events tested (tSogether taken as national response for Germany).

Figure 1. There is significant variation in the numbers of food samples collected by Member States for GMO analysis, including for the presence of asynchronous and obsolete events. The majority of countries collected on average fewer than 350 samples per annum (2009-2014)

Average number of GMO food samples per annum (2009-2014)



N.B. Sampling figures for UK are not national-level data. The response is solely in relation to point of import sampling at the border and predominantly in relation to GM legislative controls for rice and rice products from China.

Source: online survey of NCAs and CAs (N= 26 Member States)[21]

[21] Spain and Latvia did not indicate the number of food samples tested for GM material.

3.1.2 Sampling methods adopted for official controls

Question A.2. What sampling procedures are implemented for the presence of asynchronous and obsolete GM material in food in the Member States?

3.1.2.1 Context

Sampling procedures define parameters such as where and how the sample is taken, and the size or quantity that is taken. Commission Recommendation 2004/787/EC provides technical guidance for the implementation of sampling and analysis of GM material. The technical guidance includes a sampling protocol for bulk agricultural commodities (grains and oilseeds) and a sampling protocol for pre-packaged food.

Recommendation 2004/787/EC includes guidance on sampling of bulk agricultural commodities:

- how to conduct static and dynamic sampling[22]; and
- how to establish the size of the bulk sample[23] and the number of incremental samples[24] collected through either static or dynamic sampling.

Recommendation 2004/787/EC indicates that sampling of pre-packaged food and feed products should be carried out according to the procedures described in the International Organization for Standardization (ISO) standard 2859.

Current rules on GM food sampling and analysis contained in Recommendation 2004/787/EC are not binding, however, and cover products that have received authorisations for their placing on the market. Since sampling procedures specific to asynchronous and obsolete GMOs in food do not exist and GMO sampling in food is not harmonised at EU level, Member State NCAs and CAs may take different approaches and rely on different protocols from one another. Differences may exist in the approach to the sampling point chosen along the supply chain and the protocols used for sampling different types of product, whether bulk commodities or packaged foods.

3.1.2.2 Findings

This section presents the research findings on the main protocols applied by NCAs in EU Member States for the following aspects of sampling: the stage of the supply chain at which samples are collected, the characteristics of the protocols for the sampling of bulk commodities, and the protocols relating to sampling of pre-packaged foods.

Sampling point

Thirty-one NCAs and regional CAs covering 24 Member States provided information on the stages and points along the supply chain at which sampling is carried out for the presence of asynchronous and obsolete GM material in food. The majority of respondents in these countries carry out sampling activities at retail premises (23 respondents in 18 of 24 Member States), border inspection posts (18 respondents in 17 of 24 Member States) or premises of wholesalers (18 respondents in 14 of 24 Member States) (Figure 2). Eleven respondents in 10 countries undertake sampling at all three of these points

[22] Based on Recommendation (EC) 787/2004, incremental samples can be taken from different individual sampling points in the lot through the full depth of the lot (static sampling), or from the product stream during a stated portion of time (for example, during the unloading of a truck) (dynamic sampling).

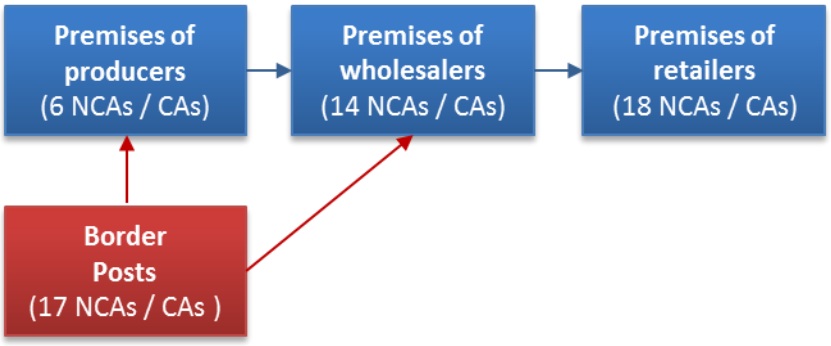
[23] The bulk sample is defined as the 'quantity of product obtained by combining and mixing the increments taken from a specific lot' (Commission Recommendation 2004/787/EC).

[24] Incremental samples are defined as the 'small equal quantity of product taken from each individual sampling point in the lot through the full depth of the lot (static sampling), or taken from the product stream during a stated portion of time (flowing commodities sampling)' (Commission Recommendation 2004/787/EC).

along the supply chain. Eight NCAs in six countries carry out sampling at food production and manufacturing sites. Two respondents in two countries take samples from storehouses.

Individual Member State responses are provided in Annex 5, Table 18.

Figure 2. Member States carry out sampling for the presence of asynchronous and obsolete GM materials at different points along the supply chain, including port and territorial inspections[25]



Source: online survey of NCAs and CAs (N= 24 Member States)

Sampling protocols – bulk commodities

Information on specific protocols used for static and dynamic sampling of asynchronous and obsolete GM materials in food was provided by 22 NCAs and CAs across 19 Member States.[26] The NCA in one Member State (Luxembourg) indicated that it does not sample any bulk agricultural commodities. NCAs in five Member States did not respond.

Seventeen respondents in 16 Member States follow the protocols for static sampling specified in Section IV Article 2(1) of Recommendation 787/2004. Sixteen respondents in 12 Member States follow the equivalent protocols for dynamic sampling contained in the Article 2(1) Recommendation. With the exception of Italy and Germany, all of the Member States which stated that they follow the static and dynamic sampling protocols contained in this Recommendation apply these protocols for all bulk commodities sampled for the presence of asynchronous and obsolete GM events. Both Italy and Germany specified that alternative sampling protocols can be used, but they did not provide details about the types of bulk commodities for which the different protocols are applied. The Italian authority clarified that, in addition to Recommendation 787/2004, protocols used are national guidelines by the Italian National Health Institute and Regulation (EC) No 401/2006[27] on the methods for sampling regarding mycotoxins. German respondents[28] specified that other protocols used include guidelines by the Federal Office of Consumer Protection and Food Safety (BVL), TS15568, EN ISO 542 and EN ISO 13690.

Five respondents in five countries (Austria, Belgium, Germany, Italy and the Netherlands) indicated that they use additional and alternative sampling protocols, including ISO and domestic standards and those established under other EU legislation (Annex 5, Table 19, Table 20).

[25] Two Member States indicated that they undertook sampling at storehouses / warehouses, but did not specify whether this related to storage facilities in food production, wholesale or retail operations.

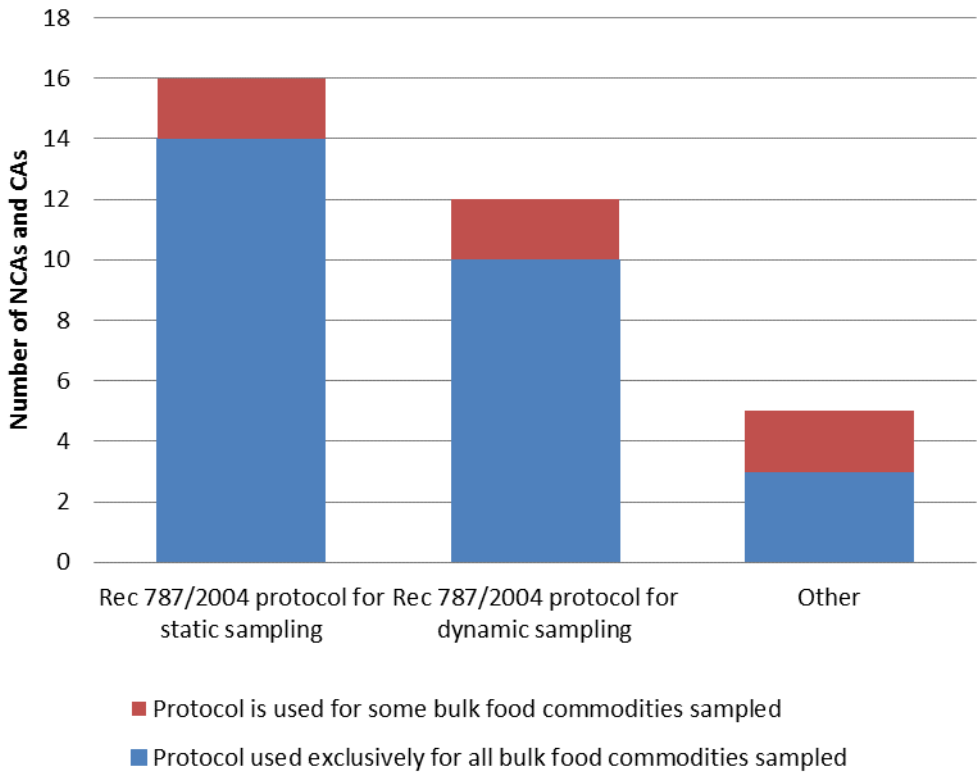
[26] This includes CAs in three German Länder and NCAs which responded to the survey question.

[27] Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

[28] Namely, the NCA in charge of sampling and CAs in two German Länder.

Figure 3. The majority of NCAs and CAs that responded to the survey use static and dynamic sampling protocols contained in Section IV, Article 2(1) of Recommendation 787/2004 to test bulk food commodities for the presence of asynchronous and obsolete GM material

Number of NCAs using static, dynamic and other sampling protocols



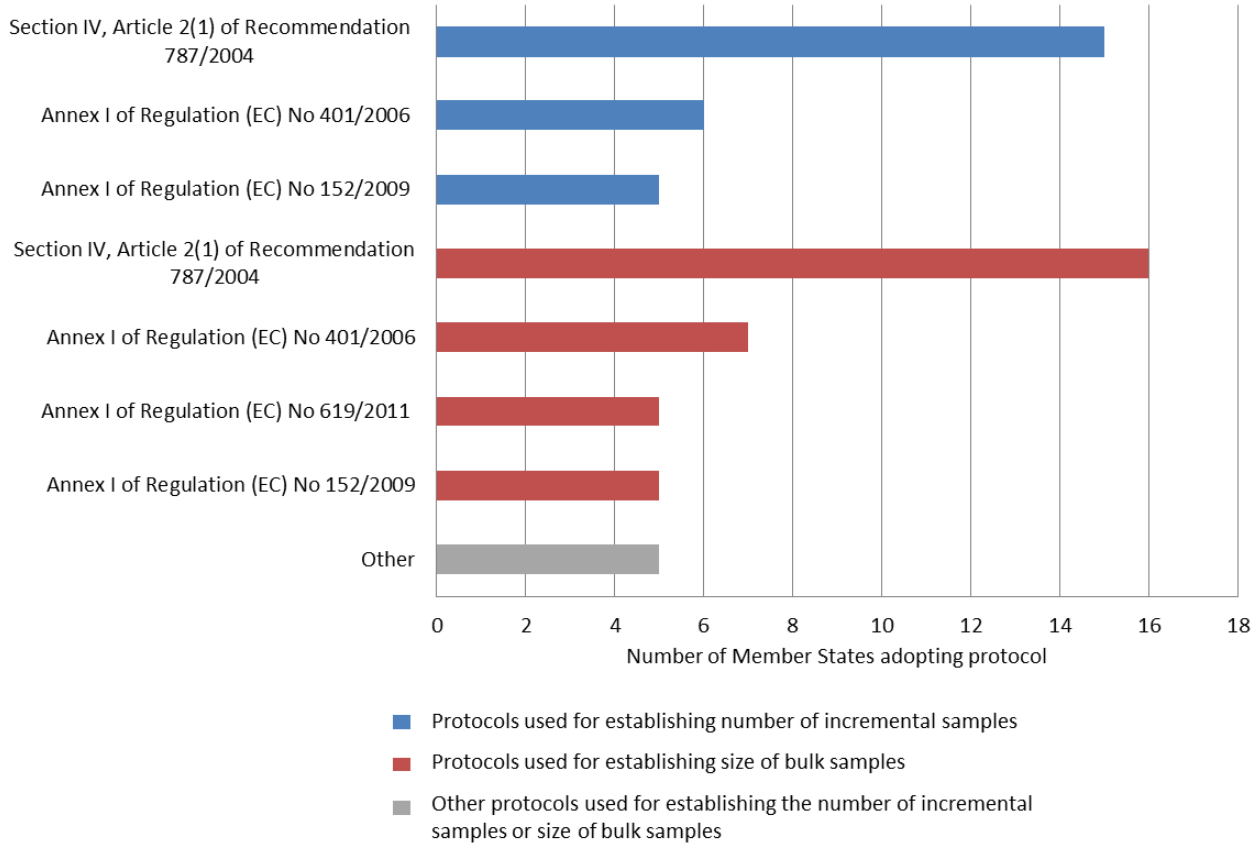
Source: online survey of NCAs and CAs (N = 19 Member States)[29]

Twenty NCAs and CAs in 18 countries provided details on the protocols used to establish the number and size of incremental samples and size of the bulk sample taken from lots of bulk agricultural commodities. Sixteen authorities (across 15 Member States) who responded adhere to Recommendation 787/2004 protocols to establish the number of incremental samples. Seventeen respondents (across 16 Member States) follow the same recommendation protocols to establish the size of bulk samples (Figure 4). Five NCAs and CAs in five countries also follow sampling protocols established under Regulation (EC) No.152/2009[30]; seven respondents in seven Member States follow Regulation (EC) No. 401/2006 to establish size of the bulk sample; six respondents in six countries follow Regulation (EC) No. 401/2006 to establish the number of incremental samples; and five countries follow Regulation (EC) No. 619/2011. Five authorities in five countries reported using other protocols, including ISO standards (Annex 5, Table 21).

[29] Response from the BVL was taken as the national response for Germany. BVL indicated that Länder were using the specified sampling protocols. Four of the seven Länder for which survey responses had been received, did not indicate whether they were using these protocols. One Land stated that it was applying the Recommendation 787/2004: protocol for static and dynamic sampling. Two Länder indicated the use of other protocols.

[30] Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed.

Figure 4. NCAs and CAs use different sampling protocols for establishing the number of incremental samples and size of bulk samples. Protocols contained in Section IV, Article 2(1) of Recommendation 787/2004 are most commonly used



Source: online survey of NCAs and CAs (N= 18 Member States)[31]

Sampling protocols – packaged food products

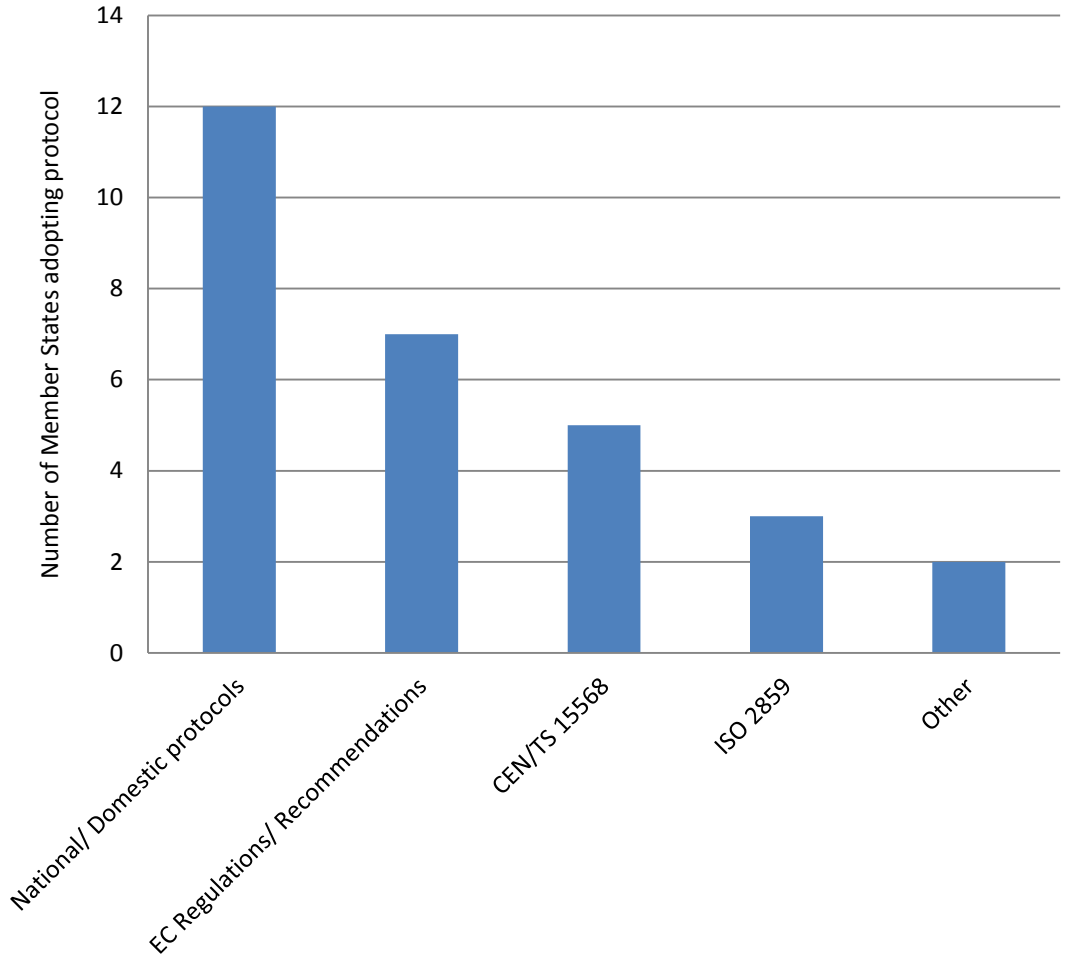
There appears to be a high degree of variance in the protocols used by NCAs and CAs in Member States for sampling packaged food products; few use the same protocol. Twenty-six authorities in 22 Member States provided information on the protocols they use: 12 respondents in 11 Member States use their own national standards,[32] six in six Member States use the European Committee for Standardization, Technical Specification (CEN/TS) 15568 standards, three in three Member States use ISO 2589 and six in six Member States follow EC regulations and recommendations (e.g. Regulation 401/2006 and Recommendation 787/2004) (Annex 5, Table 22).

[31] The response from the Federal Office of Consumer Protection and Food Safety (BVL) was taken as the national response for Germany.

[32] The information collected in this study does not include an analysis of the similarities or differences between these nationally-developed protocols.

Figure 5. NCAs and CAs most commonly use their own domestic standards for sampling packaged food products. CEN/TS 15568 and ISO 2859 are also used by some Member States

Number of Member State applying different protocols for sampling packaged food products



Source: online survey of NCAs and CAs (N = 22 Member States)

3.1.3 Harmonisation of sampling methods

Question A.3. Does the lack of harmonisation of sampling procedures have any impact on the reproducibility of test results (within Member States and between Member States)? Have Member States ever had practical experience on that?

Question A.7. Are there any beneficial or negative effects deriving from the harmonisation of sampling […]? What are these effects?

3.1.3.1 Context

Even a small difference between approaches used to sample asynchronous and obsolete GMOs in food may lead to different conclusions on the compliance of food products under the 'zero tolerance' policy. The main factors affecting the results are:

- The sample sizes: larger sample sizes increase the probability of detecting GMOs, including asynchronous and obsolete GM material. Member State approaches

regarding sample sizes can vary, thus leading to lack of harmonisation (ENGL, 2011).

- The number of incremental samples collected and the distribution of sampling points across the food lot: the distribution of GM material in food lots may be heterogeneous (Paoletti et al., 2006) and therefore it is important to collect samples at different points across the food lot in order to ensure statistical representativeness.

3.1.3.2 Findings

This section presents the findings regarding impacts from the lack of harmonised sampling protocols, and the potential benefits and negative effects from harmonisation.

Issues arising from the lack of harmonisation of sampling procedures

Thirty-seven NCAs and CAs covering 27 Member States were consulted regarding their views on harmonisation of sampling methods[33]. Fifteen NCA and CA respondents in 13 Member States felt that the lack of harmonisation of food sampling procedures impacts on the reproducibility of test results between Member States. None of the respondents (with the exception of the Belgian NCA in charge of sampling, one German Land and a UK Port Health Authority) deemed the lack of harmonisation to affect the reproducibility of test results within national borders. Fifteen respondents in 13 countries[34] felt that the lack of harmonisation does not impact on the reproducibility of test results for GM material in food either within or between Member States. Five consultees did not respond to the question on issues arising from the lack of harmonisation (Table 23).

NCAs and CAs in 11 Member States provided details on the specific factors causing impacts. The lack of harmonisation of protocols for static and dynamic sampling of bulk agricultural commodities was the most often cited factor deemed to have an impact on the reproducibility of test results **between** Member States (nine Member States). The lack of harmonisation of protocols to establish the number and size of incremental samples and size of the bulk sample regarding lots of bulk agricultural commodities, and the sampling of packaged food products were also commonly cited (eight Member States respectively). Seven Member States considered the lack of harmonisation of protocols for obtaining laboratory samples from bulk samples of lots of bulk agricultural commodities and six Member States for obtaining laboratory samples for packaged food products to affect the reproducibility of test results (Table 1).

The UK Port Health Authority indicated that the lack of harmonisation of protocols for the sampling of packaged food products could affect reproducibility of results **within** Member States, and explained that issues could arise as packaged/processed products are assumed to be homogenous. The authority reported that it had practical experiences of these impacts, but did not provide details of these experiences. A German Land CA also reported issues regarding reproducibility of results within Member States, but did not comment on experiences of these impacts. The German CA specified that absence of harmonisation of the following elements of sampling methods have an impact on reproducibility:

- Protocols for static and dynamic sampling of bulk agricultural commodities;

[33] NCAs and CAs responsible for **sampling** in all Member States were asked to provide their opinions regarding issues arising from the lack of harmonised protocols for sampling, including NCAs in Member States that did not perform testing of asynchronous and obsolete GMOs. Latvia did not provide a response to the survey on sampling.

[34] CAs in three German Länder stated that the lack of harmonisation does not impact on the reproducibility of testing results.

- Protocols to establish the number and size of incremental samples and size of the bulk sample regarding lots of bulk agricultural commodities;
- Protocols for obtaining the laboratory sample from the bulk sample regarding lots of bulk agricultural commodities; and
- Protocols for sampling of packaged food products and for obtaining the laboratory sample for packaged food products.

Table 1. Perceived impacts of the lack of harmonisation of food sampling procedures on the reproducibility of test results between Member States

	MS that believe that the lack of harmonisation of food sampling procedures has an impact on reproducibility of test results	**MS that had practical experience of these impacts**
Protocols for static and dynamic sampling of bulk agricultural commodities	9 (DE[35], BE, BG, EL, HU, IT, NL, HR, CZ, MT)	3 (DE, PL[36], HR)
Protocols to establish the number and size of incremental samples and size of the bulk sample regarding lots of bulk agricultural commodities	8 (DE, BG, HU, IT, NL, HR, CZ, MT)	3 (DE, PL, HR)
Protocols for obtaining the laboratory sample from the bulk sample regarding lots of bulk agricultural commodities	7 (DE, BG, HU, IT, NL, CZ, MT)	2 (DE, PL)
Protocols for the sampling of packaged food products	8 (DE, BG, EL, HU, IT, HR, CZ, MT)	4 (DE, EL, HR, PL)
Protocols for obtaining the laboratory sample for packaged food products	6 (DE, BG, HU, IT, CZ, MT)	1 (DE)
Other	1[37] (DE)	1 (DE)
Total MS respondents	**11 Member States**	

Based on responses of 11 Member State NCAs which perceived the lack of harmonisation of food sampling procedures to have an impact of the reproducibility of test results between Member States.

[35] Response from the Federal Office of Consumer Protection and Food Safety (BVL) was taken as the national response for Germany. One German Land also provided same response.

[36] Poland did not see the need for harmonisation of methods for sampling, analysis and interpretation of results with regard to solely asynchronous and obsolete GM material, but did see need for harmonisation of issues in relation to food and presence of GM material in general. Poland did not specifically indicate its position on impacts of harmonisation as the question related to asynchronous and obsolete GM material, although it did note practical experience of impacts.

[37] No response from the Federal Office of Consumer Protection and Food Safety (BVL), but two German Länder indicated perceived impacts from lack of harmonisation in other protocols.

Source: ICF analysis of responses to case study interviews and to the online survey of NCAs and CAs

The study team undertook in-depth interviews with NCAs in seven case study countries[38] to investigate the main issues arising from lack of harmonisation (Table 24). Consultees in Belgium and Hungary indicated that the principal issue is the potential for different results when there is heterogeneous distribution of GMOs in food lots due to variation in sampling methods, as described in the box below.

Two respondents identified the potential for a lack of harmonisation of sampling methods to lead to problems

Belgium

Authorities in Belgium indicated that the lack of harmonisation of sampling protocols could be a problem within Member States and between Member States. The main issue highlighted by Belgian consultees is that the sampling methods may not take into account the heterogeneous distribution of GMOs in the food lot. Sampling is a critical step in GMO analysis: it may happen that one inspector collects a sample of 500 grams from only one point in the food lot, while another inspector may collect a consolidated sample of 500 grams by taking smaller amounts of sub-samples from different parts of the food lot. Since the distribution of GMOs in the food lot is not homogenous, these sampling approaches could lead to diverging results. As GM material is generally present at very low levels in official samples, the potential for divergent results increases.

Hungary

The occurrence of GMOs in food is not homogeneous, therefore appropriate and unified sampling is very important. There are well-established examples in this respect in the EU for mycotoxins, metals, and dioxins. A unified, compulsory sampling procedure for GMOs would benefit Member States.

Source: case study interviews with NCAs

Potential benefits and negative effects from the harmonisation of sampling protocols

Sixty-two NCAs and CAs covering all 28 Member States were consulted regarding their views on harmonisation of sampling methods[39]. Thirty-nine NCAs and CAs (covering 23 Member States) perceived there to be **benefits** from harmonisation of sampling methods, while 18 (in 11 Member States) believed that there would not be any benefits and six (in five Member States) did not respond (see Annex 5, Table 25).

The most commonly reported benefit consisted in improved comparability of testing results (cited by 19 respondents). Three respondents explained that harmonised protocols could be beneficial in addressing the problem of heterogeneous distribution of GMOs in food lots. Two respondents specified that, in order to be beneficial, sampling protocols should be harmonised for all GMOs, and not only for asynchronous and obsolete events.

NCAs and CAs were also asked about possible **negative impacts** from the harmonisation of sampling protocols. Most respondents (35 out of 62, across 22 Member States) stated that there would not be any negative impacts. Nevertheless, 21 respondents in 12

[38] The case study countries were: Austria, Belgium, France, Germany, Hungary, Spain and the Netherlands.

[39] NCAs and CAs in all Member States were asked to provide their opinions regarding the potential benefits and negative effects from harmonisation, including NCAs responsible for analysis and NCAs in Member States that did not perform testing of asynchronous and obsolete GMOs.

Member States perceived there to be **negative impacts** associated with harmonisation of sampling methods., while 21 (in 12 Member States) reported potential negative effects and seven (in six Member States) did not respond (see Annex 5, Table 25). The reported sources of negative effects were as follows:

- Potential negative impacts cited by eight respondents were the increased effort, inconvenience and higher costs associated with implementing harmonised controls. For example, one respondent cited the need to train officials to the use of new protocols.
- Eight respondents stated that, in general, official controls do not specifically target asynchronous and obsolete GMOs and sampling protocols used are the same for all GMOs. For this reason, there could be negative effects if a completely new and mandatory protocol is introduced for asynchronous and obsolete GMOs. Example of possible issues are the reduced flexibility to use the samples for different tests and increased risk of mistakes due to the adoption of multiple sampling methods (i.e., different protocols for asynchronous/obsolete GMOs and other types of GMOs) and decreased flexibility in the choice of methods to be adopted for official controls.
- One respondent suggested that harmonised protocols will reduce the flexibility that Member States have to undertake sampling according to their own risk assessments.

3.1.4 Methods for analysis adopted for official controls

Question A.4. What test procedures are implemented in the Member States regarding the control of the presence of asynchronous and obsolete GM material in food (qualitative, quantitative, […])?

3.1.4.1 Context

Different testing strategies may be adopted by laboratories in charge of official controls on GMOs. The polymerase chain reaction (PCR) approach is the most commonly used method for GMO tests. The main steps of a tests strategy are:

- **Screening - element specific PCR**: this step includes a search for elements (targets) that are common to several GMOs (for example, a promoter or a terminator). A limited number of screening tests are able to cover the whole range of authorised GMOs and some unauthorised GMOs.
- **Screening - construct specific PCR**: this method targets the junction between elements of GMOs. This method is able to identify a more limited range of possible GMOs (but not the specific GMO event) that may be present in the sample analysed.
- **Identification - event specific PCR**: this method targets the junction between the deoxyribonucleic acid (DNA) insertion and the plant genome and therefore is specific for the relative GM event. The methods are provided by applicants for the authorisation of a GMO and validated by the European Union Reference Laboratory for GM Food and Feed (EURL GMFF).
- **Quantification** of the GM content may also be performed.

Reference methods for event-specific analyses are available at EU level and are published by the EURL GMFF, while harmonised guidance for screening is absent. Screening strategies for official controls may therefore differ across Member States. For example, the sequences of promoters targeted by methods for screening can vary.

3.1.4.2 Findings

Twenty-four of the 25 Member States that carry out official controls of asynchronous and obsolete GMOs provided details of the types of screening elements/constructs targeted during analyses. All of the laboratories that responded from these countries use both the Cauliflower Mosaic Virus p35 and Agrobacterium tumefaciens tNOS as screening elements or constructs for targeting asynchronous and obsolete GM material in food. Other screening elements and constructs are also routinely used by laboratories in these countries, with the exception of Estonia, Ireland, Latvia, Malta and one laboratory in the Netherlands. The most widely used screening elements are PAT, BAR, PFMV, CTP2-CP4 EPSPS, Cry1Ab/Ac and p35S-PAT (see Annex 5, Table 26).

Twenty-eight laboratories (in 19 Member States) use qualitative PCR methods for the identification of GM events. Twenty-one laboratories (in 15 Member States) use quantitative PCR methods. Seventeen laboratories (in 12 Member States) used both qualitative and quantitative PCR methods. No respondents indicated that they use other identification methods.

The majority of respondents who use qualitative PCR methods indicated that limits of detection (LODs) vary depending on the different methods used and the GM event that is tested. LODs range from 0.01 to 0.5 per cent. Laboratories in Austria, Lithuania and one German Land provided a list of LODs for event-specific methods (Annex 5, Table 27). Respondents in three countries reported only one limit of detection for all methods, more specifically:

- Cyprus: for all screening elements/constructs and GM events the LOD is 0.1 per cent.
- Greece: the LOD is 0.1 per cent (PCR) or 20 copies (Real Time PCR).
- Romania: the LOD is 0.04 per cent for every qualitative method.

Besides being laboratory-dependent, LODs vary across different methods and GM events; the indication of an LOD which does not vary may suggest that these countries did not estimate the LOD for each method, but rather verified that the methods are capable to detect a certain fixed GM content.

Twelve respondents using quantitative PCR methods indicated that the limits of quantification (LOQs) depend on the methods used. Laboratories indicated that for most methods and events this was at or below 0.1 per cent.[40] NCAs in five countries reported the same LOQs for all methods: the reported LOQ was 0.1 per cent in four countries (Croatia, Lithuania, Latvia and Romania) and 50 copies of target sequence per reaction in one country (Slovenia). As in the case of LODs, this may mean that these five countries did not estimate the LOQ for each method, but rather verified that the methods are capable to quantify a certain fixed GM content.

Of those using quantitative PCR methods, 14 respondents (in 11 Member States) estimate measurement uncertainty in all cases. Ten laboratories in eight Member States estimate measurement uncertainty in some cases (Table A5.12).

The methods used for the identification of GM events were discussed in more detail during interviews in case study countries. Consultees in all the seven case study Member States explained that the methods applied for official controls correspond to the reference methods published by the EURL GMFF.

[40] Austria and Cyprus indicated the use of LOQs above 0.1% for specific GM events.

3.1.5 Adoption of limits to assess compliance

Question A.4. What testing procedures are implemented in the Member States regarding the control of the presence of asynchronous and obsolete GM material in food ([…] MRPLs…)?

3.1.5.1 Context

Currently, there is no harmonised MRPL for asynchronous and obsolete GM material in food. NCAs in Member States may adopt different approaches to determine compliance of a food sample when asynchronous and obsolete GM material is detected and/or quantified. Examples of possible options are:

- The food lot is not compliant if any content of asynchronous or obsolete GMOs is detected based on the application of qualitative methods of analysis;[41] and
- The food lot is not compliant if asynchronous/obsolete GM material exceeds a specific limit, based on results from quantitative methods of analysis.

3.1.5.2 Findings

Information regarding the approaches used to assess compliance was provided by NCAs in 24 of the 25 Member States that performed analyses of asynchronous and obsolete GMOs between 2009 and 2014[42]. In the majority of cases (22 out of 24 Member States) **no quantitative limits are applied** to assess compliance of asynchronous and obsolete GMOs in food. In these Member States, NCAs and CAs use qualitative methods of analysis to detect presence of asynchronous and obsolete GMOs in food lots and verify compliance.

NCAs in two countries (Poland and UK) assess compliance based on whether asynchronous or obsolete GM material exceeds a **specific limit based on results from quantitative methods** of analysis. In both these Member States, official laboratories perform quantification of GM content in food and apply a 0.1% limit. NCAs explained that this limit is applied due to the high level of uncertainty arising from the detection of low levels of GM content. More details are provided in Annex 5, Table 29.

3.1.6 Harmonisation of methods of analysis and introduction of a MRPL for food

Question A.5. Does the lack of harmonisation in the interpretation of test results have an impact on compliance assessment (within Member States and between Member States)? Have Member States ever had practical experience on that?

Question A.6. Would the definition of a Minimum Required Performance Limit affect protocols of testing?

Question A.7. Are there any beneficial or negative effects deriving from the harmonisation of sampling and analysis and the introduction of a Minimum Required Performance Limit for food as it already exists for feed? What are these effects?

3.1.6.1 Context

Differences in the protocols adopted for analysis and the interpretation of results may lead to different approaches to compliance assessment. Examples of potential issues include:

[41] Qualitative methods identify whether any GM content is present in the sample tested, but do not quantify the amount of GM material in the sample.

[42] No analysis of asynchronous and obsolete GMOs was performed in three Member States: Bulgaria, Spain and Sweden. Latvia did not provide information regarding the approach to compliance assessment.

- The capacity to test for different GM events and the specific events covered may vary across laboratories involved in official controls.
- The adoption of qualitative or quantitative methods: as reported in Regulation (EU) No 619/2011, qualitative methods are associated with a higher risk of diverging results compared to quantitative methods. Quantitative methods are therefore deemed 'more appropriate […] for the purpose of ensuring the harmonisation of the official controls' (Regulation (EU) No 619/2011). However, not all laboratories may be equipped to conduct quantitative analyses.
- The interpretation of results and the conclusions reached regarding compliance of food products: Member States may decide that the identification of a level of GM material below a certain level is not sufficient to demonstrate non-compliance, and the level identified may vary.

3.1.6.2 Findings

Sixty-two NCAs and CAs covering all 28 Member States were consulted regarding their views on harmonisation of analysis methods (Table 30). The majority of NCAs and regional CAs (30 respondents in 17 Member States) considered the lack of harmonisation of analysis protocols to have an impact on compliance assessment between or within Member States. Twelve respondents (in 11 Member States) did not think that the lack of harmonisation has any impacts on compliance assessment. Seventeen consultees stated that the question on the harmonisation of analysis methods was not applicable to them and three did not respond. Most respondents who believed that the lack of harmonisation in the interpretation of test results has an impact on compliance assessment also reported having had practical experiences of these impacts. The adoption of different criteria to assess whether a testing result is positive or negative was cited as an example of these impacts.

Thirty-six NCAs and regional CAs across 20 Member States considered there to be **benefits** from the **harmonisation of analytical methods** (Annex 5, Table 31). Benefits cited by these respondents include greater comparability of results. Twenty-one respondents in 13 Member States did not see any benefits[43] and seven did not respond. Half of those that did not see any benefits from harmonisation (11 respondents) explained that methods are already harmonised in the EU, and six of them made reference to the use of EURL methods. Case study interviewees also generally agreed that current methods for event-specific analysis are effectively harmonised at EU level. Methods published by the EURL GMFF are used. Two Member States reported that the main stages where issues could arise are:

- screening for the potential presence of GMOs, since there are no harmonised protocols in the EU; and
- interpretation of results and adoption of limits.

The majority of respondents (41 respondents in 23 Member States) felt that there would not be any **negative impacts** from the harmonisation of methods of analysis. Thirteen NCAs and CAs in 11 Member States believed that harmonisation of analytical methods could lead to negative effects. Most of the perceived disadvantages cited by respondents relate to the increased costs of laboratory analysis and accreditation of all new analytical methods. Eight NCAs and CAs did not provide their views on negative impacts.

[43] Representatives from two CAs replied both 'yes' and 'no' to the question regarding possible benefits from harmonisation, as they believed that harmonised guidance for the interpretation of testing results could be useful, while the introduction of new protocols specific to asynchronous and obsolete GMOs would not be beneficial. Detailed for the reason for their responses are provided in Annex 5, Table 31.

Thirty-eight respondents in 22 Member States considered there to be **benefits** from the **introduction of a MRPL for food** and its harmonisation with that already existing for feed. The benefits cited included increased accuracy and comparability of results.

Respondents were evenly divided in their views on **negative impacts** associated with the harmonisation of MRPLs for food with feed. Twenty-six respondents in 15 Member States considered there to be some negative impacts, and a similar proportion (28 respondents in 18 Member States) did not foresee any adverse impacts. Perceived negative effects included the greater burden of work and costs of laboratory analysis (Annex 5, Table 32).

Consultees in case study countries also had mixed views regarding the potential benefits and negative effects from the introduction of a MRPL. For example, NCAs in both Austria and Belgium stated that a MRPL for food could enhance the comparability of test results. Consultees in these countries stated that there could also be negative impacts in terms of additional costs and resources needed by laboratories to implement the changes required by the introduction of a MRPL (Annex 5, Table 33).

Half of respondents (31 out of 62, covering 17 Member States) believed that the definition of a MRPL for food would affect protocols for testing. The most cited consequence was the need to perform quantification of GM content for those laboratories that use qualitative methods to detect asynchronous and obsolete GMOs in food. According to respondents, quantification would require additional work and resources.

3.2 Impacts on food business operators and on the market

This section summarises the sampling, analysis and risk management strategies adopted by food business operators regarding asynchronous and obsolete GM material in food. It describes the impacts arising from the lack of harmonisation of protocols for sampling and analysis, and expected impacts from the potential harmonisation of rules for food with feed, and introduction of a MRPL for food.

The findings on business impacts build on desk research, market analysis (see section 3.2.1 and Annex 4) and consultations with business representatives. The following stakeholder groups were involved in the consultation: EU and national business associations, national and multinational businesses operating in EU Member States, third country representatives, commercial laboratories and NGOs.[44]

Details on the number, type, geographic and supply chain coverage of the stakeholders consulted are provided in Table 2.

[44] The responses of one NGO (IFOAM) were included in the analysis as the organisation represents organic food producers, and the consultee provided its views regarding business impacts.

Table 2. Impacts on food business operators – stakeholders

Type of consultee	Details	Geographic coverage	Supply chain coverage	Total
EU Business Associations	Federation of the European vegetable oil and proteinmeal industry (FEDIOL)	EU (17 MS[45])	European vegetable oil and protein meal industry. Members are 12 national associations of oilseed crushers and refiners; five individual companies are members in countries where there is no association present, or where the existing association is not a member of FEDIOL. Directly and indirectly covers about 150 processing sites that crush oilseeds and/or refine crude vegetable oils, belonging to around 35 companies. More than 85% of the EU crushing and refining activity is estimated to be covered by the membership structure.	6
	European association representing the trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agrosupply (COCERAL)	EU (18 MS[46])	EU collectors, traders, importers, exporters and port silo storekeepers of cereals, rice, feedstuffs oilseeds, olive oil, oils and fats. Full members are 26 national associations in 18 Member States and 1 European association. Approximately 2,500 companies are national members. The sector trades agricultural raw materials destined to the supply of the food and feed chains, as well as for technical and energy uses. Two associated members in Switzerland and Serbia.	
	European Starch Industry Association (Starch Europe)	EU (20 MS[47])	EU starch industry. Members are 24 EU starch producing companies, together representing more than 95 per cent of the EU starch industry, and, in associate membership, 7 national starch industry associations.	
	FoodDrinkEurope	EU	Represents industry of all sizes: small and medium sized companies account for more than 90 per cent of the businesses represented either through their national federations, European sectors or direct membership of FoodDrinkEurope.	

[45] Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Poland, Portugal, Romania, Spain, Sweden, the Netherlands, UK.

[46] Austria, Belgium, Bulgaria, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Luxemburg, Poland, Romania, Slovenia, Spain, Sweden, the Netherlands and UK.

[47] Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, Spain, Sweden, the Netherlands, UK.

Type of consultee	Details	Geographic coverage	Supply chain coverage	Total
	European Lecithin Manufacturers Association (ELMA)	EU (3 MS[48])	Major producers of lecithin in the European Union. Its members are based in Germany, Spain and the Netherlands.	
	European Vegetable Protein Federation (EUVEPRO)	EU (all MS)	Businesses in the manufacturing and processing of soya flour, soya protein concentrates, and soya protein isolates for use in foods.	
National business associations	-	CZ	A consultancy in the field of food industry, with a focus on small and medium-sized businesses. It covers primary food producers, processors and retailers.	4
	-	NL	Food industry federation.	
	-	NL	Dutch producers of edible oils and fats.	
	-	ES	Oilseeds processors.	
Multinational businesses	Food processor	EU (all MS)	Ingredient processor serving the food and feed industry.	3
	Food processor (two businesses)	EU (most MS)	Manufacturers of finished food and feed products.	
National business	Food processor	UK	Manufacturer of rolled oat flakes.	1
Commercial laboratories	-	EU (most MS)	Testing covers the whole food and feed chains: from sample of raw ingredients collected at primary production to finished products sent by retailers.	2
NGO	IFOAM EU	EU	More than 160 members covering the entire supply chain, including farmers, food and feed processors, retailers, certifiers, traders.	1
Third countries	North American Export Grain	US	Private and publicly owned companies and farmer-owned cooperatives that are involved in and provide services to the bulk grain and oilseed exporting	5

[48] Germany, Spain and the Netherlands.

Type of consultee	Details	Geographic coverage	Supply chain coverage	Total
	Association (NAEGA)		industry.	
	US Department of Agriculture (USDA)	US	-	
	Ministry of Agriculture and Agri-Food	Canada	-	
	Brazilian Mission to the EU	Brazil	-	
	Ministry of Agriculture and fisheries	Argentina	-	
Total				**22**

Source: ICF analysis of consultation results

3.2.1 Findings of the market analysis

The review of impacts on food business operators and on the EU market involved research and analysis aimed at providing:

- a narrative description of the development (value and volume) of the soya and maize markets, which were identified as the most relevant markets for the purposes of this study in terms of potential impacts arising from the presence of asynchronous and obsolete GM material in food; and
- a description of the structure and operation of the market, following the supply chain from the point of production to the final consumer and explaining the forces that drive change in the market.

The complete market analysis is provided in Annex 4.

3.2.1.1 Soybean

The market analysis shows that the EU is highly dependent on imports of soybean from third countries where GMO cultivation is widespread. In the US and Brazil, more than 90 per cent of soybean planted in 2014 was GM; these two countries are the largest exporters of soybean to the EU.

In 2014, EU production of soybeans only covered about 10 per cent of total use. In the period from 2014 to 2024, soybean production in the EU is expected to increase by seven per cent: from 1.4 to 1.5 million tonnes (DG AGRI, 2014). Over the same timeframe, EU imports of soybeans are expected to decrease slightly but still remain considerably higher than domestic production. The US, Brazil and Argentina are expected to maintain their leading role as producers (USDA, 2015).

Ingredients derived from soybeans are predominantly used for food production: based on industry estimates, over 15 million tonnes of final food products are affected by the use of soy ingredients in the EU (Landmark Public Policy Advisers Europe, 2009). The most common soybean derived ingredients used for food production are soy oil and soy lecithin. Soy oil is mainly produced in the EU through the crushing of imported beans, while imports of soy oil from third countries are limited: in 2014, the EU produced 2.4 million tonnes of soybean oil and 0.3 million tonnes of oil were imported (DG AGRI, 2015).

3.2.1.2 Maize

The EU is largely self-sufficient in maize production: in 2013-2014, EU maize production was estimated at 66.8 million tonnes, and over the same period 15 million tonnes were imported (DG AGRI, 2014). Imports originated mainly from Ukraine (63 per cent), Brazil (10 per cent), Russia (7.5 per cent) and Canada (6.6 per cent), and were mainly directed to the Spanish, Dutch and Italian markets (DG AGRI, 2014). In Brazil and Canada over 80 per cent of maize cultivation is GM (James, 2014; Dessureault and Lupescu, 2014).

According to DG AGRI (2015), 4.9 million tonnes of maize were used for human consumption in 2013-2014, which corresponds to only 6.5 per cent of the total maize supply. Examples of the main food applications included: cornflakes for the preparation of breakfast cereals, fine maize grits for the snack and brewing industry, and maize flour for the snack industry.

3.2.1.3 Industry assessments regarding asynchronous and obsolete GM material in food

EU industry associations have assessed the impacts on food and feed business operators arising from asynchronous authorisations of GMOs (FEDIOL, 2014, 2011a and 2011b; EUVEPRO, 2011; Landmark Public Policy Advisers Europe, 2009; Solae, 2010 and PFP, 2011).

These assessments did not always focus on the issue of harmonisation of sampling and analysis protocols for official controls, but they provide evidence regarding the expected economic impact arising from the absence of a MRPL for food. Additional details on these assessments are provided in Annex 4, section A4.4. Soybean was identified by these assessments as the main commodity affected.

3.2.2 Sampling, analysis and risk management strategies adopted by food business operators

Question B.1. What are the sampling, analysis and risk management strategies and protocols applied by food business operators regarding asynchronous and obsolete GMOs? How many and what kind of samples are taken and what types of tests are performed on an annual basis in the framework of the own check controls?

Food business operators may implement internal procedures to avoid and manage contamination with asynchronous and obsolete GMOs. Examples of these procedures include:

- sampling and analysis to identify the presence of GMOs (including asynchronous and obsolete GMOs);
- risk management strategies to avoid contamination with asynchronous and obsolete GMOs, including, for example, segregation of supply chains or the use of GM assurance schemes;[49] and
- risk management strategies adopted when asynchronous and obsolete GMOs are detected through businesses' own checks.

This section assesses the extent to which these procedures are applied by food business operators.

3.2.2.1 Sampling

Seven consultees[50] stated that they (or their members, in the case of business associations) undertake some sampling and analysis, although sampling and analysis protocols do not represent the main control strategies for addressing asynchronous and obsolete GM material in food. Accordingly, the information provided by these consultees focussed on risk management strategies instead (see section 3.2.2.3).

Seven consultees provided information on the sampling protocols applied; the characteristics of these protocols varied significantly across businesses, although most focussed on the sampling of raw commodities. Additional details on these protocols are provided in Annex 5, Table 34.

Representatives of an EU association (ELMA), a national business association and a business operating in one Member State reported that they (or their members) do not apply any sampling protocols regarding asynchronous and obsolete GM material in food. One national business association did not provide information regarding sampling.

3.2.2.2 Analysis

Two EU associations (FEDIOL and COCERAL) and a multinational business representative explained that analysis for asynchronous and obsolete GMOs is conducted by external

[49] 'Assurance schemes' refer to voluntary standards and certification schemes applied by food businesses to ensure that food is free from GMOs. Assurance schemes are generally managed by private certification bodies, which carry out controls on food businesses to verify that the standards are met. Controls may include testing and/or document checks to ensure that adequate traceability systems are in place.

[50] Four EU business associations (COCERAL, FEDIOL, FoodDrinkEurope and EUVEPRO), two national associations, and one EU NGO.

laboratories specialised in the detection of GMOs. Representatives of two organisation providing laboratory services to multinational food companies were consulted for this study. The details of the protocols for analysis applied are described in the box below.

Examples of analysis strategies for the detection of GM content

Representatives of two commercial laboratories described the protocol for analysis applied for food and feed as follows:

- The first stage consists in **screening** for common GMO elements and constructs. These constructs/elements allow the laboratory to cover all GMOs with the screening procedure. The most commonly used elements and constructs include (but are not limited to) tNos, P35, CTP and EPSPS.
- If these elements and constructs are detected, the analysis continues to the second stage, that is, **event specific analyses**.

The following available guidelines are followed for **qualitative analyses** regarding food:

- ISO guidelines for qualitative testing;
- Regulation (EU) No 619/2011 (applied for qualitative analyses of asynchronous and obsolete GM events in both food and feed); and
- event-specific methods published by the EURL are applied and, when possible, the laboratory adheres to the limits specified in these reference methods.

One laboratory explained that for food analyses EU guidance on **measurement uncertainty** (Trapman et al., 2009) is generally followed. Sometimes also the rules in Regulation (EU) 619/2011 are followed for food analyses as they are deemed very clear.

On top of the requirements specified by these guidelines, the laboratory also seeks to have stricter internal requirements to ensure comparability of results.

Laboratories are not in charge of assessing the **legislative compliance** of food samples. If asynchronous and obsolete GMOs are detected through qualitative methods, laboratories notify food business operators and, as explained by both representatives, generally no quantification is requested for food because no MRPL applies. One of the laboratories explained that the LOD is generally close to 0.01 per cent for qualitative methods, which is one tenth of the MRPL established for feed.

Quantification of GM content in food is sometimes performed on request of food business operators. If the operator requests quantification of GM content in food, the following requirements from Regulation (EU) No 619/2011 are met:

- analyses are carried out at the level of 0.1 per cent related to the mass fraction of GM material; and
- the relative repeatability standard deviation is less than 25 per cent.

Source: interview with commercial laboratories representatives

3.2.2.3 Risk management strategies

Several consultees primarily rely on risk management strategies for controlling the presence of GMOs. Risk management strategies include:

- measures to avoid contamination with asynchronous and obsolete GMOs; and
- measures adopted when asynchronous and obsolete GMOs are detected through sampling and analysis.

Four EU business associations (COCERAL, FEDIOL, FoodDrinkEurope and EUVEPRO), two national associations, and one EU NGO (IFOAM) explained that risk management strategies are the most important control measures adopted regarding GMOs. These stakeholders explained that testing, when negative, cannot guarantee the absence of the target GM event in the consignment that is sampled. For business operators, tests can only give an indication of the statistical probability of finding a GM event, but does not enable risk management.

The main risk management strategies to avoid contamination described by consultees (COCERAL, ELMA, EUVEPRO, FEDIOL, FoodDrinkEurope and a multinational ingredient manufacturer) are:

- Pre-market monitoring of the GMOs which have reached the stage of seed multiplication in third countries: FBOs can decide not to import from areas where unauthorised GMOs are cultivated. Contracts with suppliers are signed up to a year in advance, so FBOs need to know beforehand when a country expects to cultivate unauthorised GMOs. The seed multiplication stage (i.e. when seed is produced in order to be commercialised) gives this information.
- Sourcing strategies: when possible, EU businesses avoid importing raw commodities from area(s) where GMOs that are not authorised in the EU (including asynchronous and obsolete GMOs) are cultivated at a commercial scale. When this is not possible, EU importers may establish contractual arrangements with crop suppliers to guarantee that products need to be sourced only from selected growers. In these situations, suppliers are required to establish clear traceability systems and test at origin.
- Segregation: commingling between conventional and GM consignments is avoided during bulk transport, handling and storage.

Based on information provided by EU associations (COCERAL, FEDIOL, FoodDrinkEurope and EUVEPRO), the main risk management strategies applied when asynchronous and obsolete GMOs are detected through sampling and analysis are:

- Diverting imports of non-compliant commodities to non-EU countries, assuming that the national authorities agree with the re-export of the commodities.
- Downgrading the food product to feed and other non-food products.

3.2.2.4 How many and what kind of samples are taken and what types of tests are performed on an annual basis

Four consultees were able to provide information on the number and kind of samples collected and the types of tests performed:

- A representative of a multinational food processor provided estimates of the annual number of food samples tested for the presence of asynchronous GM material (no estimates of samples for obsolete GMOs were provided). In the period from 2009 to 2014, the number of annual samples collected ranged from 500 to 7,000 samples. The consultee explained that the variation in numbers of samples was a function of the expected risk of an event commingling in the supply chain. The consultee also specified the types of test performed: in this period, samples of soy and soy ingredients were tested for the following GM events: MON88017, MIR604, Flax seed Triffid, Rice LibertyLink, and Corn StarLink[51].

[51] These tests concern the possibility of detecting traces of a plant species (such as maize or rice) in a sample of a different species (in this case, soy). The issue of contamination between different plant species is not in the scope of current harmonised rules for feed (Regulation (EU) 619/2011), and would not be affected by the extension of these rules to food.

- A representative of a multinational food business reported that in the EU its laboratories tested approximately 1,000 samples each year for GM content. Of these, about 95 per cent were food samples and the remaining were feed samples. The representative did not specify the proportion of these samples tested for asynchronous and obsolete GMOs. No details were provided on the specific GM events tested.
- A representative of a national business association representing primary food producers, processors and retailers reported that no samples were collected between 2009 and 2014 by the businesses it represented.
- One EU food business association representative reported that testing is part of annual monitoring programmes and is based on risk assessment. Intensive testing may be undertaken to address specific GMO issues. For example, in one company 1,700 samples were tested over three years in relation to an on-going GMO issue.[52]

3.2.3 Strategies adopted by business operators also involved in feed activities

Question B.2. For food business operators also involved in feed activities (i.e. crops growers and traders, crushers), what are the strategies and measures adopted and implemented to manage the two products flows for which different sampling and analysis procedures apply?

Eight consultees provided information regarding the strategies adopted to manage food and feed product flows.[53] All eight reported that the same strategies are adopted for food and feed; because food and feed supply chains are closely interconnected, the separation of the food and feed supply chains and the application of different strategies would not be feasible. A stringent approach has been adopted for food, where there is the greatest legal uncertainty, and because the supply chains are connected, this approach is also adopted for feed, rendering the current EU rules for feed less helpful than they could be if operators could apply the same rules to food that are set for feed. The risk management strategies adopted for food are described in section 3.2.2.3.

3.2.4 Impacts arising from the lack of harmonisation

3.2.4.1 Current impacts

Question B.3. Does the lack of harmonisation of sampling and analysis for official controls for the presence of asynchronous and obsolete GM material affect food business operators at EU level? If so, what are these impacts?

Twelve out of 22 consultees reported that the lack of harmonisation for **sampling** in the context of official controls affects food business operators in the EU:

- five of six EU business associations (with the exception of Starch Europe);
- three multinational businesses;
- a Dutch food industry association;

[52] No details were provided on the issue faced.

[53] Consultees for this study question were: multinational businesses (three consultees); EU business associations (six consultees); a commercial laboratory; a national business; national business associations (four consultees); and an EU NGO representing organic food producers. Third country representatives were not consulted regarding the management of food and feed product flows. Two EU associations did not reply and five consultees (a multinational business; an EU association; three national association; and one national business) reported that the question was not relevant to them as they were not involved in feed activities.

- a commercial laboratory; and
- two third country representatives (NAEGA and the Brazilian representatives).

Eight consultees reported that there are no impacts and two did not respond.

Similarly, 13 out of 22 consultees believe that the lack of harmonisation of protocols for **analysis** has an impact on food business operators, while seven stated that there are no impacts and two did not respond. Those who believed that there are impacts are:

- all six of the EU business associations consulted;
- two multinational businesses;
- the Dutch food industry association;
- one commercial laboratory; and
- two third country representatives (NAEGA and the Canadian government).

A summary of the consultee responses is provided in Annex 5, Table 35 (sampling) and Table 36 (analysis).

Six consultees (four EU associations, a national business association and the Brazilian representatives) referred to the impacts from the absence of a **MRPL** for food as the main issue arising from the current situation. Examples of these impacts are described in the box below.

Three consultees (a third country representative of grain exporters (NAEGA), the Argentinian representative and an EU multinational business importing soybean and maize from third countries for the production of food ingredients) identified trade disruption and legal uncertainty due to the absence of a low-level presence (LLP)[54] policy for asynchronous GMOs as the biggest issues arising from the current situation.

Three third country consultees (US and Canadian Governments and Argentinian mission to the EU) reported that the different timing of GMO authorisation processes in the EU and third countries is the main source of trade disruptions. According to these representatives, if the EU authorisation process for GMOs was aligned with third country procedures there would not be issues arising from asynchronous approvals.

Consultees' views on the main impacts from the current situation

The two main impacts of the absence of a MRPL identified by four EU associations (FEDIOL, COCERAL, EUVEPRO and FoodDrinkEurope) were risk of trade disruption and financial losses, both of which arise from the legal uncertainty resulting from the lack of harmonisation.

The following explanation was adapted from the joint survey response provided by FEDIOL and COCERAL:

- Risk of trade disruption: The EU is heavily dependent on soy imports. There are two major soya harvest periods (North America (US) in September/October and Latin America in March/April), and if trace contamination with asynchronous or

[54] LLP and MRPL are different concepts. For the purpose of this study and based on Regulation (EU) No 619/2011, the MRPL is defined as the lowest amount or concentration of analyte in a sample that has to be reliably detected and confirmed by official laboratories. There is no harmonised definition of the term LLP. The LLP usually refers to traces of unauthorised GMOs or GM material that can be found in food/feed consignments, and does not correspond to a specific limit. Although this study focusses on the issues arising from the absence of a MRPL, some consultees also referred to LLP issues. The concepts and issues described by consultees are reported throughout this study.

obsolete GM material were identified in incoming soya proteins, a company's soy supply for that period may have to be sourced elsewhere. Availability is not guaranteed because contracts with farmers are signed a year in advance of the harvest.

- Financial losses: Soy proteins are ingredients in many foodstuffs. The market is based on supplier contracts that are signed up to a year in advance to mitigate disruption in the supply chain. The possibility to purchase commodities on-the-spot are very limited and spot purchase results in additional costs being incurred by companies. Similarly, on-the-spot changes to a fixed contract for processed products or delivery failure can have financial implications. The cost of a low level contamination of soya protein with an asynchronous or obsolete GM event can be very high. The estimated costs associated with contamination of this kind could range from approximately €70,000 if detection is identified in an incoming delivery before distribution, enabling the consignment to be downgraded to feed use, to more than €13 million if the contamination is identified only after distribution and incorporation in consumer food products.

Source: consultation results - adapted from FEDIOL and COCERAL survey response; impacts cited and views expressed were similar across the four associations.

3.2.4.2 Potential consequences if the current situation remains unchanged

Question B.4. What would be the potential consequences for food business operators under a scenario where the current lack of harmonisation of sampling and analysis for official controls would remain unchanged? How would this affect their risk management strategies?

Ten consultees commented on the potential consequences of there being no change to the current situation. The remaining nine did not provide comments. The feedback can be summarised as follows:

- Six consultees (five EU associations and one national association) reported that the main impacts would include an increased risk of trade disruptions due to the absence of a MRPL for food. Four of the five EU associations (EUVEPRO, FEDIOL, FoodDrinkEurope and COCERAL) also reported that risk management strategies to avoid contamination were unlikely to change because they are already as stringent as possible. The box below provides elements of a response provided by EUVEPRO, which was similar to the views expressed by the other three associations.
- A multinational ingredient processor, a multinational food producer and ELMA indicated that there would be a risk of divergent analytical results amongst laboratories, and this could lead to costs due to product recalls and negative consequences for the image of the food industry.
- One consultee (a national business association) reported that there would be no consequences.

Examples of potential consequences if the current situation remains unchanged: increased risk of trade disruptions

'Although no major problems have occurred since 2009, it is to be expected that maintaining existing import flows will be more difficult to sustain in coming years. Risk assessment by crop and geography is clearly showing increased planting and harvesting of GM varieties worldwide, this together with the continuing difference in the speed of GM authorization between the exporting countries and the EU, increases

the risk that asynchronous and obsolete GM events will be found in imports. This trend was recently…confirmed by the [Food and Agriculture Organization of the United Nations (FAO)] who reported an increase of incidents related to traces of unauthorized GMOs in supplies over the last 10 years, with a significant increase since 2009.

If the current EU regulatory situation with a feed only technical solution[55] remains unchanged, soya protein producers will become increasingly exposed to the risk of supply disruption and considerable financial loss. […]

Risk management strategies are already extremely stringent […] it is not to be expected therefore that more stringent strategies would be possible.

In the event that a serious GM incident occurred in the soya protein supply chain due to the absence of a technical solution for food, it is likely that there would be a severe shortfall in material available to the food industry in Europe that could last for several months, at least'

Source: EUVEPRO survey response

3.2.5 Expected impact of harmonisation and setting of a MRPL for food

Question B.5. What would be the expected impact of harmonisation of sampling and the definition of a MRPL for food tests as regards asynchronous and obsolete GM material?

3.2.5.1 Harmonisation of sampling protocols

Representatives of most of the EU business associations consulted (FEDIOL, COCERAL, Starch Europe, FoodDrinkEurope and EUVEPRO) and the representative of a commercial laboratory agreed that harmonisation of sampling would provide benefits for business operators in the EU. The most common benefits described by EU associations were equal treatment of operators across Member States and legal certainty for food business operators.

The representatives of ELMA and an EU multinational producer of food ingredients had mixed views and reported that impacts of the harmonisation of sampling protocols would not necessarily be positive. For example, the ELMA representative mentioned that 'if [harmonised protocols for] sampling [are] established for unprocessed beans or high protein containing foods only, and not for more refined ingredients such as lecithin, this would result in quantification errors and inconsistencies in analytical results, and legal uncertainty and potential supply disruption for the lecithin producers.' The EU multinational reported that a harmonised approach to sampling could be evaluated and adopted if reasonable. The remaining six EU stakeholders did not provide comments on impacts. A summary of the consultee responses is provided in Annex 5, Table 37.

Third country consultees had the following views:

- Possible benefits from harmonisation were mentioned by two third country consultees (USDA and NAEGA). These benefits may include predictability for exporters and for the marketplace.
- The Canadian and Argentinian representatives had mixed views on harmonisation. They reported that there is no scientific guarantee that harmonisation of sampling and analysis will improve detection and reproducibility of results. The Argentinian consultee stated that asymmetries in authorisation processes between the EU and third countries would still cause trade effects, even in presence of harmonisation.

[55] Consultees used the terms 'technical solution' and 'MRPL' interchangeably.

The Canadian consultee also noted that harmonisation could result in increased costs to laboratories.

- The Brazilian representative did not comment on specific impacts from the harmonisation of sampling.

3.2.5.2 Harmonisation of analysis protocols

Representatives of five EU business associations covering different stages of the supply chain (FEDIOL, COCERAL, Starch Europe, FoodDrinkEurope and EUVEPRO) reported that the harmonisation of protocols for analysis would generate benefits for food business operators. These benefits would be similar to those arising from the harmonisation of sampling protocols, such as improved legal certainty and equal treatment of food business operators in the EU. Potential benefits were also reported by representatives of the two commercial laboratories consulted, a multinational food producer and a Dutch food business association. The representative of IFOAM had mixed views and reported that the harmonisation of analysis could potentially damage EU organic producers if a MRPL is introduced (see also section 3.2.5.3). The remaining EU representatives did not comment on potential impacts. A summary of the consultee responses is provided in Annex 5, Table 38.

The two US representatives stated that harmonisation would provide benefits in terms of legal certainty. The Argentinian and Canadian representatives had mixed views on both sampling and analysis (see section 3.2.5.1) and the Brazilian representatives did not comment on impacts from harmonisation of analysis protocols.

3.2.5.3 Setting a MRPL for food

The following EU consultees reported that the introduction of a MRPL for food would provide benefits for food business operators:

- Five EU business associations (FEDIOL, COCERAL, Starch Europe, FoodDrinkEurope and EUVEPRO);
- A multinational food producer; and
- A Dutch food industry association.

The five EU associations indicated that the benefits would include reduced legal uncertainty for positive test results below 0.1%, since all Member States would adhere to the same protocols, helping to ensure the reliability of the compliance assessment across the EU.

Two consultees (representing ELMA and a multinational food ingredient manufacturer) had mixed views. ELMA reported that if a MRPL is established for unprocessed beans or high protein containing foods only, and not for more refined ingredients such as lecithin, this would result in quantification errors and inconsistencies in analytical results. The multinational company stated that a uniform approach could be adopted if feasible, but did not provide additional information.

The representative of IFOAM believed there could be negative impacts and specified that a MRPL would imply a tolerance threshold for GM presence in food, and this could increase the risk of GMO contamination. The IFOAM consultee explained that 'withdrawing the zero tolerance policy would imply more costs for [organic producers]: more analysis would be required as there would be a higher risk of having GMO contamination […]. This would be an issue especially for small companies'.

The remaining six EU consultees did not comment on potential impacts. A summary of the consultee responses is provided in Annex 5, Table 39.

The two US consultees and the Brazilian consultee favoured setting a MRPL for food. The Brazilian representative added that, to be beneficial, the food MRPL should be higher than the current MRPL for feed. The Canadian and Argentinian representatives believed that the setting of a MRPL would not necessarily guarantee harmonised compliance assessment. The Argentinian representative specified that the 0.1 per cent MRPL for feed is too low and did not provide trade benefits. Thus, a similar MRPL for food would not assist in trade. The Canadian representative added that the setting of a MRPL for food could result in increased costs to laboratories.

3.3 Impacts on consumers

Question B.6. Does the harmonisation of testing and sampling, or the lack of harmonisation thereof, affect consumers in the EU? If so, how?

3.3.1 Context

As reported in section 3.2, a number of consultees consider that there is an increasing risk of trade disruptions and market withdrawals. These issues may have implications for consumer welfare. Decreased availability of products resulting from such disruptions could inflate consumer prices, restrict choice and add to inconvenience. Suppliers could also pass on higher costs associated with increased economic and legal uncertainties in the form of higher prices.

Harmonisation may also affect consumers where, for example, the introduction of a MRPL for food could mean that asynchronous GMOs could enter the EU food chain with potential consequences on consumer confidence (Friends of the Earth Europe, ARGE, Coop Italy, EuroCoop, Greenpeace EU and VLOG, 2013).

This section investigates consumer impacts from the current lack of harmonised protocols for sampling and analysis, and potential impacts from harmonisation.

3.3.2 Findings

Among those who took part in the surveys and interviews covering consumer issues (17 consultees; see section A3.1.2 and A3.1.1), the following provided comments on consumer impacts:

- EU NGOs (three interviewees);
- EU business associations (six survey respondents);
- National associations (one survey response);
- A multinational business (one survey response)

Consultees were asked about the issues arising from the lack of harmonised protocols for sampling and analysis, and the potential impacts from the harmonisation of sampling and analysis as well as the potential introduction of a MRPL for food. An overview of the responses is provided in Table 3. Detailed discussion is presented in sections 3.3.3 and 3.3.4.

Table 3. Impacts on consumers

	Yes	No	Did not respond	Total responses
Does the lack of harmonisation of sampling and testing affect consumers in the EU?	6	3	8	17
Would the harmonisation of sampling and testing affect consumers in the EU?	9	2	6	
Are there any beneficial effects from the setting of a MRPL for food?	5	3	9	
Are there any negative effects from the setting of a MRPL for food?	3	1	13	

Source: ICF analysis of consultation responses. Consultees were: 3 EU NGOs, 6 EU business associations, 4 national business associations, 3 multinationals, and one national business.

3.3.3 Impacts arising from the lack of harmonisation

According to three respondents (two EU NGOs and one national business), there are no consumer impacts arising from the current lack of harmonisation. Two NGOs made reference to the Rapid Alert System for Food and Feed (RASFF) notifications regarding asynchronous and obsolete GM material in food, and observed that between 2012 and March 2015 there have only been three notifications concerning asynchronous GM material in food. For this reason, these NGOs believed that from a consumer perspective there is no need to modify the current situation regarding sampling and analysis.

Six respondents (five EU business associations and a multinational business) believe that the current lack of harmonisation has an impact on consumers. According to these respondents, the main causes of these impacts are:

- the absence of a MRPL for food (mentioned by four out of the six respondents);
- the lack of harmonised protocols for analysis (two respondents);
- the lack of harmonised rules for sampling (one respondent);
- increased cultivation of GM crops in countries providing raw materials to the EU (one respondent); and
- the lack of a LLP tolerance policy for food (one respondent)[56].

Respondents provided examples of possible consumer impacts:

- 'The impact could be severe for consumers in the event of a major supply chain disruption and a large scale consumer recall due to the lack of technical solution for food. Such impact would include massive increase in cost and limit the available food alternatives. This would also probably have a negative impact on consumer confidence in the food supply chain'.
- 'In case of a major supply chain disruption and product recall – originated [*sic*] by the lack of a technical solution for food - consumers would be clearly impacted, due to the increase in cost of limited available products'.

[56] Multiple options could be selected by respondents.

- 'The price of food and ingredients is higher to balance the cost of the extra tests required'.

The remaining consultees (eight of 17) did not provide feedback regarding this issue.

3.3.4 Expected impact of harmonisation and setting of a MRPL for food

Consultees were asked if the harmonisation of sampling and testing and setting of a MRPL for food would affect consumers in the EU. More than half of respondents (nine of 17) mentioned that there would be consumer impacts. Two respondents stated that there would be no impacts, and the remaining six did not respond.

Most of those who reported impacts (eight of nine) focussed on the potential consequences of the introduction of a MRPL for food. The views on the possible types of impacts (negative or positive) varied across the responses mentioned by consultees, more specifically:

- Negative impacts: Three of the nine consultees who reported impacts (three NGOs) explained that the introduction of a MRPL for food would mean that contamination with GMOs that are not authorised in the EU would be possible. NGOs also added that EU consumers oppose the presence of GMOs in food, and have the right to have products that are 100 per cent GM-free. The introduction of a MRPL would deprive consumers of this choice. NGOs therefore agreed that the EU should maintain the current 'zero tolerance' policy regarding asynchronous and obsolete GM material in food.
- Positive impacts: Five consultees (three EU business associations, one national business association and one multinational business) reported that the introduction of a MRPL for food would have a positive impact. Three consultees explained that the introduction of a MRPL for food would reduce the likelihood of the trade disruptions (these effects were described in section 3.3.3). In this case, the main benefits for consumers would be increased security of food supply and choice. Two consultees also mentioned beneficial impacts in terms of a potential decrease in the cost of food ingredients and avoidance of future cost increases of food commodities due to trade disruptions. One EU association stated that the benefits from harmonisation of protocols for sampling and analysis would not necessarily be 'seen' by consumers, since these would primarily relate to the increased likelihood of food business operators being able to maintain regular and consistent product supply.

4 Conclusions

This section summarises our conclusions on potential impacts arising from the lack of harmonised protocols for sampling and analysis and the absence of a MRPL for food. The conclusions consider impacts on:

- official control activities for the sampling and analysis of asynchronous and obsolete GMOs (section 4.1);
- food business operators in the EU, including issues regarding trade with third countries (section 4.2).
- consumers (section 4.3).

4.1 Lack of harmonisation of methods of sampling and analysis for the official control of asynchronous and obsolete GMOs / setting of a MRPL

The consultation with NCAs and CAs indicates that there is no consensus on whether the lack of harmonisation of food sampling procedures has an impact on the reproducibility of

test results. According to 17 respondents in 14 Member States, the lack of harmonised sampling procedures affects the reproducibility of test results between and/or within Member States. Fifteen respondents in 13 Member States reported no impacts. The lack of harmonisation in the interpretation of test results gives rise to different approaches to compliance assessment.

The majority of consultees expect that the harmonisation of protocols for sampling and analysis would provide benefits in the form of increased comparability of results and accuracy of testing. Those who identified negative effects from harmonisation cited the increased costs and lack of flexibility arising from the introduction of new mandatory protocols that differentiate between official controls for asynchronous/obsolete GMOs and other GMOs. If harmonised protocols are introduced it would be appropriate to consider their consistency with the protocols already applied for official controls for all GMOs.

Views on the potential benefits and drawbacks of setting a MRPL are more mixed. Of the 62 NCA and CA consultees, 38 respondents in 22 Member States foresee benefits in improved comparability of results. There is, however, some concern about the financial implications, with 26 respondents in 15 Member States suggesting that a harmonised MRPL would increase analysis costs. In that context a possible assessment of whether policy action is needed to set a harmonised MRPL could usefully be informed by an analysis of the associated costs and their implications.

Conclusions for each of the study questions that relate to official controls are provided in Table 4.

Table 4. Summary table of study questions and conclusions – official controls

Study question	Conclusions
A.1. How many official food samples are tested annually for presence of asynchronous and obsolete GM material in the Member States?	Complete data on the number of official food samples tested for presence of asynchronous and obsolete GM material in the Member States are not available but the study provides a measure of the scale of such activity. Twenty-five Member States tested for the presence of asynchronous and obsolete GM events between 2009 and 2014. Authorities in 14 Member States provided specific data on the number of samples tested annually: the numbers ranged from an average of one sample per year or less (in Cyprus and Estonia) to more than a thousand (in Germany). NCAs and CAs in other Member States were not able to provide detailed data on the number of samples collected: NCAs and CAs do not always collect data on sampling that is specific to asynchronous and obsolete GMOs.
Which asynchronous and obsolete GMO events are tested?	The types of asynchronous and obsolete GM events tested vary. They include: LLRICE 62, Soy A5547-127, DP356043, DP 305423, MIR604, MON88017 and MON89034.
A.2. What sampling procedures are implemented for the presence of asynchronous and obsolete GM material in food in the Member States?	There is variation in the sampling procedures adopted by Member State NCAs and CAs for both bulk commodities and for packaged food products. For bulk commodities the sampling procedures established by Recommendation 787/2004 are most commonly used. Authorities most commonly use their own domestic standards when sampling packaged foods. Samples are collected from different stages of the supply chain, including at border inspection posts, wholesalers and retail premises.

Study question	Conclusions
A.3. Does the lack of harmonisation of sampling procedures have any impact on the reproducibility of test results (within and between Member States)?	Competent authorities are split on whether the lack of harmonisation of food sampling procedures has an impact on the reproducibility of test results. Of the 37 NCAs and CAs consulted on issues arising from the lack of harmonisation of sampling procedures, 15 respondents in 13 countries indicated that this did have an impact on reproducibility of results between Member States. Fifteen respondents in 13 countries indicated that there are no impacts. Only three respondents[57] thought that the lack of harmonisation affects the reproducibility of test results within their own jurisdictions; two of them reported that they had practical experience of these issues. The remaining five consultees did not respond.
Have Member States ever had practical experience on that?	Respondents in four Member States had practical experiences of impacts on the reproducibility of test results between Member States. The lack of harmonisation of protocols for static and dynamic sampling of bulk agricultural commodities was the factor most often cited as having an impact on the reproducibility of test results.
A.4. What test procedures are implemented in the Member States regarding the control of the presence of asynchronous and obsolete GM material in food (qualitative, quantitative, MRPLs)?	There are differences in the screening procedures applied to control of asynchronous and obsolete GM material in the Member States, although some common aspects were identified (such as the types of elements and constructs used for screening). Event-specific methods are largely harmonised (EURL GMFF methods are widely adopted) but there is variation in the limits applied. To identify GM events 28 laboratories (in 19 Member States) use qualitative PCR methods while twenty-one laboratories (in 15 Member States) use quantitative PCR methods. Seventeen laboratories (in 12 Member States) used both qualitative and quantitative PCR methods. Limits of detection range from 0.01 to 0.5 per cent, and limits of quantification are at or below 0.16 per cent.
A.5. Does the lack of harmonisation in the interpretation of test results have an impact on compliance assessment (within and between Member States)?	The lack of harmonisation in the interpretation of test results gives rise to different approaches to compliance assessment: NCAs in two countries assess compliance based on whether asynchronous or obsolete GM material exceeds a specific limit (0.1 per cent in both cases), while in other cases no limits are applied.
Have Member States ever had practical experience on that?	The majority of NCAs and regional CAs (30 respondents in 17 Member States) considered the lack of harmonisation of analysis protocols to have an impact on compliance assessment between or within Member States. Most respondents who believed that the lack of harmonisation in the interpretation of test results has an impact on compliance assessment also reported practical experiences of

[57] Multiple options could be selected by respondents.

Study question	Conclusions
	these impacts. The adoption of different criteria and limits to assess whether a testing result is positive or negative was cited as an example.
A.6. Would the definition of a Minimum Required Performance Limit affect protocols of testing?	Half of respondents (31 out of 62, covering 17 Member States) believed that the definition of a MRPL for food would affect protocols for testing. The most cited consequence was the need to perform quantification of GM content for those laboratories that use qualitative methods to detect asynchronous and obsolete GMOs in food. According to respondents, the setting of a MRPL would require additional work and resources due to the need to implement quantitative methods.
A.7. Are there any beneficial or negative effects deriving from the harmonisation of sampling and analysis and the introduction of a Minimum Required Performance Limit for food as it already exists for feed? What are these effects?	The beneficial effects from the harmonisation of sampling methods include increased comparability of sampling results and fewer disputes between Member States. Most respondents (36 NCAs and regional CAs across 20 Member States) also believed that there would be benefits from the harmonisation of analytical methods, including greater comparability of results. A majority also expect that setting a MRPL would result in beneficial effects that include improved comparability of results. Most respondents did not foresee negative effects from the harmonisation of sampling and analysis, but 26 respondents in about half of the Member States expected adverse effects from setting a MRPL, such as greater burden of work and costs of laboratory analysis.

4.2 Impacts on food business operators and on the market

Operators mainly rely on risk management measures, such as sourcing strategies and supply chain segregation, to exclude asynchronous and obsolete GMOs from their products.

The current absence of harmonisation of protocols for official controls is a source of legal uncertainty due to divergent approaches to compliance assessment that then arise.

There are some examples of the detection of asynchronous and obsolete GMOs leading to supply chain disruption. With increased cultivation of GMOs in source countries, the risk of such incidents occurring is expected to increase. The harmonisation of sampling and analysis and setting of a MRPL were regarded by most consultees as a possible solution to addressing these risks. Table 5 provides conclusions for each of the study questions regarding impacts on food business operators.

Table 5. Summary table of study questions and conclusions – impacts on food business operators and on the market

Study question	Conclusions
B.1. What are the sampling, analysis and risk management strategies and protocols applied by food business operators regarding asynchronous and obsolete	Most industry respondents do not apply sampling and analysis protocols for asynchronous and obsolete GMOs. Operators use risk management strategies that rely primarily on avoiding the possibility of contamination at source in producer countries and segregation of conventional and GM products

Study question	Conclusions
GMOs?	throughout the supply chain. If asynchronous or obsolete GMOs are detected, companies consider options that will generally include diverting imports of non-compliant commodities to non-EU countries and downgrading food products to feed status. Food samples are generally taken when the risk management approach indicates there may be contamination and so the number of samples taken rises and falls according to the associated risk.
How many and what kind of samples are taken and what types of tests are performed on an annual basis in the framework of the own check controls?	Respondents did not provide information on the number of samples taken for asynchronous and obsolete GM analyses, but indicated the total numbers of samples tested for GMO analyses. These ranged from zero to about 7,000 samples per year. One consultee provided information on the type of tests performed, which concerned contamination between different plant species.
B.2. For food business operators also involved in feed activities (i.e. crop growers and traders, crushers), what are the strategies and measures adopted and implemented to manage the two products flows for which different sampling and analysis procedures apply?	The supply chains for food and feed are highly interconnected. Businesses involved in food and feed activities reported that the same strict control strategies and measures are applied to both food and feed and that these are stricter than would be required under the rules for feed because of the legal uncertainty surrounding compliance results for food.
B.3. Does the lack of harmonisation of sampling and analysis for official controls for the presence of asynchronous and obsolete GM material affect food business operators at EU level? *If so, what are these impacts?*	About half of stakeholders consulted, including business associations covering most stages of the food supply chain, believe that the lack of harmonised protocols for sampling and analysis for official controls has impacts on food business operators at EU level. The absence of harmonisation creates legal uncertainty for operators relying on imports of raw commodities from third countries. There is an increasing risk of supply disruption and serious financial losses arising from the detection of traces of asynchronous or obsolete GMOs in imported food.
B.4. What would be the potential consequences for food business operators under a scenario where the current lack of harmonisation of sampling and analysis for official controls would remain unchanged? How would this affect their risk management strategies?	In the absence of harmonisation, consultees believed that the current impacts are expected to become more significant. The risks of trade disruption and financial losses are expected to increase under a scenario where GMO cultivation is increasing worldwide. The position of the business representatives that responded was that risk management strategies are already extremely stringent, and the implementation of more stringent strategies would not be feasible. If faced with recurring losses due to the absence of a MRPL, operators may be forced to temporarily or permanently cease crushing activities in the EU.
B.5. What would be the expected impact of harmonisation of sampling and analysis and the definition of a MRPL for food tests as regards	Most of the consultees who commented on expected impacts believed that the harmonisation of sampling and analysis and the setting of a MRPL would provide benefits to food business operators in the EU. Benefits include reduced legal

Study question	Conclusions
asynchronous and obsolete GM material?	uncertainty and increased reliability of the compliance assessment across the EU.

4.3 Impacts on consumers

Food business operators and NGOs had different perspectives on the impacts on consumers of harmonisation. Food business operators suggested that it would reduce costs and risks in the food chain, and that this would benefit consumers. NGO respondents were concerned that introduction of a MRPL would lead to a reduction in consumer choice because GMO presence up to the limit would be allowed. The conclusions on consumer impacts are provided in Table 6.

Table 6. Summary table of study questions and conclusions – impacts on consumers

Study question	Conclusions
B.6. Does the harmonisation of testing and sampling, or the lack of harmonisation thereof, affect consumers in the EU? If so, how?	Almost half of the stakeholders consulted did not provide views on consumer impacts arising from the lack of harmonisation. Amongst those who did, industry representatives believe that the lack of harmonisation results in higher food costs due to the additional testing controls required by operators and could result in higher costs in the event of trade disruption or a food recall and/or reduced availability of food products. The industry respondents see harmonisation as a means to reduce current existing and potential costs, to the benefit of consumers. NGO respondents, by contrast, suggested that there is no need to harmonise testing and sampling. NGOs felt that introducing a MRPL in particular would have negative impacts in the form of reduced consumer choice because food products could be contaminated with GMOs up to the level of a MRPL.

ANNEXES

Annex 1 Terms of reference

SANCO/2014/E1/024 - Technical study in the context of the assessment of the need for harmonisation of methods of sampling and analysis for GM material in food

Lead Unit: DG SANCO E1

1. Purpose of the Contract

This contract aims to perform an ad-hoc study to contribute to the assessment of the need and the feasibility for harmonisation of methods of sampling and analysis for official controls at the EU level as regards the presence **in food** of genetically modified material, in particular for which an authorisation procedure is pending or the authorisation of which has expired.

The performance of an in-depth Impact assessment for a potential legislative proposal will be considered at a later stage.

1.1 Context of the study work

Currently, EU legislation does not set in all cases obligatory specific rules for the official control of material which contains, consists of or is produced from GMOs.

In the **feed sector**, Regulation (EC) No 152/2009, as amended by Regulation (EU) No 691/2013, lays down the methods of sampling and analysis for the official control of feed, including sampling methods for the control of GM material.

In the **food sector**, Recommendation 2004/787/EC provides technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms. However, this Recommendation is not binding for Member States and, due to its limited practicability on large product lots, it is not always implemented by Member States' Competent Authorities. Therefore, in a number of cases, enforcement authorities adopt alternative sampling strategies for the control of GM material in food (as pointed out in some FVO audit reports) and this results in a lack of harmonisation across the EU.

As regards method of analysis, Regulation (EC) No 1829/2003 requires that applicants provide methods for detection and identification of the transformation event when submitting a request for marketing authorisation. These methods are validated by the European Union Reference Laboratory on GM food and feed (EURL-GMFF) and made available to official laboratories. Although event- specific methods are harmonised at European level, **interpretation of relative results may differ among official control authorities when presence of GM material is at very low levels, close to the limit of detection of the method**. Experience has shown, for example, that some Member States decide that analytical results obtained below a certain level are not sufficiently reliable and reproducible between laboratories to take a decision regarding the compliance of a lot. This results in the fact that a product may be considered as compliant in one Member State and not in another.

It should be considered that this lack of harmonisation affects the official control in general terms. However divergences in the interpretation of analytical results are expected to have a marginal impact in the **enforcement of labelling**

requirements set by the EU legislation. In fact in this case compliance is established with respect to the labelling threshold set at 0.9%, which, at least for raw material, is far above the limit of detection of the validated analytical methods currently used.

The impact is much higher in the **enforcement of the EU "zero tolerance policy"[58]** with non- authorised GMOs, since in many cases compliance must be evaluated for **trace levels which are close to the limit of detection** of the methods, where a higher **analytical uncertainty** is expected. This is the reason why this study is focusing on non-authorised GM events.

This lack of harmonisation could bring two main effects: significant differences as regards decisions taken on compliance by competent authorities, and **legal uncertainty** along with the derived economic risk for food operators due to these differences.

The first effect would hinder the implementation of effective and harmonised measures to manage non- compliances across the EU, when different interpretations are provided by different laboratories, or by the enforcement laboratory and the laboratory carrying out the analysis for defence.

Concerning the second effect, **operators of the food and feed chain**, which are fully responsible at all stages of production, processing and distribution within the business under their control[59], **should apply internal quality systems and control procedures** to ensure the absence of non-authorised GMOs in a commodities' lot or in the food and feed chain. **In order to properly define their internal control systems, operators need to have clear and EU-wide understanding on required sampling and analysis protocols and on rules for the interpretation of the results of the analysis aiming at demonstrating the absence of GMOs**. They claim that absence of such clear and predictable criteria across the EU, as described above, make them face legal uncertainty and potential risk of economic damages for instance in the case of commodities supply disruption, and/or food and feed product recalls.

The EU imports significant quantities of commodities produced in third countries, where GMO cultivation is widespread, for use in the food and feed chain. For example, about 80% of the vegetable proteins (mainly soybean and soymeal) used for feed in the EU are imported, and it is estimated that 75% is GM[60]. However the EU authorisation's timeframe[61] differs from those of its trading

[58] According to Regulation (EC) No 1829/2003 on genetically modified food and feed, GMOs can be placed on the EU market for food and feed use only after having been authorised on a case-by-case basis, following a stringent risk assessment by the European Food Safety Authority (EFSA) having demonstrated their safety for human and animal health and for the environment. In other words, the EU applies a "zero tolerance policy" as regards the presence of non-authorised GMOs on its territory.

[59] Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

[60] Proceedings of a workshop on "market for non-genetically modified identity preserved crops and derived products" organised by the Commission Joint Research Center http://ftp.jrc.es/EURdoc/JRC76117.pdf

[61] 4 The EU does not recognise the risk assessments performed and authorisations granted by third countries. There are three situations where GMOs produced in third countries are not authorised in the EU: i) asymmetric authorisation, when a GMO approved in (a) third country(ies) is not intended to be authorised in the EU as no application was made by the operator, who e.g. has no intention to market this product in the EU, or could not file an application compliant with the EU criteria; ii) asynchronous authorisation, when due to differences in authorisation criteria and procedures, but also agricultural or trade policy choices, a GMO may be already

partners. This issue was emphasized in the Evaluation of the EU legislative framework in the field of GM food and feed[62], published in 2011.

The EU established legal clarity and predictability to operators as regards the issue of the presence of **asynchronous** and **obsolete** GM material in **feed**[63]. Regulation (EC) No 619/2011 harmonises the implementation of the zero-tolerance policy on non-authorised GM material in feed, by establishing harmonised methods of sampling and analysis for the official controls performed by Member States and setting up a Minimum Required Performance Limit (MRPL) for detection of asynchronous and obsolete GM material in feed. These harmonised rules are based on Article 11(4) of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Several publications, including a report from the Commission Joint Research Center (JRC)[64], highlight that in the coming years the number of GMO authorisations is expected to steeply increase worldwide.

Since the adoption of Regulation (EC) No 619/2011, crops traders, grain processors, the food industry and retailers, and agricultural commodities exporting countries as well, have been **calling for an harmonisation of methods of sampling and analysis for food, on the grounds that they would keep facing legal and economic uncertainties when handling commodities for food use in the EU**, and/or when marketing food products derived from these commodities, due to the existing variation in GMO official controls for food in the Member States. The food and feed **Industry** claims also that, considering the interconnectedness of food and feed sectors (e.g. soya beans are used for both food (oil) and feed (meal)), the lack of harmonisation in the food sector makes Regulation (EC) No 619/2011 not fully effective in a number of cases, and therefore advocate for an extension of its scope to food.

On the contrary, a **non-industry** and **non-trader** stakeholder has contended that Regulation (EC) No 619/2011, and any extension of its scope to food, would fail to deliver legal certainty for operators and could even result in increasing costs and administrative burdens for both operators and Member States' control authorities. According to this opinion, it would be easier for food operators to check whether or not raw materials are contaminated with non-authorised GMOs, rather than to determine the exact level of any contamination.

In light of the abundant, but sometimes contradictory and incomplete elements of information described above, the **Commission wants to collect from all relevant sources, and to analyse in further details, data concerning the impacts of the current situation on national official control authorities,**

---

authorised in third countries, while in the EU the application file has been submitted and declared valid by EFSA, but the authorisation procedure is still pending.; and iii) obsolete authorisation, when the authorisation may have expired in the EU due to the phasing-out/non-renewal of the product by the marketing authorisation holder.

[62] http://ec.europa.eu/food/food/biotechnology/evaluation/index_en.htm

[63] The scope of the Regulation was limited to feed on the grounds that while imported commodities can be used both in the production of food and feed, the vast majority of imported commodities likely to contain GMOs are destined to the feed sector, thereby entailing a higher risk of trade disruption for that sector.

[64] The global pipeline of new GM crops. Implications of asynchronous approval for international trade. 2009 J. Stein, E. Rodriguez-Cerezo.

food business operators and other relevant stakeholders, where methods of sampling and analysis of asynchronous and obsolete GM material in food are not harmonised at EU level.

1.2 Objectives and general approach of the study

The aim of the study is to collect and analyse **data** and **information** allowing to draw an extensive and clear picture of the **current** and **forthcoming situation** linked to the **lack of harmonisation** of methods of sampling and analysis for official controls at the EU level as regards the presence in **food** of non-authorised **asynchronous** and **obsolete** GM material. The data and information will be collected from EU Member States' Competent Authorities and official control services and from actors along the whole food supply chain. The findings will help the Commission to identify and scrutinize possible problems linked to this situation, in particular as regards the implementation of the zero tolerance policy in food, and to assess whether a policy action is needed to address them.

Two overall policy objectives have to be taken in account while performing the study: fostering the **internal market** and **safeguarding consumer choice and welfare**.

These activities will be performed with a unique set of tools and methods, from extensive literature review, surveys and interviews, to cost assessment and market analysis.

1.3 Sponsor and user of the contract

Technical unit in charge is SANCO unit E1.

2. Task to be performed by the contractor

The successful tenderer will be asked to perform the following tasks which also form the basis of the indicators of achievement and assessment of deliverables:

2.1 Scope of the study

2.1.1 Time frame

The time period 2009 - 2014 should be covered by the Study.

2.1.2. Geographical coverage

This study should cover the EU28 and relevant third countries growing GM-crops and exporting crops and derived products to the EU, such as Argentina, Brazil, Canada and United States.

2.1.3 Actors

The **EU Member States Competent Authorities and official control services** are affected by the current situation and should be consulted.

The following **stakeholders in the food chain** are also concerned: Agricultural commodities exporting countries (regulatory authorities and relevant operators); Crops traders; Transporters; EU grain crushers/processors (for food and feed uses); EU food sector, including SMEs; EU retailing sector.

Organisations dealing with **consumer protection and rights, environmental protection etc**, should also be consulted.

In order to perform the study, the contractor should collect data and views from the abovementioned actors (**including individual companies and/or professional organisations**).

An **indicative list** of relevant stakeholders to consider is provided in annex I.

2.2 Study Questions

This study should bring data and information allowing answering the following set of indicative questions:

A. Lack of harmonisation of methods of sampling and analysis for the official control of asynchronous and obsolete GMOs/ Definition of a MRPL:

A.1. How many official food **samples** are tested annually for presence of asynchronous and obsolete GM material in the Member States? Which asynchronous and obsolete GMO events are tested?

A.2. What **sampling** procedures are implemented for the presence of asynchronous and obsolete GM material in food in the Member States?

A.3. Does the lack of harmonisation of **sampling** procedures have any impact on the reproducibility of testing results (within Member States and between Member States)? Have Member States ever had practical experience on that?

A.4. What **testing** procedures are implemented in the Member States regarding the control of the presence of asynchronous and obsolete GM material in food (qualitative, quantitative, MRPLs,…)?

A.5. Does the lack of harmonisation in the interpretation of **testing results** have an impact on compliance assessment (within Member States and between Member States)? Have Member States ever had practical experience on that?

A.6. Would the definition of a **Minimum Required Performance Limit** affect protocols of **testing**?

A.7. Are there any beneficial or negative effects deriving from the harmonisation of sampling and analysis and the introduction of a Minimum Required Performance Limit for food as it already exists for feed? What are these effects?

B. Impacts on operators and on the market

B.1. What are the **sampling, analysis** and ris**k management strategies and protocols** applied **by food business operators** regarding asynchronous and obsolete GMOs? How many and what kind of samples are taken and what types of tests are performed on an annual basis in the framework of the own check controls?

B.2. For food **business** operators also involved in feed activities (i.e. crops growers and traders, crushers), what are the strategies and measures adopted and implemented to manage the two products flows for which different sampling and analysis procedures apply?

B.3. Does the lack of harmonisation of sampling and analysis for official controls for the presence of asynchronous and obsolete GM material affect food **business** operators at EU level? If so, what are these impacts?

B.4. What would be the potential consequences for food **business** operators under a scenario where the current lack of harmonisation of sampling and analysis for official controls would remain unchanged? How would this affect their risk management strategies?

B.5. What would be the expected impact of harmonisation of sampling and the definition of a **MRPL** for food tests as regards asynchronous and obsolete GM material?

B.6. Does the harmonisation of testing and sampling, or the lack of harmonisation thereof, affect **consumers** in the EU? If so, how?

2.3 Tasks

The Commission expects the contractor to perform the following tasks:

2.2.1 Task 1: Structuring and methodology

The contractor has to establish a **general work plan** and methodology based on the objectives and tasks in order to collect data and views of interest and process and analyse them, providing an overview over the task to be considered.

The contractor should **identify the main food sectors and products, such as soya**, on which the study needs to focus and m**ap relevant competent authorities and official control services, stakeholders** and other sources (scientific literature, databases, etc.) most relevant for the collection of data.

Based on the findings of the **mapping**, and in order to respond to the study questions outlined in point 2.2, the contractor has to **prepare a questionnaire** to conduct **surveys towards Member States' authorities and relevant European and international stakeholders** in order to perform task 2. The questionnaire will be fine-tuned with and validated by the Commission within one month following the kick off meeting.

The contractor will propose a list of relevant Member States (such as Germany, Netherlands, Spain, Belgium, France, Austria and Hungary) where to perform an in-depth analysis providing insight of the different approaches adopted as regards methods of sampling and analysis.

The contractor will have to gather the findings of the data collection (task 2) and analysis process (task 3) into a synthetic format to be agreed with the Commission.

2.3.2 Task 2: Observing

- Description of national authorities and stakeholders' approaches to handle the lack of harmonised methods for sampling and analysis for pending and obsolete GM material in food in the EU

The contractor is expected to organise and conduct a **survey** towards national authorities, food **business** operators (including those involved in both food and feed related activities) and relevant stakeholders in order to collect data and views allowing to answer to the questions mentioned in section 2.2. of the terms of reference.

- Description of market's and supply chain's specifications and trends for the identified main products

The contractor should provide a **comprehensive description** of the concerned markets sizes (value and volume) and temporal evolution (past, present, future), and about structures and functioning of supply chains from fields to consumers, in the EU and worldwide; this **market study** should in particular investigate main factors influencing variations in supply and demand, with a particular focus on adventitious presence of asynchronous and obsolete GMOs in traded commodities.

The contractor will have to develop a methodology allowing to collect appropriate data and views via desk research and survey (questionnaire and telephone/face to face interviews) towards the regulatory authorities/stakeholders.

2.3.3 Task 3: Analysing

Based on the information collected during task 2, the contractor is expected to provide answers to the questions listed in section 2.2 and to make suggestions on **approaches to address the possible identified problems**.

The collected data should be assessed along the criteria referred in section 1.2 (functioning of the Internal Market and consumer welfare).

3. Description of Experts and additional information

The contractor should possess a proven level of knowledge in official control procedures (with notions in sampling and detection), economics and market analysis in the food and feed sector, public policy and agrofood policy analysis, as well as in data collection, analysis and policy development.

The contractor should:

- Indicate profile, background and categories of the experts of the contractor's team.

- Designate the expert to be team leader for the study to be carried out. The team leader should have at least 15 years of professional experience of which at least 7 must be relevant to the sectors concerned and the type of tasks to be performed under the contract.

The team leader should ensure uninterrupted coordination with the European Commission.

- Designate the members of the team according to the necessary knowledge and skills for performing the various tasks and subtasks required.

- Good English language skills are required, both written and spoken.

- Demonstrated capability to access documents and interact with informants as necessary for the completion of the tasks.

4. Organisation of the work

4.1 Budget allocated

A price band from 80.000 € up to a maximum of 100.000 €.

4.2 Overall management of the contract

The contractor is requested to produce records/minutes of each meeting with the Commission and to submit them to the Commission for approval the week following the meeting.

4.3 Deliverables & documentation

The study must be completed within **6 months** after the signature of the contract.

The present assignment includes the submission of a series of deliverables: reports and presentations. The contractor will deliver the following reports at key stages of the evaluation process: **inception report, interim report, draft final report** and **final report**. Each report should be written in English, and critically assessed as it provides the basis for tracking the quality of the work done by the evaluator. These reports will be submitted by the Commission to the established **steering group**, which may ask for complementary information or propose adjustments in order to redirect the work as necessary. Reports must be approved by the Commission. With work progressing and in the light of new findings, revisions of reports already approved may be necessary.

It is essential that all the reports be clear, concise, unambiguous and comprehensive. They should also be understandable for non-specialists. The presentation of the texts, tables and graphs has to be clear and complete and correspond to commonly recognised standards for studies to be published. A structured and precise elaboration of add-ons based on previous deliverables at every stage of the process is requested (for example, this could be done via colour-coding parts of the report developed at the offer, inception, interim and draft final stage). An indicative size of each report to be provided is (excluding annexes):

- inception report: up to 50 pages
- interim report: up to 100 pages
- final report: up to 200 pages

The reports should be provided to the Commission in both MS-Word and Adobe Acrobat (PDF) format with the charts in Excel. They should be accompanied, where requested, by appropriate annexes and delivered in accordance with the deadlines and requirements set out in the Terms of Reference and agreed with the Steering Group.

Every two weeks, the contractor should submit a **short progress note** to the Commission reporting on the state of execution of the tasks. Furthermore, the following reports and presentations shall be delivered:

Kick-off meeting report

After signature of the contract, the contractor will participate in a kick-off meeting with the Steering Group. The purpose of this meeting is to verify:

- the contractor's understanding of the Terms of Reference

- the proposed general approach to the work (methodology, planning, structure of deliverables etc.)

- the composition and eligibility of the contractor's team. The stakeholder mapping will be discussed during that meeting.

Inception report *– within 1 month after the kick off meeting*

The inception report completes the **structuring phase** of the study. It aims at describing the organisation of the work, adapting and substantiating the overall approach, the methodology required for each evaluation question and/or specific task requested as well as the work plan outlined in the proposal. It should set out in detail how the proposed methodology will be implemented, and in particular lay out clearly in tabular form how the method allows each task to be answered via establishment of judgement criteria and within these, of evaluation indicators. A further column highlighting choice of relevant evaluation tools should complete the table. The inception report should develop such a chart to a level that allows the Steering Group to gain a good understanding of the evaluation tools and related methodological steps proposed.

The report may complete and/or suggest additional evaluation questions the contractors consider suitable. As such, this document will provide an opportunity to make a final check on the feasibility of the method proposed and the extent to which it corresponds with the task specifications.

The known sources of information, use of tracers (case studies), contact persons, as well as the way the contractor will interact with representatives will be fully clarified at this stage.

The inception report is submitted to the Commission, which will forward it to the Steering Group. On the basis of discussion, including with the contractor, changes and improvements may be requested. Final version of evaluation tasks/questions suggested by the contractor and evaluation indicators to be used will be validated by the Steering Group and the Commission at this stage. The contractor will submit a final version within two weeks.

Interim report *– within 4 months of the signature of the contract*

This report will provide information on the analysis of data collected. The evaluator should already be in a position to provide: a) aggregated data, and b) **preliminary findings and conclusions**.

The report will provide the Commission and the Steering Group with an opportunity to check whether the study is on track and whether it has focused on the specified information needs.

The contractor will submit a revised interim report with the necessary updates of the report after Commission discussion with the Steering Group.

Draft final report *– within 6 months of the signature of the contract*

This document will provide the **draft final conclusions** of the contractor with respect to the tasks set in the present assignment. Any judgements provided should be clear and explicit. It will also provide a technical overview of the study process highlighting limitations and possible bias therein.

The draft final report should include an **executive summary** of not more than 5 pages (synthesis of analyses and conclusions), the main report (structure to be confirmed by the Commission services but planned to reflect the content of the

assignment), technical annexes (inter alia the Task Specifications and a compilation of all requested country-based information) and a draft one-page summary of the Key Messages (conclusions in bullet form) of the evaluation. The latter should precede the executive summary. This executive summary report has to be in English and French.

Final report *- to be submitted within 15 days of communication of comments made by the Commission on the draft final report*

The final report should have the same structure as the draft final report. It will take account of the results of the comments and discussions with the Steering Group regarding the draft final report insofar as they do not interfere with the autonomy of the contractor in respect to the conclusions. The executive summary (including the Key Messages section preceding it) should be provided.

The copyright of the reports remains with the Commission.

4.4 Quality Assessment

The contractor will establish robust means to ensure the reliability, validity, and comparability of the information collected as well of its analysis and of its reporting.

The Steering Group will have to agree on a quality assessment of the final report.

For details on minimal requirements regarding quality assessment of the deliverables, please see

Annex III.

In order to ensure the necessary quality for such work, contractors should be constantly minded that:

- the evaluation shall respond to the information needs, in particular as expressed in the terms of reference and following discussions with the steering group;

- the methodology and design shall be adequate for proceeding to the evaluation tasks and for obtaining the results needed to answer the evaluation questions;

- collected data must be adequate for their intended use and their reliability must be ascertained;

- data shall be analysed systematically to answer the evaluation questions and to cover all the information needs in a valid manner;

- findings shall follow logically from and be justified by the data/information analysis and by interpretations based on pre-established and rational criteria;

- conclusions for being valid shall be non-biased and fully based on findings.

5. Timetable and physical location

5.1 Timetable for the work and deliverables

The contractor is to start the desk-work in November 2014 and the contract should be completed within 6 months from the signature of the contract.

ANNEX I

Indicative list of relevant stakeholders

BEUC Bureau européen des unions de consommateurs

CELCAA Comité européen de liaison des commerces agroalimentaires

COCERAL Comité du commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures de l'Union européenne

COPA-Cogeca Comité des organisations professionnelles agricoles de l'Union européenne – Confédération générale des coopératives agricoles de l'Union européenne

ECVC European Coordination Via Campesina

ESA European Seed Association

EUROCOMMERCE European Representation of Retail, Wholesale and International Trade

EUROCOOP European Community of Consumer Cooperatives

EUROPABIO European Association of Bioindustries EUVEPRO European Vegetable Protein Association FEDIOL The EU Vegetable Oil and Proteinmeal Industry FoEE Friends of the Earth Europe

FOODDRINKEUROPE Confederation of Food and Drink Industries

Greenpeace

PFP Primary Food Processors

UGAL Union des groupements de détaillants indépendants de l'Europe

ANNEX II

Existing data

- EU supply and demand: crops, origins, challenges and current questions marks. COCERAL, Presentation of COCERAL Annual General Meeting, 2014.

- Results of Member States' testing in the context of reporting obligations in Art. 6.2 of Regulation 619/2011.

- Multi-Annual National Control Plans

- GM crops in the pipeline: An Update for 2013/2014. C. Parisi, P. Tillie. European Commission, JRC- IPTS, 2013. Unpublished draft manuscript.

- Upholding the principle of zero tolerance in GM food. Letter from Friends of the Earth Europe, ARGE, Coop Italy, EuroCoop, Greenpeace EU and VLOG, 2013.

- Low level presence of not yet EU authorized GM events. Impact assessment on the EU vegetable oil industry resulting from the absence of a Technical Solution (TS) applicable to food. FEDIOL, 2011.

- The Low Level Presence of not yet EU Authorised GM Events on the European Vegetable Protein Industry in the Absence of a Technical Solution (TS) Applicable to Food. Impact Assessment. EUVEPRO, 2011.

- GMO study: Imports of conventional and GM crops in the EU. C. Freitag, K. Minol, A.J. Stein, Genius GmbH, FoodDrinkEurope, 2011.

- Provisions concerning sampling and analysis of animal feed for genetically modified material on the basis of Regulation (EC) No 882/2004. Legal opinion on a proposal by the European Commission. Anwaltsbüro Gaßner, Groth, Siederer & Coll, 2011.

- Implications of Asynchronous GMO Approvals for EU Imports of Animal Feed Products. EuropeanCommission, DG AGRI, 2010. http://ec.europa.eu/agriculture/analysis/external/asynchronous-gmo-approvals/index_en.htm

- Maintaining the EU's comprehensive and integrated approach on food and feed with regards to the low level presence (LLP) of genetically modified material in raw materials. SOLAE, 2010.

- The cost of low level presence of GMOs in food products in Europe. An impact assessment based on the recent RASFF 2009.1037 & 2009.1165. Landmark Public Policy Advisers Europe, 2009.

- The global pipeline of new GM crops: introduction to the database. A.J. Stein, E. Rodríguez-Cerezo, European Commission, JRC-IPTS, 2009. http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=2199

- Economic Impact of Unapproved GMOs on EU Feed Imports and Livestock Production. EuropeanCommission, DG AGRI, 2007 http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf

- Adventitious traces of genetically modified seeds in conventional seed lots: current situation inMember States. Central Science Laboratory, 2007.

ANNEX III

Offer

The methodology of this study must be drawn by the tenderers taking into account the objectives and scope described above and existing good practice. The final methodology will be agreed by the Commission and the Contractor during the inception phase.

The tenderers are required to:

- prove understanding of the scope and objectives by drafting an intervention logic,

- prove ability to address the tasks envisaged by breaking them down as in the attached model (model - table n°1),

- clearly detail the different steps of the process specifying required resources (human and financial) and time (model - table n°2),

- present timetable of main milestones of the process

Table n°1

Evaluation task	**Judgement criteria**	**Indicators**	**Data Sources**

Table n°2

Task	**Expert (name, category specialisation)**	**Time required**

Tenderers are not expected to restrict themselves to listed minimum requirements. Proposals for additional methodological tools that may contribute to addressing the evaluation questions in a more satisfactory manner will be considered positively when evaluating the proposals.

Inception report

This report will describe in more detail the way the evaluation will be conducted and the methodology. It will provide proposed content of the questionnaires, interview questions, focus group outlines and the list of organisms and stakeholders to be consulted and also the number of interviewees and their positions and names (model - table n°3).

This document will provide the Commission with the opportunity to check the feasibility of the method proposed and the extent to which it corresponds with the needs outlined in the terms of reference.

Table n°3

Evaluati	Judgem	Indicat	Data	**Survey**	**List of**	**Timetable**

on task	ent criteria	ors	sourc es	**questio ns, intervie w questio ns, focus group outlines**	**organisms to be consulted, interview ees, their positions and names**	**of consultati ons**

Interim Report

This report shall describe the work completed (most of the fieldwork should be finished):

- list of reviewed documents,
- number of questionnaire and interviews completed,
- summary of preliminary results of the investigation,
- validation of data,
- the way the contractor intends to make the results of interviews comparable,
- (if relevant) list of problems the contractor faced in his work in the framework of the specific contract,
- a process advancement table with critical analysis on the progress of the fieldwork.

Draft Final Report

Evidence from evaluation tools	**Findings**: factual statements derived from the available evidence	**Conclusions**: the evaluators' interpretation of the evidence, applying transparent judgment criteria	**Possible recommendations**: recommended changes or improvements

.

Annex 2 Evaluation matrix

Table 7. Evaluation matrix

Evaluation tasks / study questions	Judgement criteria	Indicators	Data sources	Evaluation tools	Results
A. Lack of harmonisation of methods of sampling and analysis for the official control of asynchronous and obsolete GMOs/ Definition of a MRPL					
A.1. How many official food samples are tested annually for presence of asynchronous and obsolete GM material in the Member States? Which asynchronous and obsolete GMO events are tested?	Description of current situation regarding sampling for the presence of asynchronous and obsolete GM material	Number of official food samples tested annually for presence of asynchronous GM material Number of official food samples tested annually for presence of obsolete GM material Types of asynchronous and obsolete GMO events tested	Desk research: Food and Veterinary Office (FVO) audit reports evaluating official controls on GMOs Consultation with MS competent authorities	NCA survey Survey of NRLs and official laboratories	Section 3.1.1
A.2. What sampling procedures are implemented for the presence of asynchronous and obsolete GM material in food in the Member States?	Description of current situation regarding sampling for the presence of asynchronous and obsolete GM material	Number of NCAs applying the protocols for sampling foreseen by EU guidance and legislation, including: Recommendation 787/2004, Regulation (EC) No 152/2009, Regulation(EC) No 401/2006, and Regulation (EU) No 619/2011	Consultation with MS competent authorities	NCA survey NCA interview topic guide	Section 3.1.2
A.3. Does the lack of harmonisation of sampling procedures have any impact on the reproducibility of test results (within and between Member States)? Have Member States ever had practical experience on that?	Testing results are not reproducible within and between MS due to lack of harmonisation of sampling procedures	Number of NCAs reporting impacts on reproducibility of test results	Consultation with MS competent authorities	NCA survey NCA interview topic guide NRLs and official laboratories topic guide NRLs and official laboratories topic guide	Section 3.1.3
A.4. What test procedures are implemented in the Member	Description of the current situation regarding test	Number of NCAs requesting quantification of GM events in	Consultation with MS competent authorities	NCA survey	Section 3.1.4

Evaluation tasks / study questions	Judgement criteria	Indicators	Data sources	Evaluation tools	Results
States regarding the control of the presence of asynchronous and obsolete GM material in food (qualitative, quantitative, MRPLs)?	procedures for the presence of asynchronous and obsolete GM material	food Number of NRLs and official laboratories applying a specific screening method, including: construct-specific PCR, element-specific PCR, event-specific PCR Number of NRLs and official laboratories applying qualitative methods Number of NRLs and official laboratories applying quantitative methods Number of NCAs using MRPLs to assess compliance		Survey of NRLs and official laboratories NCAs topic guide NRLs and official laboratories topic guide	
A.5. Does the lack of harmonisation in the interpretation of test results have an impact on compliance assessment (within and between Member States)? Have Member States ever had practical experience on that?	Different procedures for interpretation of test results determine different conclusions on compliance assessment within and between Member States	Number of NCAs reporting impacts on compliance assessment	Consultation with MS competent authorities	NCA survey Survey of NRLs and official laboratories NCAs topic guide NRLs and official laboratories topic guide	Section 3.1.5 Section 3.1.6
A.6. Would the definition of a Minimum Required Performance Limit affect protocols of testing?	Extent to which Member States need to adapt their protocols of testing by including or modifying the limits of detection applied	Number of NCAs, NRLs and official laboratories reporting that the definition of a MRPL would affect protocols of testing	Consultation with MS competent authorities	NCA survey Survey of NRLs and official laboratories	Section 3.1.6
A.7. Are there any beneficial or negative effects deriving from the harmonisation of sampling and analysis and the introduction of a Minimum Required Performance Limit	Scale/significance of effects identified	Results of Member States' tests in the context of reporting obligations in Art. 6.2 of Regulation 619/2011 Number of NCAs, NRLs and official laboratories identifying	Consultation with MS competent authorities	NCA survey Survey of NRLs and official laboratories NCAs topic guide	Section 3.1.5 Section 3.1.6

Evaluation tasks / study questions	Judgement criteria	Indicators	Data sources	Evaluation tools	Results
for food as it already exists for feed? What are these effects?		beneficial effects from each of the following: harmonisation of sampling methods, harmonisation of methods for analysis, and introduction of a MRPL Number of NCAs, NRLs and official laboratories identifying beneficial effects from each of the following: harmonisation of sampling methods, harmonisation of methods for analysis, and introduction of a MRPL		NRLs and official laboratories topic guide	
B. Impacts on operators and on the market					
B.1. What are the sampling, analysis and risk management strategies and protocols applied by food business operators regarding asynchronous and obsolete GMOs? How many and what kind of samples are taken and what types of tests are performed on an annual basis in the framework of the own check controls?	Description of the current situation regarding food business operators own controls for detecting asynchronous and obsolete GMOs	Number of businesses applying sampling, analysis and risk management strategies and protocols regarding asynchronous and obsolete GMOs Number of businesses applying protocols for sampling foreseen by EU guidance and legislation, including: Recommendation 787/2004, Regulation (EC) No 152/2009, Regulation(EC) No 401/2006, and Regulation (EU) No 619/2011 Number of businesses applying other protocols for sampling and description of these protocols Number of samples tested on an annual basis in the	Consultation with food business operators and representative bodies Consultations with companies providing testing / assurance services	Industry associations survey Survey for individual businesses Industry associations topic guide Individual businesses topic guide Topic guide for commercial laboratories	Section 3.2 Section 3.2.2

Evaluation tasks / study questions	Judgement criteria	Indicators	Data sources	Evaluation tools	Results
		framework of own controls Number of businesses applying reference methods available from the EU Database of Reference Methods for GMO Analysis in the framework of own controls Number of businesses applying other methods and description of these methods			
B.2. For food business operators also involved in feed activities (i.e. crop growers and traders, crushers), what are the strategies and measures adopted and implemented to manage the two products flows for which different sampling and analysis procedures apply?	Description of strategies and measures adopted and implemented to manage the two products flows for which different sampling and analysis procedures apply	Consultation responses (descriptive analysis)	Consultation with food business operators and representative bodies Consultations with companies providing testing / assurance services	Industry associations survey Survey for individual businesses Industry associations topic guide Individual businesses topic guide Topic guide for commercial laboratories	Section 3.2.3
B.3. Does the lack of harmonisation of sampling and analysis for official controls for the presence of asynchronous and obsolete GM material affect food business operators at EU level? If so, what are these impacts?	Significance (type, scale, consequences) of market impacts	Costs of contamination incidents Economic damages due to legal uncertainty Lack of access to market Legal / other costs Additional assurance / verification costs Identification of cases where a lot was not accepted in one MS but probably would have been accepted in another	Consultation with food business operators and representative bodies Consultations with companies providing testing / assurance services	Industry associations survey Survey for individual businesses Industry associations topic guide Individual businesses topic guide Topic guide for commercial laboratories	Section 3.2.4

Evaluation tasks / study questions	Judgement criteria	Indicators	Data sources	Evaluation tools	Results
		(and *vice versa*)			
B.4. What would be the potential consequences for food business operators under a scenario where the current lack of harmonisation of sampling and analysis for official controls would remain unchanged? How would this affect their risk management strategies?	Significance (type, scale, consequences) of impacts Scale/significance of strategic responses	Expected costs (using measures above) in a business-as-usual scenario, in the context of expected development of the food / feed markets and use of GMOs Descriptive analysis of consultations responses – firms' strategic responses and approaches to risk management	Consultation with food business operators and representative bodies Market projections and analysis	Industry associations survey Survey for individual businesses Industry associations topic guide Individual businesses topic guide	Section 3.2.4
B.5. What would be the expected impact of harmonisation of sampling and analysis and the definition of a MRPL for food tests as regards asynchronous and obsolete GM material?	Expected direct / indirect impacts on businesses, the supply chain, and the market	Increased / decreased costs of contamination incidents	Consultation with food business operators and representative bodies Consultation with civil society organisations	Industry associations survey Survey for individual businesses Industry associations topic guide Individual businesses topic guide Topic guide for commercial laboratories	Section 3.2.5
B.6. Does the harmonisation of testing and sampling, or the lack of harmonisation thereof, affect consumers in the EU? If so, how?	Evidence of impacts on prices, product availability, consumer confidence	Number of businesses and NGOs reporting impacts on consumers Social research data (e.g. on consumer survey evidence) Market research data, e.g. on price impacts of current approach	Desk research (e.g. Eurobarometer on consumer attitudes towards GMOs) Consultation with food business operators Consultation with civil society organisations	Industry associations survey Survey for individual businesses NGOs topic guide	Section 3.2.1
C. Description of market's and supply chain's specifications and trends for the identified main products					
C.1. What are the most	Dependence from third	Share of imports compared to	Desk research (e.g.	Industry associations survey	Section 3.2.1

Evaluation tasks / study questions	Judgement criteria	Indicators	Data sources	Evaluation tools	Results
relevant food sectors and products with regards to the presence of obsolete and asynchronous GM material in traded commodities?	countries for the supply of certain food commodities Cultivation of GM crops in exporting third countries	domestic production Proportion of commodities that is GM	EUROSTAT) Consultation with food business operators	Survey for individual businesses Market analysis	Annex 4
C.2. What are the sizes (values and volumes) of the EU and global markets for the main food products identified?	Values and volumes of production and imports for the main commodities identified		Desk research (e.g. EUROSTAT) Consultation with food business operators	Industry associations survey Survey for individual businesses Market analysis	Section 3.2.1 Annex 4
C.3. What are the temporal evolution (past, present, future), structures and functioning of supply chains from fields to consumers, in the EU and worldwide, for the main food products identified?	Trends in production and imports for the main commodities identified	Outlook data on production and imports for the main commodities identified	Desk research (e.g. EUROSTAT) Consultation with food business operators	Industry associations survey Survey for individual businesses Market analysis	Section 3.2.1 Annex 4
C.4. What are the main factors influencing variations in supply and demand of the main food products identified?	Evidence of factors influencing demand and supply, with a focus on factors related to the presence of asynchronous and obsolete GMOs	Costs arising from trade disruption and legal uncertainty	Desk research (e.g. EUROSTAT) Consultation with food business operators	Industry associations survey Survey for individual businesses Market analysis	Section 3.2.1 Annex 4

Annex 3 Detailed description of research method and stakeholder consulted

This annex provides a detailed description of the research tasks completed for this study (surveys, interviews, case studies and market analysis), including an overview of the types and numbers of stakeholders consulted. This annex also summarises the frameworks for data analysis and data validation.

A3.1 Description of research tasks and stakeholders consulted

A3.1.1 Consultations – survey

A survey was conducted with:

- NCAs and CAs across the EU-28 Member States; and
- Businesses, via the representative associations, through an open-ended survey that the associations could circulate to their members and complete with a representative view from across the membership.

The survey was delivered as a 'smart PDF' file that allowed users to complete the survey off-line and return it to the study team in a form that automatically integrated responses into a central database.

A rapid testing of the questionnaire was conducted with business representatives and competent authorities to ensure that the terminology was appropriate to the different communities of interest involved.

The survey data was downloaded from smart PDF into Excel. The results were then analysed by the ICF study team. Responses received in a language other than English were translated by a native or fluent language speaker.

The status of survey responses received from each of the stakeholder groups within the scope of this study is summarised in Table 8. Additional information on NCA survey responses is provided in Table 9.

Table 8. Summary of survey responses received

Consultee group	Number of requests sent	Number of survey responses received
NCAs in charge of sampling	28 Member States	Responses covered 27 Member States (only Latvia did not respond). More specifically, responses were received from: 28 national level authorities; and 8 regional level authorities.
NCAs in charge of analysis	28 Member States	Responses covered 27 Member States (Bulgaria did not respond). More specifically, responses were received from: 31 national level authorities; and 8 regional level authorities.
EU industry associations	16	6
Individual businesses and business associations at national level	N/A[65]	One food company operating in an EU Member State, a national business association and a multinational company

Table 9. Survey responses received from NCAs – detailed overview

MS	Survey on sampling	Survey on analysis	Respondents per MS
AT	NS	NA	2
BE	NSA	NSA; 3 NA	4
BG	NS	DNP	1
CY	NSA	NSA	1
CZ	NS	NA	2
DE[66]	NS; 6 CSA; CS	NA; 6 CSA; 2 CA	11
DK	NS	NA	2
EE	NS	NA	2
ES[67]	NSA	NSA	1
FI	NSA; NS	NSA	2

[65] Requests to individual businesses and national associations were sent through EU business associations.

[66] A response was submitted by the central competent authority responsible for sampling and analysis in Germany. Responses to the sampling survey were also received from competent authorities in the following Länder: Saxony, Hamburg, Rheinland-Pfalz, Lower Saxony, Hessen, Thuringia, Berlin. Responses to the analysis survey were received from competent authorities in Saxony, Hamburg, Rheinland-Pfalz, Lower Saxony, Hessen, Thuringia, Berlin and Mecklenburg.

[67] The Spanish NSA did not submit responses to survey questionnaires, but provided written responses to interview questions. These responses were integrated in the analysis.

MS	Survey on sampling	Survey on analysis	Respondents per MS
FR	NS	NA	2
EL	2 NS	NA	3
HR	NS	NA	2
HU	NS	NA	2
IE	NSA	NSA	1
IT	NS	NA	2
LT	NSA	NA	2
LU	NS	NA	2
LV	DNP	NA	1
MT	NS	NA	2
NL	NSA	NSA; NA	2
PL	NS	NA	2
PT	NS	NA	2
RO	NS	NA	2
SE	NSA	NSA	1
SI	NS	NA	2
SK	NS	NA	2
UK[68]	CS	NA	2
Total	**28 national and 8 regional authorities, covering 27 MS**	**31 national and 8 regional authorities, covering 27 MS**	**62 (52 representatives of national and 10 representatives of regional authorities, covering 28 MS)**

NS = NCA only responsible for sampling, NA = NCA only responsible for analysis, NSA = NCA responsible for both sampling and analysis, CS = Regional CA only responsible for sampling, CA = Regional CA only responsible for analysis, CSA = Regional CA responsible for both sampling and analysis. DNP = did not participate in the consultation

A3.1.2 Consultation – interviews

The study team conducted semi-structured phone interviews with the stakeholders listed in Table 10. Interviews were based on targeted topic guides prepared for each of the stakeholder categories consulted.

[68] The UK's response to the sampling survey was not provided by a national competent authority, as data is collected and held by local authorities around the country. A response was provided by the Suffolk Coast Port Health Authority.

Table 10. Summary of interviews completed

Stakeholder contacted	Requests sent	Interviews completed	Note
Third countries	4	4	Interview requests were sent to the representatives of the diplomatic missions to the EU of US, Canada, Argentina and Brazil. Three representatives (US, Canada and Argentina) submitted a written response. A phone interview was completed with Brazilian representatives.
National competent authorities (NCAs) and National reference laboratories (NRLs)	7	7	Interviews covering both sampling and analysis have been completed for all case study Member States with the exception of Spain. Spanish authorities preferred to submit a written response to the interview topic guides on sampling and analysis.
EU business associations	3	3	A meeting with the European Vegetable Protein Industry Association (EUVEPRO), EU Vegetable Oil and Proteinmeal Industry Association (FEDIOL) and FoodDrinkEurope took place on 8 April 2015.
Individual businesses and national associations in the case study countries	23	5	Six industry stakeholders declined to take part in the interview: most of them (five) preferred to participate through their EU representative associations, and one stated its organisation did not have the information necessary to contribute to the study. The remainder did not respond.
Laboratories providing testing services to industry stakeholders	2	2	Interviews are completed with two laboratories.
Non-governmental organisations (NGOs)	7	3	Four NGOs did not respond to the request.

A3.1.3 Case studies

Based on the terms of reference requirements and as agreed with DG SANTE, case studies were conducted in the following Member States: Germany, the Netherlands, Spain, Belgium, France, Austria and Hungary. The seven case study countries were chosen to provide a representation of different circumstances at Member State level in terms of imports, supply chain structures (e.g. numbers and size of crushing facilities) and geography.

We prepared for the case studies by:

- Identifying data sources relevant to each case study country.
- Identifying stakeholders to be contacted in each country.
- Preparing 'topic guides' to support semi-structured interviews with these stakeholders. These topic guides were designed to gather the kind of qualitative information that is more difficult to obtain from a survey.
- Preparing a case study template to be used by the research team. The adoption of a standard template ensured consistency in the presentation of the information collected by the research team.

A3.1.4 Market analysis

A market analysis was conducted to investigate the products and sectors mostly affected by the presence of asynchronous and obsolete GMOs. The objectives, scope and results of the market analysis are described in more detail in Annex 4. The market analysis was based on desk research and interviews with representatives of FBOs.

A3.2 Framework for data analysis

The synthesis process involves drawing results together, analysis, and formulating conclusions. This stage involves an overall assessment of the robustness of evidence and consideration of whether the findings are consistent across the evidence base, and why inconsistencies arise.

Our approach was based on the synthesis and triangulation:

- data synthesis / triangulation of evidence gathered from different sources (views and opinions expressed by different stakeholder groups);
- researcher synthesis / triangulation of information collected by different researchers, joined-up through regular team briefing / de-briefing sessions; and
- methodological synthesis / triangulation of evidence gathered through different methods (i.e. desk research, interviews, online surveys and case studies).

Synthesis and triangulation is a useful approach for cross-examining evidence and overcoming biases that can arise from single method / observer / theory studies.

- Inputs to the overall appraisal in this instance include:
- a write-up of the survey results, including use of figures and tables to illustrate results where necessary;
- summaries of the individual country case study findings and comparison across them;
- market analysis and desk research components; and
- write-ups of interviews with key stakeholders (e.g. selected industry representative bodies).

The information is presented according to the report structure and sequence of reporting previously agreed with the Commission.

Reporting material is evidence-based and fully referenced with more technical and/or in-depth supporting material contained within boxes and annexes as appropriate so as not to disrupt the flow of the main text.

The lead researchers for individual case studies and other researchers were required to write up interviews to a prescribed format and or submit a recording of the interview for transcription. Interview write-ups / transcripts were analysed by the core study team to ensure a consistent approach to the analysis. As per standard research guidance,

interview content was anonymised unless the interviewee had given their consent for their details to be released and attribution of the quote or evidence.

The case studies provided analytical depth across a range of products and different Member States. In carrying out the case studies we investigated the representativeness of the cases examined to help us to draw conclusions which are meaningful for the EU and the market as a whole.

A3.3 Validation of data

When conducting data analysis, it is important to adopt measures to avoid potential errors and inconsistencies. Measures to minimise the risk of errors were adopted before the launch of stakeholder consultations and data collection: this included, for example, the piloting of survey questionnaires with the support of a small number of Member State and business representatives. At the stage of data synthesis and analysis, some possible sources of errors and gaps may include the following:

- **Consultees might have wrongly recalled or estimated certain details when factual questions were asked**. For example, during interviews consultees were requested to provide technical information, such as the qualitative methods used for the analysis of GMOs. To avoid the possibility of errors, consultees were requested to submit official documentation on the sampling and analysis protocols when possible. Additionally, the information provided in the course of interviews was compared with the details provided in writing as part of questionnaire responses (for those consultees which took part both in surveys and interviews).
- **Consultees might have given inaccurate answers to questions regarding expectations of the future**, including questions on the expected impacts from the harmonisation protocols for sampling and analysis. This may be done, for example, in order to influence the outcome of the study and this may lead to bias in the survey results. To avoid such errors, consultees were asked to provide evidence and examples regarding expected impacts. The data analysis highlighted those cases where consultees were able to provide such evidence.
- **Certain respondents might not have put in sufficient effort to answer the questions accurately**. This can make responses incomplete or inconsistent. Incompleteness can be detected if the number of 'don't know' answers or refusals is high for a given respondent. It was expected that some respondents would not be able to reply to all questions for various reasons (e.g. the highly technical aspects of the questionnaire). Incomplete responses were also included in the analysis, and 'did not answer' responses included in the sample size. Tables and graphs include information on the sample size and number of 'did not answer'. When needed, footnotes try to explain the reasons of the low response rate to specific questions or questionnaires.
- **Reponses may have been submitted twice**: the same consultee may have mistakenly submitted the same survey response twice. This was the case, for example, of representatives of some NCAs. To highlight possible duplicates, a table of consultees registering the responses received was kept updated by the study team. Additionally, the content of the survey responses submitted was checked to exclude duplicates from the data analysis.
- **Multiple questionnaires are submitted from the same group of consultees**: in some cases, separate questionnaires were submitted by consultees as an alternative to a consolidated response. This was the case, for example, regarding the questionnaires on sampling and analysis submitted separately by the regional authorities of Member States. These questionnaires were analysed separately, and data was aggregated at a national level. Divergences between responses were

noted. For example, if data analysis highlighted a variation in some of the responses submitted by the different German States, this was reported as part of the analysis.

- **There may be missing values**. In some cases, respondents left blank one part of the question, but responded to a correlated sub-question. For example, respondents may not have selected a tick box indicating that one element of sampling has determined impacts, but then mention that they had experience of these impacts. In this case, the 'blank' answer may not mean a 'no' response. Unclear responses are reported (e.g. in footnotes). Where possible, issues were clarified directly with respondents.
- **Non-relevant responses are submitted.** The format adopted for the survey was a Smart PDF, which allowed for the collection and consolidation of responses from multiple consultees (such as the members of an industry association). This format, however, did not allow for the routing of questions. For this reason, some respondents may have completed parts of questionnaires that were not relevant to them. Where possible, these issues were clarified with survey respondents. Some questions in the survey for competent authorities were not relevant to those Member States that do not test for the presence of asynchronous and obsolete GM events. For completeness, these Member States are listed in the tables with aggregate data from survey and interview responses and are coded as follows: DNT (Member State does not test for the presence of asynchronous and obsolete GM events).
- **Non-respondents and non-participants:** it is necessary to differentiate between those who took part in the consultations but did not respond to a specific survey or interview question (non-respondents) and those who were invited but did not participate in the consultation (non-participants). Tables with aggregate data from NCAs and CAs responses to survey and case study questions (Annex 5) provide information on both non-participants and non-respondents. This approach provides a complete picture of the consultation outcome, covering all Member States. The two categories are coded differently: NR (no response) and DNP (did not participate). Non-participants are not counted in the totals presented at the bottom of each table.

Table 11 summarises these issues and the study team's response measures.

Table 11. Data validation – summary

Source of possible errors	Examples	Our response
Consultees wrongly recall or estimate certain details when factual questions are asked	Responses to questions requesting technical information on sampling and analysis	Supporting documentation requested; triangulation between survey responses, interview write-ups and documents provided
Inaccurate answers to questions regarding expectations towards the future	Questions on the expected impacts arising from harmonisation	Evidence of expected impacts was requested
Respondents do not put in sufficient effort in answering the questions accurately	High number of 'don't know' answers or refusals to respond	Incomplete responses included in the analysis, and possible reasons for the low response rate provided
Reponses submitted	This was the case, for	Cross-check tables

twice	example, of representatives of some NCAs	registering the number of responses and contact details of consultees
Multiple questionnaires submitted from the same group of consultees	Separate questionnaires submitted by regional authorities, instead of a response at national level	When identified, divergences between responses are noted
Missing values	Respondents left blank one part of the question, but responded to a correlated sub-question	Issues related to missing values and unclear responses are reported
Non-relevant responses are submitted	Issues deriving from the lack of routing options	Issues clarified directly with survey respondents
Non-participants and non-respondents	It is necessary to differentiate between those who took part in the consultations but did not respond to a specific survey or interview question (non-respondents) and those who were invited but did not participate in the consultation (non-participants)	Information on non-participants and non-respondents is provided for completeness, and different coding is used

Annex 4 Market analysis – results

A4.1 Introduction

A4.1.1 Objectives

The objective of this market analysis is to provide:

- A narrative description of the market's development (value / volume) to the present and forecasts of its future outlook, concentrating on the products identified as the most relevant for the purposes of this study.
- A description of the structure and operation of the market, following the supply chain from point of production to the consumer and explaining the forces that drive change in the market.

The work focusses in particular on attributes of the market pertinent to adventitious presence of asynchronous and obsolete GMOs in traded commodities.

A4.1.2 Scope

This market analysis follows a mapping exercise that identified the main food sectors and products potentially affected by the presence of asynchronous and obsolete GM material. The mapping exercise involved desk research and scoping interviews with industry representatives.

The mapping exercise showed that the EU is largely self-sufficient in the production of maize, but highly dependent on imports of soybeans which are used widely in the food industry (e.g. in soy derivatives such as soy oils and lecithin). Previous assessments by EU industry associations (including FEDIOL, 2011; EUVEPRO, 2011; Landmark Public Policy Advisers Europe, 2009; Solae, 2010 and PFP, 2011) focussed on the impacts on soybean imports deriving from asynchronous authorisations. Scoping interviews undertaken by the study team with industry representatives confirmed that the main issues relate to soybean.

For these reasons, the market analysis focusses on the **soybean** supply chain. It also considers the structure of the maize market as maize is the only food product covered by obsolete authorisations. The market analysis considers the EU's trade with the US, Canada, Brazil and Argentina as these countries are the main global producers of GMO soybean and maize and major exporters to the EU.

As required by the terms of reference for this study, the analysis describes the current market situation, its recent history (2009 – 2014) and the expected future outlook.

The analysis is structured as follows:

- Section A4.2 describes the soybean supply chain from primary production to final consumption of food products.
- Section A4.3 describes the maize supply chain.
- Section A4.4 summarises the outcome of assessments conducted by food business operators, with a focus on the presence of asynchronous and obsolete GMOs in traded commodities.

A4.2 The soybean supply chain

This section focusses on the following stages of the soybean supply chain:

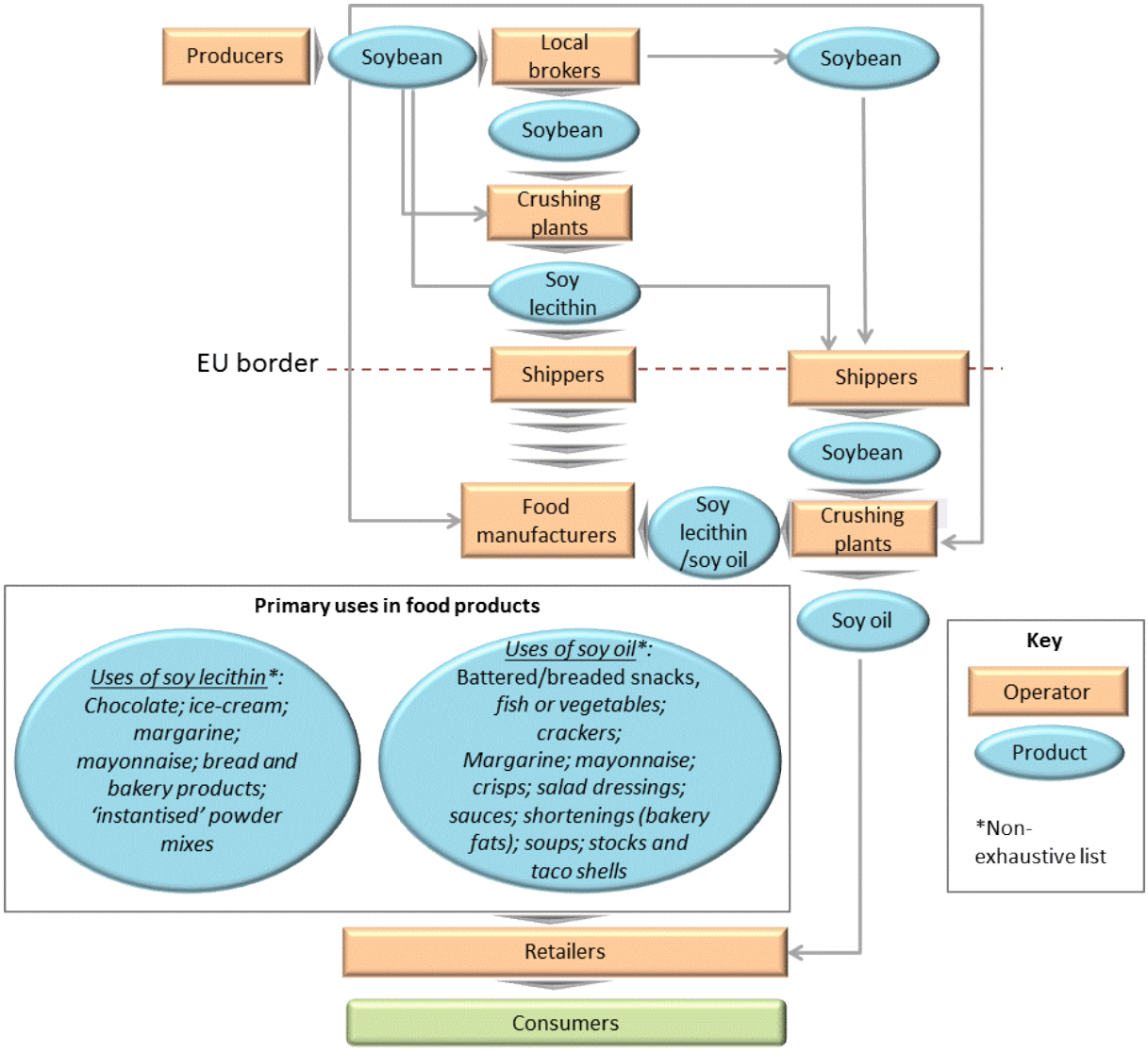
- primary production of soybeans;
- trade between the EU and third countries, with a focus on raw commodities;

- EU crushing activity; and
- processing and food production.

The supply chain outlook is summarised in section A4.2.5.

Table 12 provides a mapping of the main food operators along the soybean supply chain. A graph summarising the food supply chain and the interactions between these operators is presented in Table 12.

Figure 6. Soybean and derived food products supply chain



Source: ICF

Table 12. Stakeholders involved in the soy supply chain

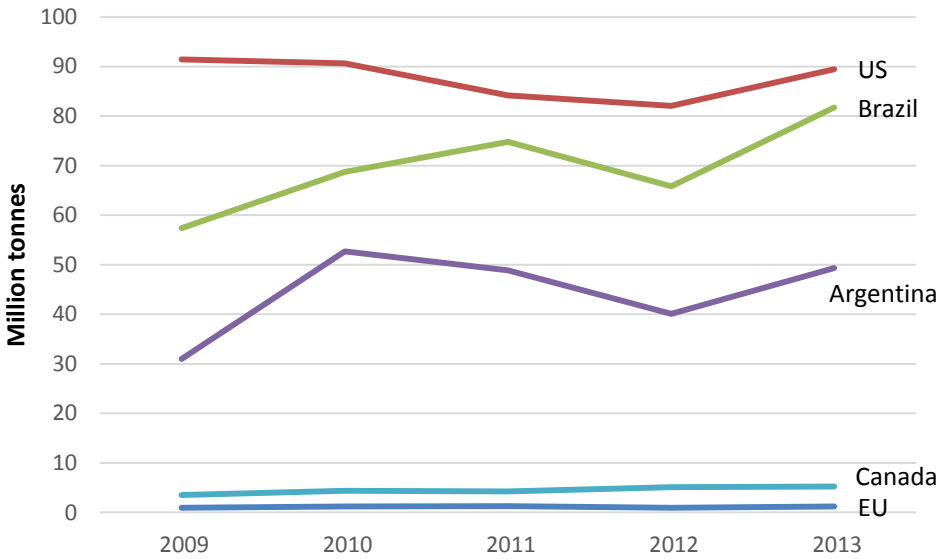
Stakeholder group	Description	Governance
Producers	Primary producers are responsible for the planting, harvesting and sale of soybeans. Growers may sell soybeans to brokers or directly to processing plants. In some cases growers may bypass commodity traders in the country of production and sell directly to buyers in the destination country. This is increasingly the case for non-GMO soybeans used for the production of foods such as tofu or edamame (HighQuest Partners and Soyatech, LLC, 2011).	Soybean producers are generally large businesses; a small number of large organisations account for the majority of soy produced in Brazil and exported to the EU. Smaller businesses are also involved in soybean production and are more common in India and China (HighQuest Partners and Soyatech, LLC, 2011).
Local brokers	Local brokers purchase soybean direct from producers, aggregate it, and then sell it on to crushing plants or commodity traders. Local brokers are likely to have a more significant role in India where there are relatively (compared to Brazil) higher numbers of smaller soybean producers.	There are large numbers of small sized brokers operating locally in producing countries.
Crushing plants	Crushing plants are where raw soybeans are processed into soymeal and soy oil. Crushing plants are located in the country of origin but there are also plants in Europe. Many crushing plants are owned by soybean producers or by commodity traders.	In 2011, four companies covered close to 80 per cent of soybean processing capacity: ADM, Cargill, Bunge North America and Ag Processing Inc. (HighQuest Partners and Soyatech, LLC, 2011). The major crushing plants in Europe are owned by US crushers: for example, ADM Germany is the largest EU oilseeds crushing and refinery complex (ADM, 2015) and the two leading crushing plants in the Netherlands are owned respectively by ADM and Cargill: in 2013 these two plants crushed 2.4 million tonnes of soybeans, representing 76 per cent of all soybeans imported by the Netherlands (The Dutch Soy Coalition, 2014). Bunge is a leading soybean crusher, refiner and trader in Spain and the largest

Stakeholder group	Description	Governance
		oilseed processor in Hungary (Bunge, 2015).
Commodity traders	Commodity traders are multi-national corporations involved in the production, processing, shipping and sale of agricultural commodities. Commodity traders own and operate soybean crushing plants (in countries of origin and the EU) and own and operate shipping companies. They are involved in the financing of soybean production, for example through contracts to supply seeds, pesticides and fertilizers to producers in return for harvested soybean.	A small number of commodity traders exert significant influence along the soybean supply chain. The main commodity traders in the soybean supply chain are: ADM, Cargill, Bunge and Louis Dreyfus Group.
Shippers	Shippers are responsible for transporting soybean and soybean products from source countries to the EU. The availability of sufficient shipping capacity can have a significant influence on the availability and price of soybean. Some commodity brokers own, or have interests in, companies shipping soybean and soybean products to the EU.	A large number of soy shippers operate in exporting countries. In some cases, major crushers, such as Cargill, also provide sea freight services. In other cases soybeans are shipped by smaller companies that may be also involved in the production and storage of soybeans (see, for example, Midwest Shippers Association, 2012).
Food manufacturers	Food and drink companies are responsible for transforming soymeal and soy oil into products designed for human consumption.	Germany, France, Italy, the UK and Spain are the largest EU food and drink producers. Together they account for 62% of the industry's total turnover (FoodDrinkEurope, 2014). Oils and fats represent 5% of the sector's turnover (FoodDrinkEurope, 2014).
Retailers	Retailers are at the end of the supply chain.	In 2011 there were about 3.6 million retail companies in the EU (Eurostat). In 2010, 75 per cent of the production value of the EU retail sector was concentrated in Germany, UK, Italy, Spain, Poland and the Netherlands. In 2010 the market share of the top three supermarket chains in each of the mentioned counties ranged from 24% (Italy) to 57% (UK) of total national retail sales (FoodDrinkEurope, 2013).

A4.2.1 Primary production

The US, Canada, Brazil and Argentina are the largest soybean producing countries. Together they are responsible for 82 per cent of worldwide soybean production. Figure 7 compares the quantities produced in these countries and in the EU from 2009 to 2013.

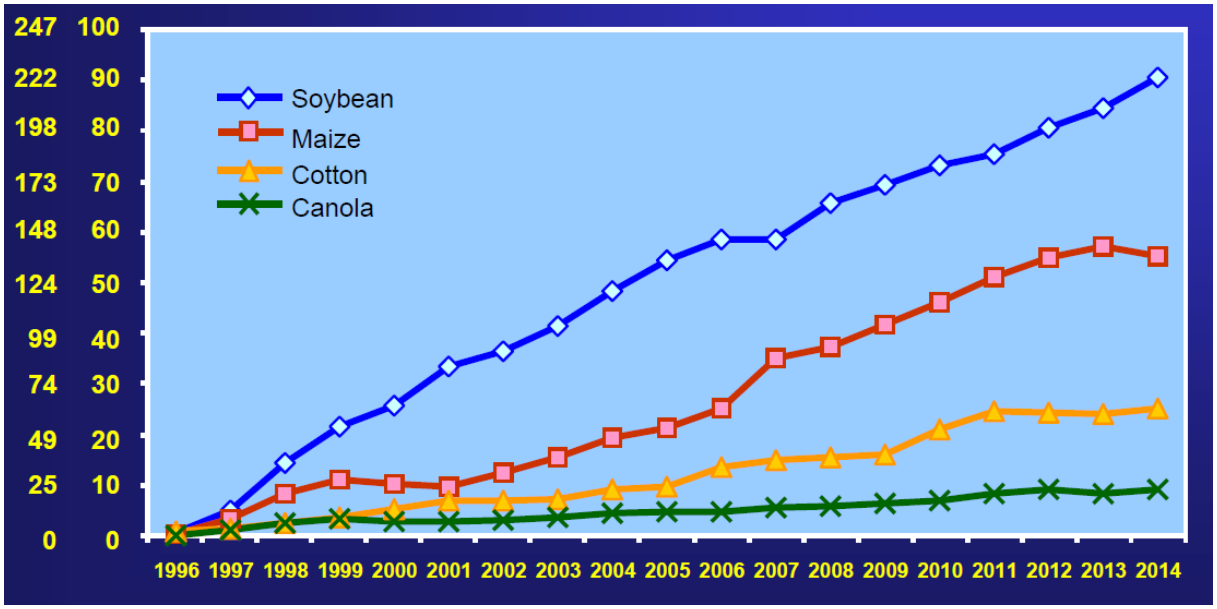
Figure 7. Soybean production in the EU, US, Canada, Brazil and Argentina – million tonnes per annum



Source: FAOSTAT, 2015

It is estimated that 82 per cent of total soybean cultivation was GM in 2014 (James, 2015). The US, Canada, Brazil and Argentina are the top four global producers of GM soybean. In the US and Brazil, the two largest exporters of soybean to the EU, more than 90 per cent of soybean planted in 2014 was GM (Figure 8). Other countries where GM soy is cultivated include Canada, Bolivia, Chile, Costa Rica, Mexico, Paraguay, Uruguay and South Africa (James, 2015). The global area of cultivation of GM soybean and other GM crops has continuously grown since 1996.

Figure 8. Global area of GM crops, 1996 to 2014 (million hectares, million acres)



Source: James, 2015

Table 13 provides an overview of the rate of adoption of GM soybean in the US, Canada, Brazil and Argentina.

Table 13. Rate of GM adoption in soybean cultivation

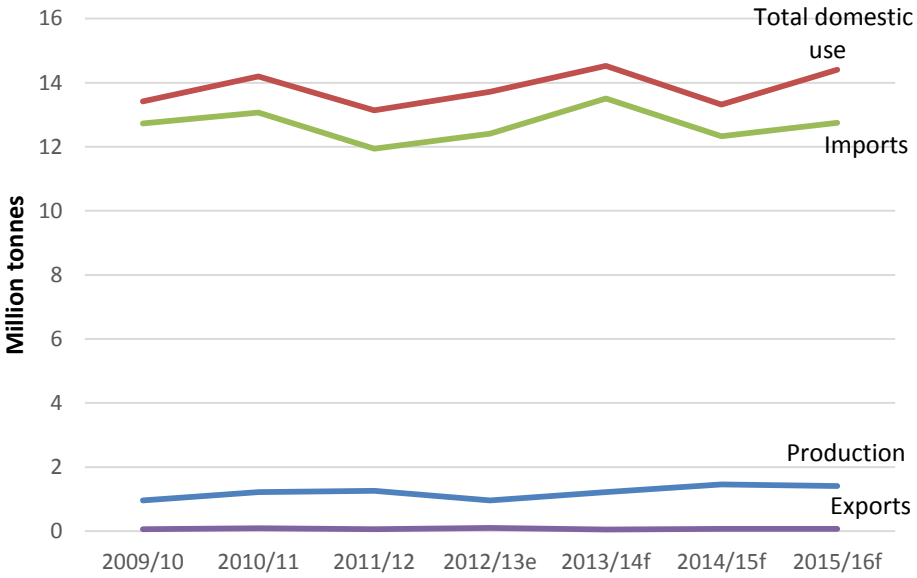
Country	GM soybean cultivation area, 2014* (million hectares)	Proportion of total soybean cultivation area that is GM
US	34.3	94%
Brazil	27	91%
Argentina	20.5	100%
Canada	1.4 (USDA estimate)	62% (USDA estimate)
	2.2 (ISAAA estimate, as reported in Canadian Biotechnology Action Network)	98% (ISAAA estimate, as reported in Canadian Biotechnology Action Network)

Sources: USDA, 2014; Dessureault and Lupescu, 2014; Yankelevich, 2014; Silva, 2014; Canadian Biotechnology Action Network, 2014; and James, 2015.

A4.2.2 Trade

About 14 million tonnes of soybeans are consumed annually in the EU for food and feed uses. As illustrated in Figure 9, the EU is largely dependent on imports from third countries: the annual domestic production of soybeans can only cover about 10 per cent of total use.

Figure 9. EU 28 soybean balance: domestic use, imports, production and exports

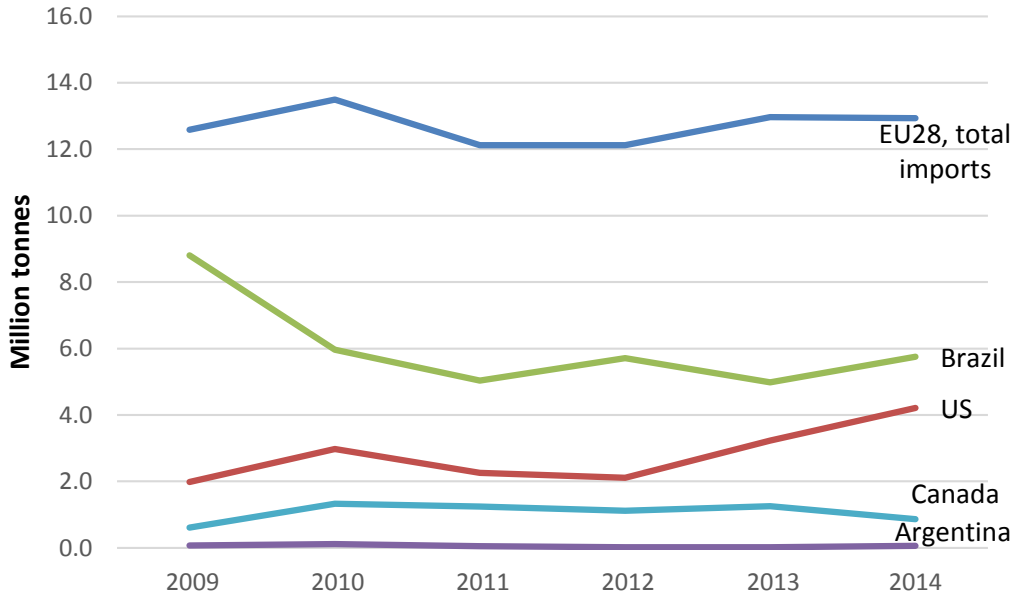


Source: DG AGRI, 2015 (e=estimate; f=forecast)

In 2014, the EU imported 12.9 million tonnes of soybean from third countries. The main sources of this product were Brazil, the US, Paraguay and Canada. Together these countries provided 93 per cent of the total yearly quantity of soybeans imported. A smaller quantity (0.06 million tonnes, less than one per cent of total imports) was imported from Argentina in 2014. The main points of entry for soybeans were Spain, the Netherlands and Germany: in 2011, they received about two thirds of total imports from third countries (Eurostat, 2015). The market destinations for soybean within the EU are unknown (Tillie and Rodríguez-Cerezo, 2015).

Figure 10 shows how imports of soybeans from the principal sources countries changed between 2009 and 2014.

Figure 10. Soybean imports from third countries, million tonnes



Source: Eurostat, 2015

Segregation systems and GM-free certification have been introduced in exporting countries to meet importers' demand for GM-free products. Demand originates with the organic sector and producers of food labelled as GM-free (Lefebvre, Polet and Williams, 2014).

Brazil is the largest EU provider of soybean certified as non-GM. In 2011 it was estimated that 4.8 million tonnes of soybeans imported by the EU from Brazil were certified to the standards of one of the four main non-GM soybean certifiers (Cert ID). Considering imports of soybeans subject to audits by other certifiers, the total amount of non-GM identity preserved (IP) soybeans imported from Brazil was likely to be higher (Tillie et al., 2012).

GM-free soybean is also supplied through EU cultivation and imports from countries where GM soybean cultivation is not undertaken, such as India (Lefebvre, Polet and Williams, 2014).

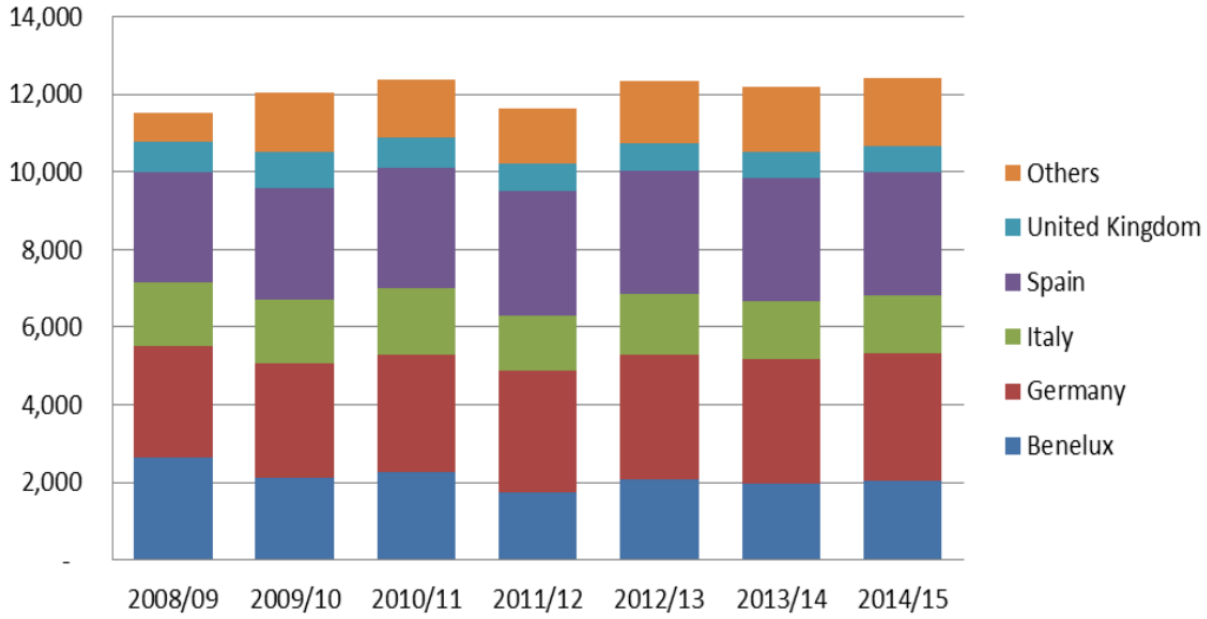
A4.2.3 EU soybean crushing activity

Soybean crushing produces soybean meal (approximately 80 per cent by mass) and oil (approximately 20 per cent) (Landmark Public Policy Advisers Europe, 2009). In 2014, the EU produced 2.4 million tonnes of soybean oil and 9.5 million tonnes of soybean meal. Significant quantities (18.7 million tonnes) of soy meal were also imported in 2014, as well as smaller quantities (0.3 million tonnes) of soy oil (DG AGRI, 2015).

In the US, the processing industry is highly concentrated. In 2011, four companies (ADM, Cargill, Bunge North America and Ag Processing Inc.) controlled close to 80 per cent of soybean processing capacity (HighQuest Partners and Soyatech, LLC, 2011). The major crushing plants in Europe are owned by US crushers, as outlined in Table 12.

In the EU, most soybean crushing takes place in Spain, Germany, Italy and Benelux countries. It is estimated that 10 million tonnes of the 12 million tonnes crushed in the EU were processed in these countries during 2014-2015 (Krautgartner et al., 2014) (see Figure 11).

Figure 11. Main soybean crushers, EU 28 (million tonnes)



Source: Krautgartner et al., 2014

A4.2.4 Processing and food production

Based on industry assessments (Brookes, 2008; FEDIOL, 2011a) the most common soybean derived ingredients used for food production are soy oil, which is directly derived from crushing and soy lecithin, which is derived from the further processing of soy oil.

Based on industry estimates (Landmark Public Policy Advisers Europe, 2009), the EU market for soy and soy derived ingredients for food use includes one million tonnes of soy oil (representing 40 per cent of the total EU production of soy oil) and 30,000 tonnes of soy lecithin.

The proportion of soy derived ingredients in the final food product varies significantly, ranging from 0.3 per cent (when the ingredient is incorporated in a highly processed food product) to 100 per cent (for example, when soybean oil is sold as cooking oil) (Brookes, 2008). Based on industry estimates, over 15 million tonnes of final food products are affected by the use of soy ingredients in the EU (Landmark Public Policy Advisers Europe, 2009). The estimate considers all food applications of soy derived ingredients.

A4.2.5 Market outlook and forecasts

Over the 2014-2024 timeframe, DG AGRI forecasts suggest that soybean production in the EU will increase by seven per cent (from 1.4 to 1.5 million tonnes) (DG AGRI, 2014). There are initiatives to increase domestic production of non-GM soya, such as the Danube Soya Association, which promotes the production and processing of non-GMO soy in the Danube region. Since January 2013, 13 countries have taken part in the initiative[69] (Danube Soya, 2015). According to the Danube Soya Association the production potential for soybeans in the Danube region is four million tonnes (Krautgartner et al., 2013).

EU imports of soybeans are expected to decrease slightly over the next decade but still remain considerably higher than domestic production. USDA forecasts suggest that total

[69] Croatia, Serbia, Switzerland, Bosnia, Republika Srpska, Hungary, Bulgaria, Slovenia, Slovakia, Romania, Poland, Germany and Austria.

imports will decrease from about 13 million tonnes to 11 million tonnes between 2014 and 2024. The US, Brazil and Argentina are expected to maintain their leading role as producers (USDA, 2015).

A4.3 The maize supply chain

This section focusses on the following stages of the maize supply chain:

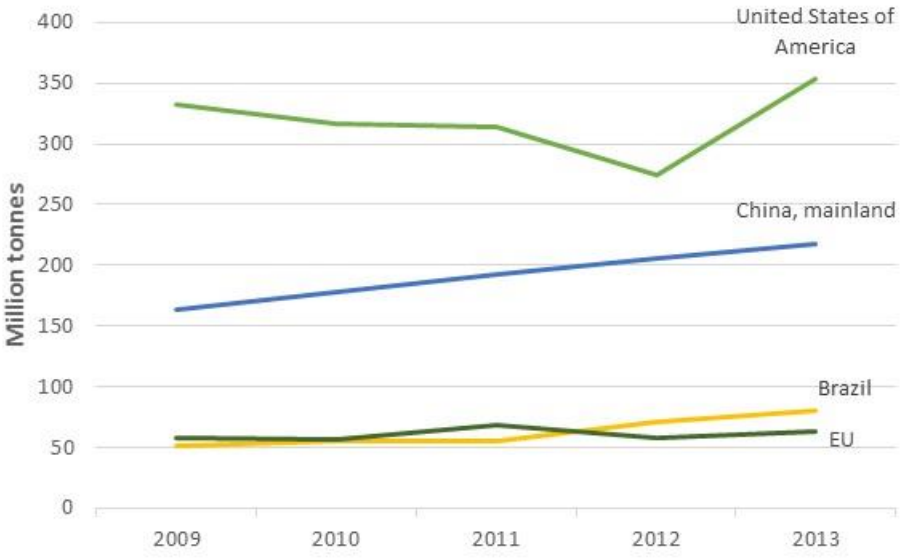
- primary production of maize;
- trade between the EU and third countries, with a focus on raw commodities;
- EU crushing activity; and
- processing and food production.

The supply chain outlook is summarised in section A4.2.5.

A4.3.1 Primary production

The US, China, Brazil and the EU are the world's largest producers of maize. Together they account for more than 70 per cent of total maize world production. Figure 12 shows their respective production volumes since 2009.

Figure 12. Maize production in the United States, China, Brazil and the EU – million tonnes per annum



Source: FAOSTAT

In 2014, 30 per cent of the 184 million hectares of globally grown maize were GM varieties (James, 2014). Of the 55 million hectares of GM maize planted globally, 63 per cent (35.1 million ha) was in the USA and 23 per cent (13 million ha) in Brazil. Other countries growing more than one million hectares of GM maize in 2012 were Argentina (3.3 million), South Africa (2.4 million) and Canada (1.6 million). In the leading producing countries for GM maize, adoption rates are generally high, reaching a maximum of 95 per cent in Argentina (Yankelevich 2014). According to Europabio (2014), five countries (Spain, Portugal, Czech Republic, Romania and Slovakia) were responsible for the total EU production of GM maize yields (148,031 hectares) in 2013, with Spain accounting for more than 90 per cent of the total yields (131,538 hectares in 2014). In Spain, this represented 32 per cent of the total surface sowed with grain maize (Europabio 2014).

Table 14 provides an overview of the GM maize acreage per country and the rate of adoption.

Table 14. Rate of GM adoption in maize cultivation

Country	GM maize cultivation area, 2014* (million hectares)	Proportion of total maize cultivation area that is GM
US	35.1 (2013 figures)	90%
Brazil	13.0	82%
Argentina	4.4	95%
South Africa	2.4	87%
Canada	1.0	83%
Spain	0.13	32%

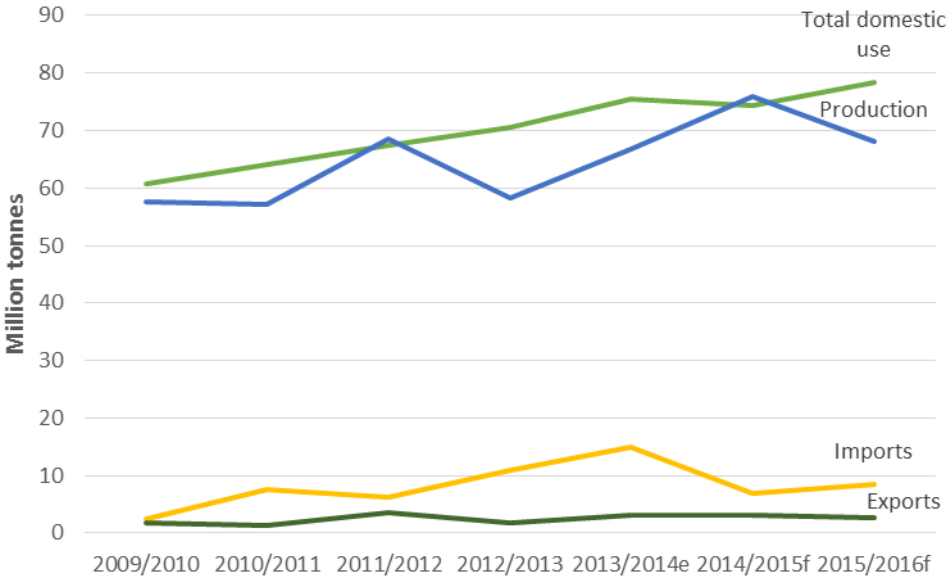
Sources: James, 2012; Fernandez-Cornejo et al., 2014 ; Silva, 2014 ; Yankelevich, 2014 ; Esterhuizen, 2014 ; Dessureault, Lupescu, 2014 ; Europabio 2014.

In China, commercialization of GM maize crops has stalled according to a 2014 GAIN report. Although GMO Safety Certificates were issued to domestically developed GM maize crops in 2009 (high phytase corn variety), these expired in 2014 'without completing the final required registration step needed for commercialization' (Anderson-Sprecher and Jie, 2014). However, it is reported that Chinese seed companies are still working on developing GM seeds and 'hope to be able to commercialize domestically developed varieties of biotech corn in the next three to five years' (Anderson-Sprecher and Jie, 2014).

A4.3.2 Trade

EU maize imports peaked at 15 million tonnes in 2013-2014.

Figure 13. EU-28 maize: total domestic use, production, imports and exports



Source: DG AGRI

EU maize production in 2013-2014 was estimated at 66.8 million tonnes and is expected to reach 76 million tonnes in 2014-2015 (EC 2014). In 2013-2014, the only GM maize

authorized for cultivation in the EU was MON810, a variety of Bt[70] maize. While the total cultivated area has been rising steadily over the last 10 years (reaching more than 148,000 hectares in 2013), its use has been concentrated in only five EU countries. Spain has accounted for around 90 per cent of the total cultivated area, which represented more than 30 per cent of Spain's total maize production. In 2013-2014, the remaining countries cultivating MON810 maize were Portugal, the Czech Republic, Romania, and Slovakia (Levebvre, Polet and Williams, 2014).

The EU is a major importer of maize products, with 15 million tonnes of maize imported in 2013-2014. Imports originated mainly from Ukraine (63 per cent), Brazil (10 per cent), Russia (7.5 per cent) and Canada (6.6 per cent), and were mainly directed to the Spanish, Dutch and Italian markets (EC 2014). While production of GM maize is not officially allowed in Ukraine, some sources have suggested that one third of the maize grown in the country would be GM (Levebvre, Polet and Williams, 2014). According to the authors, the share of GM products of total imports was estimated at around 25 per cent for maize in 2014 (Levebvre, Polet and Williams, 2014).

In 2013-2014, the EU exported around three million tonnes of maize. Romania, Bulgaria and France were the largest EU maize exporting countries. Exports were mainly directed to Egypt, South Korea and Turkey (EC 2014).

A4.3.3 EU maize crushing activity

According to FEDIOL annual statistics (FEDIOL, 2014), crushing activities take place in only six Member States. Belgium and Italy are the largest maize germ crushers (110,000 tonnes each) followed by Hungary (70,000 t), Spain (40,000 t), France (29,000 t) and Bulgaria (16,000 t).

A4.3.4 Processing and food production

Maize has four possible uses: as food, as feed for livestock, as seed and as raw material for the industry (e.g. bioethanol). According to DG AGRI (2015), 4.9 million tonnes were used for human consumption in 2013-2014, which corresponds to only 6.5 per cent of the total maize supply.[71]

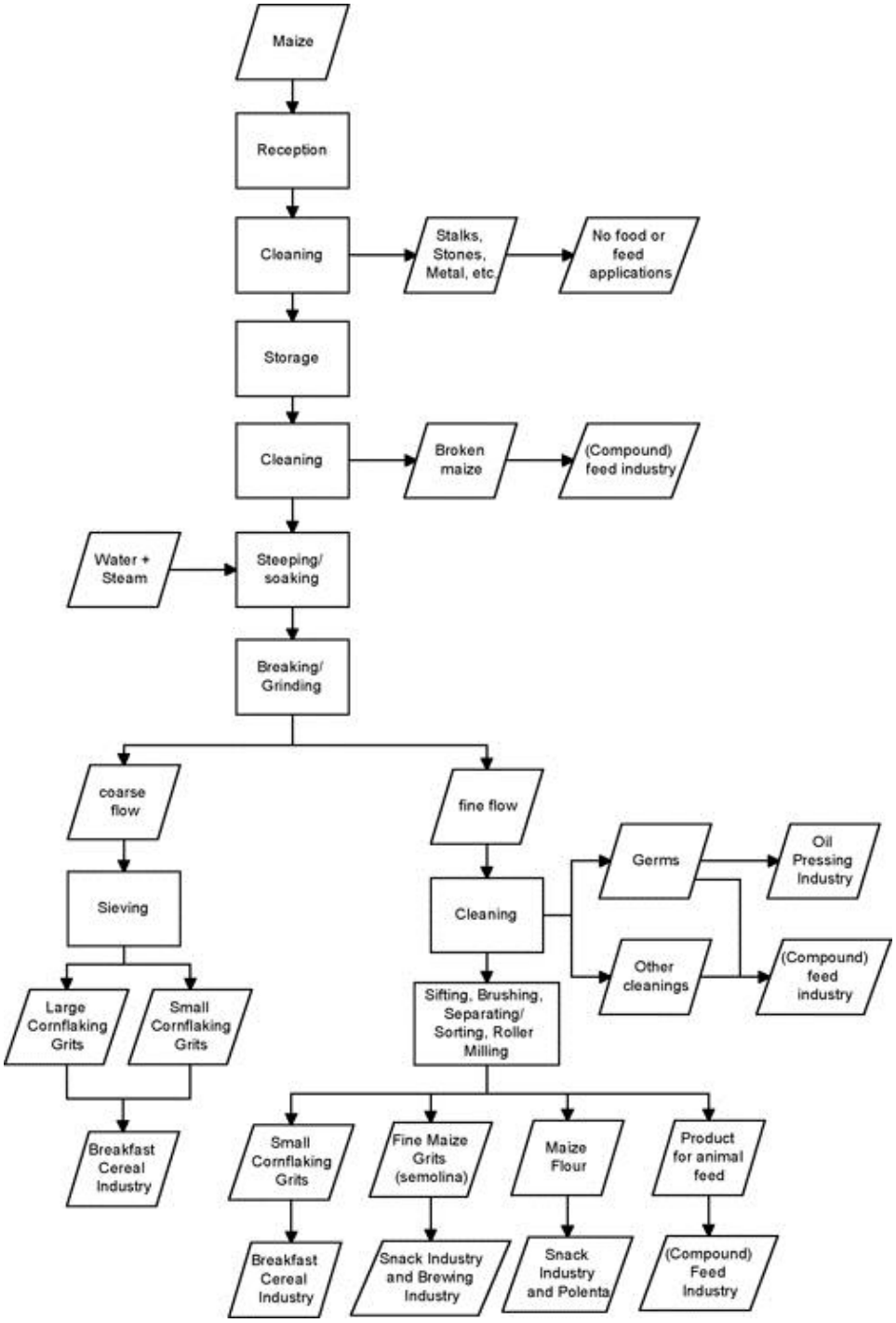
Two different industrial processes are employed to transform maize grains into products designed for human consumption: dry and wet milling. Industrial dry milling involves 'particle size reduction of clean whole maize with or without screening separation, retaining all or some of the original maize germ and fiber' (Gwirtz, Garcia-Casal, 2014). Industrial wet milling comprises the separation of maize into 'relatively pure chemical compound classes of starch, protein, oil, and fiber' (Gwirtz, Garcia-Casal, 2014). While the products and coproducts obtained from wet milling are not typically directly used by consumers, those derived from wet milling (e.g. maize grits of different particle size, coarse or granulated maize meal, maize flour and flaking grits) are much more numerous and used in daily consumption (Gwirtz, Garcia-Casal, 2014). Flaking grits, for example, are used for the ready-to-eat breakfast cereal 'cornflakes'. Coarse or granulated meal is used in pancakes and muffin mixes, snacks and other bakery uses (Euromaisiers, 2015).

Euromaisiers (2013) reports that around 800,000 million tonnes were produced by the dry milling industry in the EU in 2013. Around 36 per cent of the mill was transformed in brewers' grits, 32 per cent in corn grits, 19 per cent in flaking grits and 13 per cent in maize flour. Figure 14 gives an overview of the dry milling supply chain for maize.

[70] *Bacillus thuringiensis*

[71] The total maize supply is made of beginning stocks, total maize production and total imports, representing 5,147 million tonnes, 64,675 million tonnes and 15,919 million tonnes respectively in 2013-2014.

Figure 14. Dry milling process



Source: Euromaisiers, 2015

A4.3.5 Market outlook and forecasts

In 2016, production of maize is expected to remain steady at around 68 million tonnes (DG AGRI, 2015). According to the Short Term Outlook issued by the European Commission, imports are expected to reach below average levels in 2015-2016, at around 8.5 million tonnes (DG AGRI, 2015). By contrast, Knight (2015) presents a rather more bullish view of imports, predicting they will reach 12 million tonnes as a result of

sustained demand from the animal feed sector and anticipated increased imports from Ukraine under the duty free quota.

A4.4 Impact assessments conducted by the industry regarding the impacts of asynchronous and obsolete GM material in food

For EU food businesses importing agricultural commodities from third countries, the EU's zero tolerance policy implies that consignments that test positive for GM must be rejected. According to the business representatives, the main issue with the current situation relates to the lack of a 'technical zero' for food.

According to the European association representing the trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agrosupply (COCERAL) the growing adoption of biotechnology in third countries exporting to the EU increases the risk of contamination. In the past, LLP incidents caused significant trade disruptions. For example, COCERAL reported that in 2012 asynchronous GMO material (MIR 162) was detected in feed commodities from the US (namely, corn gluten feed and dry distiller's grains). Following the LLP incident, monthly EU imports of these products from the US decreased from 285,000 tonnes in September 2011 to 25,000 tonnes in February 2012 (Vogel, 2014; Babuscio, 2014). According to COCERAL, similar trade disruption effects would occur for LLP incidents involving asynchronous GMO food (Vogel, 2014).

The association of Primary Food Processors (PFP) also highlighted the need to extend to food products the 'technical solution' adopted for feed (PFP, 2011). In the absence of such a solution, food business operators face the risk of not being able to sell imported products on the EU market due to LLP incidents. As reported by the PFP, supply disruptions are likely to cause significant damage to the industry, due to the large number of food applications involving the use of products such as soy proteins and soy-based ingredients.

The European Vegetable Protein Industry Association (EUVEPRO) conducted an impact assessment regarding the absence of a technical solution for the LLP incidents affecting food imports (EUVEPRO, 2011). According to the impact assessment, the impacts of the lack of a MRPL for food may vary depending on different situations:

- When LLP of asynchronous GM material below the 0.1 limit is identified at the arrival of a shipment in the EU, this means that the shipment (initially intended for food consumption) can be sold instead as feed, as it complies with Regulation (EU) No 619/2011. The costs incurred by food business operators to 'downgrade' the shipment to feed are estimated at €63,000 per shipment. The presence of a MRPL of 0.1 for food could avoid these costs.
- When asynchronous GM material is found to be above the 0.1 limit at arrival of a shipment in the EU, this means that the shipment needs to either be destroyed (although this option is expensive and therefore less likely) or sent to a non-EU market where the GM material is authorised (or where requirements for the placing on the market of GM food are less strict than EU requirements).

The EU Vegetable Oil and Proteinmeal Industry Association (FEDIOL) also conducted an assessment of the absence of a technical solution for food. FEDIOL's assessment (FEDIOL, 2011a) focusses on the implications for EU food crushers of detecting asynchronous GM content below the 0.1 limit in soybean intended for food production. Three different scenarios are assessed, as summarised in Table 15. FEDIOL concluded that the absence of a technical solution imposes a significant cost on EU-based crushers: the lack of certainty makes crushing operations 'too risky and therefore economically unviable'. Soybean crushing operations may therefore be transferred outside the EU.

Table 15. Low level presence GM events not yet authorized in the EU: impacts on the EU vegetable oil industry resulting from the absence of a technical solution applicable to food

Scenario	Impact
Scenario 1: Isolated case of asynchronous GMO falling under the 0.1 MRPL for feed, detected before crushing	The impact assessment assumes the presence of an EU-based soybean crusher receiving shipments of soybeans of 55,000 tons per shipment. The assessment also assumes that the crusher has a contract to sell 4,400 tons of the soybean oil derived from crushing to businesses involved in food production. Once an LLP case is detected in his cargo the crusher will have to: Find alternative supplies of 4,400 tons of oil to supply the food client; and Sell the 4,400 tons of soybean oil which is non-food compliant for feed or technical use. The price difference between the purchase price of food compliant oil and the sales price of non-food compliant oil for feed or technical use is between €50 and €60 per metric ton. The consequential additional cost for the EU soybean crusher ranges between €220,000 and €264,000. This will reduce significantly the crushing margin[72] and may lead to the decision of stop crushing.
Scenario 2: Isolated case of asynchronous GMO falling under the 0.1 MRPL for feed, detected after crushing	There could be two cases: The food customer has not yet processed the uncompliant soybean oil into a food product: in this case, the costs of transport, cleaning and replacement can total between €484,000 and €528,000. The refined soybean oil has already been processed into a food product: in this case, the final products have to be recalled. The crusher will have to bear the costs of compensation, which can amount to about €15 million. If the crusher had known of the loss, the operator would have stopped the crushing activity.
Scenario 3: Re-occurring case of asynchronous GMO falling under the 0.1 MRPL for feed	In the absence of a food technical solution and in the absence of viable alternatives to food application sales of soybean oil in the EU, crushers may be forced to stop crushing soybeans due to low crushing margins.

Source: FEDIOL, 2011a

[72] Defined by FEDIOL as the revenue from oil plus the revenue from meal minus the costs for beans.

Annex 5 Aggregated data from survey responses and interviews

This annex provides aggregated data from the results of the stakeholder consultation undertaken for this study. The annex is structured as follows: section A5.1 provides data on issues faced by NCAs regarding the lack of harmonisation of sampling and analysis protocols, and section A5.2 provides data on the perspectives of FBOs on market impacts. Data regarding issues for consumers are presented in section 3.3.

Details on the stakeholders consulted and research methods used are provided in Annex 3.

A5.1 Lack of harmonisation of methods of sampling and analysis for the official control of asynchronous and obsolete GMOs and setting of a MRPL

Table 16. Member States testing for presence of asynchronous and obsolete GM material in food

Member State	Test food samples for the presence of asynchronous and obsolete GM material
AT	✓
BE	✓
BG	×
CY	✓
CZ	✓
DE	✓
DK	✓
EE	✓
EL	✓
ES	×
FI	✓
FR	✓
HR	✓
HU	✓
IE	✓
IT	✓
LT	✓
LU	✓
LV	✓
MT	✓
NL	✓
PL	✓
PT	✓

RO	✓
SE	×
SI	✓
SK	✓
UK	✓
Total	**25**

Source: ICF analysis of survey and case study responses (N=28 Member States)

Table 17. Number of GM samples taken in each Member State per annum

MS	Number of samples tested for the presence of asynchronous and obsolete GM material						Total number of samples tested for the presence of GM material						Proportion of samples collected for GMO analysis that was tested for the presence of asynchronous and obsolete GM material					
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
AT	TDS	TDS	TDS	TDS	TDS	TDS	NR	18	19	13	10	12	-	-	-	-	-	-
BE	TDS	TDS	TDS	TDS	TDS	TDS	155	117	220	240	213	236	-	-	-	-	-	-
BG	DNT	DNT	DNT	DNT	DNT	DNT	NR	NR	89	100	100	127	-	-	-	-	-	-
CY	1	3	2	0	0	0	165	174	254	214	209	131	1%	2%	1%	0%	0%	0%
CZ	NR	NR	NR	54	40	40	215	163	97	54	40	40	-	-	-	100%	100%	100%
DE[73]	NR (1461)	NR (1336)	NR (1227)	NR (1250)	NR (956)	NR (1147)	NR (3040)	NR (2914)	Est 5000 (2839)	Est 5000 (2740)	Est 5000 (2201)	Est 5000 (2279)	(48%)	(46%)	(43%)	(46%)	(43%)	(50%)
DK	28	26	40	43	51	40	28	26	40	43	51	40	100%	100%	100%	100%	100%	100%
EE	0	0	0	0	1	0	20	20	10	2	12	17	0%	0%	0%	0%	8%	0%
EL	40	42	30	31	29	29	120	163	126	128	106	140	33%	26%	24%	24%	27%	21%
ES	DNT	DNT	DNT	DNT	DNT	DNT	NR	NR	NR	NR	NR	NR	-	-	-	-	-	-
FI	148	171	137	152	188	187	148	171	137	152	188	187	100%	100%	100%	100%	100%	100%
FR	61	88	74	49	66	60	95	92	81	72	96	94	64%	96%	91%	68%	69%	64%
HR	253	-	108	108	108	145	253	108	108	108	108	145	100%	-	100%	100%	100%	100%
HU	78	98	103	154	96	142	255	361	354	460	275	378	31%	27%	29%	33%	35%	38%

[73] The figures for the total number food samples collected in Germany for GMO analysis are based on estimates provided by the federal ministry (Federal Office of Consumer Protection and Food Safety) for the years 2011 to 2014. National figures were not provided by the central ministry for samples collected to test for presence of asynchronous and obsolete GM events. The figures in parentheses indicate aggregated responses from CAs in seven out of 16 state governments (Länder) who also individually responded to the survey. The aggregated responses from five CAs in the Länder which provided data on the number of samples specifically tested for the presence of asynchronous and obsolete GM material are used as a basis for percentage calculations. CAs in two Länder also specified that asynchronous and obsolete materials were not specifically tested and were included in figures for the total number of samples collected for GMO analysis.

MS	Number of samples tested for the presence of asynchronous and obsolete GM material						Total number of samples tested for the presence of GM material						Proportion of samples collected for GMO analysis that was tested for the presence of asynchronous and obsolete GM material					
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
IE	TDS	TDS	TDS	TDS	TDS	TDS	65	63	58	46	55	45	-	-	-	-	-	-
IT	TDS	TDS	TDS	TDS	TDS	TDS	1038	1021	935	909	1005	905	-	-	-	-	-	-
LT	48	42	38	21	26	14	219	145	143	167	171	225	22%	29%	27%	13%	15%	6%
LU	65	71	NR	41	34	43	135	150	NR	130	110	125	48%	47%		32%	31%	34%
LV	TDS	TDS	TDS	TDS	TDS	TDS	NR	NR	NR	NR	NR	NR	-	-	-	-	-	-
MT	11	NR	NR	NR	10	NR	11	NR	NR	NR	10	NR	100%	-	-	-	-	100%
NL	0	0	0	0	0	0	136	137	69	86	222	240	0%	0%	0%	0%	0%	0%
PL	TDS	TDS	TDS	TDS	TDS	TDS	614	633	597	625	588	606	-	-	-	-	-	-
PT	TDS	TDS	TDS	TDS	TDS	TDS	4	15	27	NR	65	31	-	-	-	-	-	-
RO	TDS	TDS	TDS	TDS	TDS	TDS	NR	NR	620	654	793	632	-	-	-	-	-	-
SE	DNT	DNT	DNT	DNT	DNT	DNT	39	16	16	14	10	8	0%	0%	0%	0%	0%	0%
SI	16	10	10	4	39	21	97	62	30	20	100	75	16%	16%	33%	20%	39%	28%
SK	TDS	TDS	TDS	TDS	TDS	TDS	329	239	190	175	210	159	-	-	-	-	-	-
UK[74]	NR	NR	NR	50	50	50	NR	NR	NR	50	50	50	-	-	-	100%	100%	100%
Total[75]	**789**	**593**	**572**	**738**	**767**	**800**	**7,181**	**6,808**	**9,220**	**9,462**	**9,797**	**9,648**	-	-	-	-	-	-

TDS = Member State tests for the presence of asynchronous and obsolete GM events but did not provide specific data on number of samples tested, DNT = Member State does not test for the presence of asynchronous and obsolete GM events, NR = No response

Source: ICF analysis of survey and case study responses (N=28 Member States)

[74] Sampling figures for UK are not national-level data. The response is solely in relation to point of import sampling at the border and predominantly in relation to GM legislative controls for rice and rice products from China.

[75] Totals reflect Länder data for Germany where centralised national estimates were not provided.

Table 18. Stage of supply chain where samples are taken to be tested for the presence of asynchronous and obsolete GM material in food

MS	Stage of supply chain at which sampling is carried out for the official control of asynchronous and obsolete GM material in food			
	Border inspection posts	**Wholesaler premises**	**Retail premises**	**Other**
AT	✓		✓	✓**
BE	✓	✓	✓	
BG	DNT	DNT	DNT	DNT
CY	✓	✓	✓	
CZ	✓	✓	✓	
DE	✓ (NCA; 1 Land CA)	✓ (NCA; 4 Länder CA)	✓ (NCA; 5 Länder CA)	✓ (3 Länder CA)**
DK		✓		
EE	✓	✓	✓	✓**
EL	✓			
ES	DNT	DNT	DNT	DNT
FI[76]	✓ (NCA)	✓ (NCA)	✓ (NCA)	✓***
FR		✓	✓	
HR	✓	✓	✓	
HU	✓	✓	✓	✓**
IE	✓		✓	

[76] Information for Finland was integrated from survey responses from two national competent authorities – Finnish Customs Laboratory and the Finnish Food Safety Authority – which share responsibilities for sampling at different points along the supply chain.

MS	Stage of supply chain at which sampling is carried out for the official control of asynchronous and obsolete GM material in food			
	Border inspection posts	**Wholesaler premises**	**Retail premises**	**Other**
IT	✓	✓	✓	
LT	✓	✓		
LU			✓	
LV	DNP	DNP	DNP	DNP
MT			✓	
NL	✓		✓	
PL				✓**
PT	✓			
RO		✓	✓	✓**, ***
SE	DNT	DNT	DNT	DNT
SI			✓	
SK	✓	✓	✓	
UK	✓			
Total NCAs/CAs	**18 (17 MS)**	**18 (14 MS)**	**23 (18 MS)**	**9 (7 MS)**

** Only deal with authorised or unauthorised GMOs; ** Food producer / manufacturer premises; *** Storehouses/warehouses*

Blank cells indicate where respective options within a question were not selected.

DNP = did not participate in the consultation, DNT = Member State does not test for the presence of asynchronous and obsolete GM events, NR = No response (to entire question)

Source: ICF analysis of survey and case study responses (N = 25 Member States where official testing of asynchronous/obsolete GMOs was conducted between 2009 and 2014)

Table 19. Protocols used for static and dynamic sampling when carrying out official controls regarding asynchronous and obsolete GM material in food on lots of bulk agricultural commodities

MS	Section IV, Article 2(1) of Recommendation 787/2004: protocol for static sampling	Section IV, Article 2(1) of Recommendation 787/2004: protocol for dynamic sampling	Other
AT			Domestic protocols and procedural instructions are used. These protocols are in line with Recommendation 2004/787/EC.
BE			There are no specific sampling protocols for asynchronous and obsolete GM material in food. A domestic protocol for GMO sampling is adopted; this protocol is described in a technical information form provided by the NCA to food inspectors in charge of sampling. Protocols used vary depending on the product to be analysed. These protocols do not always take into account the heterogeneous distribution of GMOs in the food lot.
BG	DNT	DNT	DNT
CY	✓	✓	
CZ	✓	✓	
DE	✓ (NCA; 1 Land CA)	✓ (5 Länder CA)	Other protocols used include[77]: TS15568 EN ISO 542 EN ISO 13690
DK	✓	✓	
EE	✓	✓	
EL	✓	✓	

[77] Federal guidelines on sampling protocols can be found in the sample collection scheme - unauthorized GMOs (ALS Recommendations 2008). See: http://www.bvl.bund.de/EN/06_Genetic_Engineering/08_Detection/02_Sampling/genetic_engineering_detection_Sampling_node.html

MS	Section IV, Article 2(1) of Recommendation 787/2004: protocol for static sampling	Section IV, Article 2(1) of Recommendation 787/2004: protocol for dynamic sampling	Other
ES	DNT	DNT	DNT
FI	✓	✓	
FR	✓		
HR	✓	✓	
HU	✓	✓	
IE	NR	NR	NR
IT	✓	✓	Regulations 401/2006 and Amendments Specific guidelines of the Italian National Health Institute.
LT	✓	✓	
LU			No sampling of bulk commodities is conducted
LV	DNP	DNP	DNP
MT	NR	NR	NR
NL			In case of prior knowledge about a particular shipment or product, targeted sampling and analysis will be deployed. For example, in the case of Chinese rice, on arrival in the port the containers are unloaded and a scheme designed for sampling for mycotoxins is applied. Also sampling methods used for other food contaminants can be applied to GMO sampling.
PL	NR	NR	NR
PT	✓		
RO	✓	✓	
SE	DNT	DNT	DNT
SI	NR	NR	NR
SK	✓		
UK	✓		

MS	Section IV, Article 2(1) of Recommendation 787/2004: protocol for static sampling	Section IV, Article 2(1) of Recommendation 787/2004: protocol for dynamic sampling	Other
Total NCAs/ CAs	**17 (16 MS)**	**16 (12 MS)**	**6 (5 MS)**

Blank cells indicate where respective options within a question were not selected.

DNP = did not participate in the consultation, DNT = Member State does not test for the presence of asynchronous and obsolete GM events, NR = No response (to entire question)

Source: ICF analysis of survey and case study responses (N = 25 Member States where official testing of asynchronous/obsolete GMOs was conducted between 2009 and 2014)

Table 20. Sampling methods - results from case studies

MS	Protocol used for sampling and analysis of asynchronous and obsolete GM material	Description of the protocol and reference to EU and international guidance	Main factors influencing the choice of protocol
AT	Austria has implemented a harmonised quality management system in food control, which includes specific procedural instructions, protocols, and regulations for sampling for GMO material.	National guidelines and protocols are applied. Protocols were developed in line with Recommendation 2004/787/EC.	The sampling process and sizes of sampled portions depend on the nature of the lot (e.g. packaged, loose, liquid; from products individually packaged for retail, or from large lots).
BE	There are no specific sampling protocols for asynchronous and obsolete GM material in food. An overall protocol for GMO sampling is described in the technical information form provided by the NCA to food inspectors in charge of sampling.	Different protocols exist for pre-packaged food and for bulk commodities. For pre-packaged food, the technical information form describes the quantity to be collected for the sample. For the sampling of rice, the Commission Recommendation 2004/787/EC concerning the controls to ensure compliance with Regulation (EC) No 1830/2003[78] is followed. For other cereals, the officer doing the sampling is responsible to ensure representativeness of the sample. EU rules on sampling regarding mycotoxins (Commission Regulation (EC) No 401/2006) may be used as a guidance.	Due to the analytical difficulties of detecting GMOs in highly processed products, official controls for the presence of GM material in Belgium focus on raw materials and lightly processed food. The species covered by official controls include maize, soybean and rice. Inspectors have the responsibility to ensure the representativeness of the sample collected.
DE	Protocols for sampling are harmonised across the 16 Länder	In 2007, the ALS established and published sampling protocols for GMO detection in food. The	The main factor influencing the choice of protocol is the state of the food, e.g. if

[78] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

MS	Protocol used for sampling and analysis of asynchronous and obsolete GM material	Description of the protocol and reference to EU and international guidance	Main factors influencing the choice of protocol
	through the protocols developed by the Working Group of Experts in Food Chemistry (ALS).	protocols were based on EU Recommendation 2004/787/EC, draft standard prCEN/TS 21568:2005, and standards EN ISO 542 and 13690. An additional protocol set for sampling in case of suspected contamination with unauthorised GMO material was published in 2008. These protocols were adapted from Decision 2006/754/EC[79] (11/2006); Recommendation 2004/787/EC; CEN/TS 15568; EN ISO 542; and EN ISO 13690. Both sets of sampling protocols are for bulk consignments and for packaged food products. A simplified protocol based on the bulk protocols is used.	packaged or not packaged, in sacks, big packs, or bulk, and the type of packaging, e.g. cartons (also depending on size of individual package). This determines how many units and how much of each unit is tested.
ES	Autonomous Communities in Spain adopt a sampling protocol for authorised GMOs; there are no specific protocols for asynchronous and obsolete GM material.	Sampling should be based on Recommendation 2004/787/EC.	No details provided.
FR	There are no specific protocols for asynchronous and obsolete GMOs. A protocol for official controls regarding cereals is applied.	The protocol for static sampling is based on Recommendation 2004/787/EC. The NCAs did not have experience of undertaking dynamic sampling for asynchronous and obsolete GMOs. It was explained that, while Recommendation 2004/787/EC offers a good framework to ensure the representativeness of the samples collected, in	Different protocols are in place depending on the type of food product inspected (for example, there is a protocol for cereals) and the degree of heterogeneity of the substance investigated.

[79] Commission Decision of 6 November 2006 amending Decision 2006/601/EC on emergency measures regarding the non-authorised genetically modified organism 'LL RICE 601' in rice products.

MS	Protocol used for sampling and analysis of asynchronous and obsolete GM material	Description of the protocol and reference to EU and international guidance	Main factors influencing the choice of protocol
		practice it is sometimes difficult to follow the recommendation. The main issues relate to the time and efforts required to collect the number of samples required.	
HU	There is no specific protocol for asynchronous and obsolete GM materials. National guidelines for GMO sampling are used.	The national sampling guidelines are based on different EU rules and recommendations: The quantities of samples to be collected are defined according to Recommendation 2004/787/EC in respect of bulk goods (crops, oily seeds), and according to Regulation 401/2006/EC regarding packaged goods. The sampling of bulk goods is carried out according to ISO 6644 (for dynamic sampling) and ISO 13690 (for static sampling) principles. Sampling of packaged products weighing less than 3kg are carried out according to Regulation (EC) 401/2006, because in such cases the occurrence of GMOs is similar to mycotoxins and this also helps minimising costs.	There are separate guidelines on how to take samples from bulk and packaged goods (number/weight of samples).
NL	The Netherlands Food and Consumer Product Safety Authority (NVWA) applies a general sampling strategy for sampling products on the implementation of GMO labelling requirements and the presence of asynchronous and obsolete material at the same time. There	In case of prior knowledge about a particular shipment or product, targeted sampling and analysis will be deployed. For example, in the case of Chinese rice, on arrival in the port the containers are unloaded and a scheme designed for sampling for mycotoxins is applied. Mycotoxins usually have a pattern of contamination (concentrated spots) similar to that of GMOs. For this reason samples taken for controls on the presence of mycotoxins	The NVWA takes 70-240 at random samples per year from products containing maize, soya and rice in grocery stores and retail business. Bulk agricultural commodities (grains, oilseeds, meal) are not sampled and tested by the NVWA.

MS	Protocol used for sampling and analysis of asynchronous and obsolete GM material	Description of the protocol and reference to EU and international guidance	Main factors influencing the choice of protocol
	is no separate sampling protocol for asynchronous or obsolete GM material.	are sometimes used for GMO analysis. Also sampling methods used for other food contaminants can be applied.	

Source: case study interviews with NCAs

Table 21. Protocols used to establish the number and size of incremental samples and size of the bulk sample for lots of bulk agricultural commodities

MS	Section IV, Art. 2(1) Recommendation 787/2004 – protocol to establish the number of incremental samples	Section IV, Art. 2(1) Recommendation 787/2004 – protocol to establish the size of the bulk sample	Annex I Reg. (EC) No. 152/2009 – protocol to establish the number of incremental samples	Annex I Reg. (EC) No. 152/2009 – protocol to establish size of the bulk sample	Annex I Reg. (EC) No 401/2006 – protocol to establish the number of incremental samples	Annex I Reg. (EC) No 401/2006 – protocol to establish size of the bulk sample	Annex I Reg. (EC) No 619/2011 – protocol to establish size of the bulk sample	Other
AT	✓	✓						
BE								Domestic protocol: for grains, for example, a total quantity of one kilogram should be collected.
BG	DNT	DNT	DNT	DNT	DNT	DNT	DNT	DNT
CY	✓	✓	✓	✓				
CZ	✓	✓	✓	✓	✓	✓	✓	

MS	Section IV, Art. 2(1) Recommendation 787/2004 – protocol to establish the number of incremental samples	Section IV, Art. 2(1) Recommendation 787/2004 – protocol to establish the size of the bulk sample	Annex I Reg. (EC) No. 152/2009 – protocol to establish the number of incremental samples	Annex I Reg. (EC) No. 152/2009 – protocol to establish size of the bulk sample	Annex I Reg. (EC) No 401/2006 – protocol to establish the number of incremental samples	Annex I Reg. (EC) No 401/2006 – protocol to establish size of the bulk sample	Annex I Reg. (EC) No 619/2011 – protocol to establish size of the bulk sample	Other
DE*	✓ (NCA; 1 Land CA)	✓ (NCA; 1 Land CA)						CEN TS15568 EN ISO 542 EN ISO 13190[80]
DK	✓	✓	✓	✓	✓	✓	✓	
EE	✓	✓						
EL	✓	✓						Automatic sampling by mechanical means for cereals
ES	DNT	DNT	DNT	DNT	DNT	DNT	DNT	DNT
FI	NR	NR	NR	NR	NR	NR	NR	
FR	✓	✓						
HR	✓	✓			✓	✓		EN ISO 6644, EN ISO 13690, EN ISO 542
HU	✓	✓						
IE								

[80] Ibid

MS	Section IV, Art. 2(1) Recommendation 787/2004 – protocol to establish the number of incremental samples	Section IV, Art. 2(1) Recommendation 787/2004 – protocol to establish the size of the bulk sample	Annex I Reg. (EC) No. 152/2009 – protocol to establish the number of incremental samples	Annex I Reg. (EC) No. 152/2009 – protocol to establish size of the bulk sample	Annex I Reg. (EC) No 401/2006 – protocol to establish the number of incremental samples	Annex I Reg. (EC) No 401/2006 – protocol to establish size of the bulk sample	Annex I Reg. (EC) No 619/2011 – protocol to establish size of the bulk sample	Other
IT	✓	✓			✓	✓		Regulation (EC) No 519/2014[81]
LT	✓	✓	✓	✓	✓	✓	✓	
LV	DNP	DNP	DNP	DNP	DNP	DNP	DNP	DNP
LU	NR	NR	NR	NR	NR	NR	NR	
MT	NR	NR	NR	NR	NR	NR	NR	
NL	NR	NR	NR	NR	NR	NR	NR	
PL	NR	NR	NR	NR	NR	NR	NR	
PT		✓				✓		
RO	✓	✓					✓	
SE	DNT	DNT	DNT	DNT	DNT	DNT	DNT	DNT
SI	NR	NR	NR	NR	NR	NR	NR	
SK	✓	✓	✓	✓	✓	✓	✓	

[81] Commission Regulation (EU) No 519/2014 of 16 May 2014 amending Regulation (EC) No 401/2006 as regards methods of sampling of large lots, spices and food supplements, performance criteria for T-2, HT-2 toxin and citrinin and screening methods of analysis Text with EEA relevance.

MS	Section IV, Art. 2(1) Recommendation 787/2004 – protocol to establish the number of incremental samples	Section IV, Art. 2(1) Recommendation 787/2004 – protocol to establish the size of the bulk sample	Annex I Reg. (EC) No. 152/2009 – protocol to establish the number of incremental samples	Annex I Reg. (EC) No. 152/2009 – protocol to establish size of the bulk sample	Annex I Reg. (EC) No 401/2006 – protocol to establish the number of incremental samples	Annex I Reg. (EC) No 401/2006 – protocol to establish size of the bulk sample	Annex I Reg. (EC) No 619/2011 – protocol to establish size of the bulk sample	Other
UK	✓	✓						
Total NCAs/CAs	**16 (15 MS)**	**17 (16 MS)**	**5 (5 MS)**	**5 (5 MS)**	**6 (6 MS)**	**7 (7 MS)**	**5 (5 MS)**	**5 (5 MS)**

Blank cells indicate where respective options within a question were not selected.

DNP = did not participate in the consultation, DNT = Member State does not test for the presence of asynchronous and obsolete GM events, NR = No response (to entire question)

Source: ICF analysis of survey and case study responses

Table 22. Protocols used for sampling packaged food products

MS	ISO 2859	CEN/TS 15568	National / domestic protocols	EC Regulations / Recommendations	Other	Detail
AT			✓			
BE			✓			
BG	DNT	DNT	DNT	DNT	DNT	DNT
CY			✓			The sampling of packaged food products is based on the Food (Control and Sale) Law of 1996 to 2013 (National Law). Based on the provisions of this law, each sample comprises three sub-samples (of the same product). The first sub-sample (laboratory sample) is submitted to the State General Laboratory for the necessary laboratory analysis, the second sub-sample (defence sample) is given to the food business operator responsible for the product and the third sub-sample (reference sample) is kept by the Public Health Services.
CZ		✓				
DE[82]		✓ (NSA; 1 Land CSA)	✓ (NSA; 2 CSAs)	✓ (CSA)	✓: ISO 542; EN ISO 13190 (NSA, CSA)	Individual Länder responses: i. Commission Decision 2006/754/EC, Recommendation 2004/787/EC, CEN/TS 15568 (3/2007), EN ISO 542 (4/1995), EN ISO 13190 (1999) (response provided by one CSA). ii. See German "Probenahmeschema Gentechnik (2007/42)" and "Probenahmeschema Gentechnik - nicht zugelassene GVO (2008/49)" from ALS[83] (2 CSAs). iii. Authorized and non-authorized GMO sampling plans by BVL;

[82] Data for Germany reflects responses received from four Länder and the central competent authority at federal level (BVL).

[83] Federal guidelines on sampling protocols can be found in the sample collection scheme - unauthorized GMOs (ALS Recommendations 2008). See: http://www.bvl.bund.de/EN/06_Genetic_Engineering/08_Detection/02_Sampling/genetic_engineering_detection_Sampling_node.html

MS	ISO 2859	CEN/TS 15568	National / domestic protocols	EC Regulations / Recommendations	Other	Detail
						ASU § 64 LFGB L 00.00-117 (http://www.methodensammlung-bvl.de/) (CSA). iv. EN ISO 542, EN ISO 13190; sample collection scheme - unauthorized GMOs (ALS Recommendations 2008) (NSA).
DK				✓		Annex I of Regulation (EC) No 401/2006 – protocol to establish the size of the bulk sample.
EE	✓					
ES	DNT	DNT	DNT	DNT	DNT	DNT
EL[84]	✓ (NS)		✓ (NS)	✓ (NS)	✓: ISO 24333:2009 (NS)	Sampling sites: according to article 15 of Regulation (EC) No 882/2004 Sampling: according to "Code of Foodstuffs, Beverages and Objects of Common Use" of Greece Sampling for rice products from China: according to Annex II of Commission Implementing Decision 2011/884/EU ISO 13690 revised by: ISO 24333:2009 for sampling in warehouses ISO 2859 sampling procedures for big packages
FI[85]			✓ (NSA; NS)			i. In-house method (minimum 3 packages/lot or batch) (NSA). ii. Packaged food samples are taken from unbroken packages, while making sure that they are from the same lot. Normally three packages are taken but if packages are very small, like chocolate bars, six samples are collected (NS).

[84] Data for Greece reflects responses from two NCAs.

[85] Data based on responses from two NCAs responsible for food sampling in Finland.

MS	ISO 2859	CEN/TS 15568	National / domestic protocols	EC Regulations / Recommendations	Other	Detail
FR		✓				When possible, the CEN/TS 15568 protocol is used. However, the number of samples can be adapted in consideration of the following elements: The heterogeneity of distribution of GMOs in the lot: in the case of grains, it can be assumed that GMOs distribution is heterogeneous, while in processed food the distribution is homogenous. Opened packages cannot be sold. Therefore sampling should consider the possibility to ensure representativeness of the sample while minimising the number of packages to be opened. Some samples are collected at retail stages, where generally only few other units from the same food lot can be identified.
HR			✓			Laboratory Recommendation.
HU				✓		Based on Regulation (EC) No 401/2006. Number of packages or units in the lot: number of packages or units to be taken 1 to 25: 1 package or unit; 26 to 100: about 5 %, at least two packages or units; and > 100: about 5 %, at maximum 10 packages or units.
IE			✓			Random sampling of prepacked foods is carried out.
IT		✓		✓		Regulation (EC) No 401/2006 or UNI CEN/TS 15568 rule.
LT	NR	NR	NR	NR	NR	
LV	DNP	DNP	DNP	DNP	DNP	DNP
LU			✓			Selective sampling with samples of minimum 1.2 kilograms.

MS	ISO 2859	CEN/TS 15568	National / domestic protocols	EC Regulations / Recommendations	Other	Detail
MT				✓		In 2009, Recommendation 787/2004 was used.
NL			✓			Take a least two packages with a minimum amount of 500 grams. When required by legislation (for instance, in the case of Chinese rice products) special sampling protocols are used, mainly based on mycotoxin.
PL	✓					
PT				✓		Recommendation 787/2004 and Regulation (EU) No 401/2006.
RO	NR	NR	NR	NR	NR	
SE	DNT	DNT	DNT	DNT	DNT	DNT
SI			✓			Internal instructions have been prepared which detail the minimum amount of laboratory sample to be collected.
SK		✓				
UK[86]			✓			Sampling in accordance with CEN/TS 15568:2007 as specified in 2013/287/EU has yet to be fully implemented. We have therefore previously taken 5 incremental samples of 500g each.
Total NCAs /CAs	**3 (3 MS)**	**5 (5 MS)**	**12 (11 MS)**	**6 (6 MS)**	**2 (2 MS)**	

Blank cells indicate where respective options within a question were not selected.

DNP = did not participate in the consultation, DNT = Member State does not test for the presence of asynchronous and obsolete GM events, NR = No response (to entire question)

Source: ICF analysis of survey and case study responses

[86] UK did not provide a national level response. Data received from a sub-national Port Health Authority.

Table 23. Does the lack of harmonisation of food sampling procedures have any impact on the reproducibility of testing results within your Member State and/or between Member States?

MS	The lack of harmonisation impacts on the reproducibility of testing results within my MS	The lack of harmonisation impacts on the reproducibility of testing results between MSs	The lack of harmonisation does not impact on the reproducibility of testing results	Did not respond	Total respondents per MS
AT			✓ (NS)		1
BE	✓(NS)	✓ (NS)	✓ (NA)		2
BG		✓ (NS)			1
CY			✓ (NSA)		1
CZ		✓ (NS)			1
DE	✓ (CSA)	✓ (NS; CSA)	✓ (3 CSA)	✓ (CSA; SA)	8
DK			✓ (NS)		1
EE			✓ (NS)		1
EL[87]		✓ (NS)		✓ (NS)	2
ES		✓ (NSA)			1
FI		✓ (NSA; NS)			2
FR			✓ (NS)		1
HR		✓ (NS)			1
HU		✓ (NS)			1
IE			✓ (NSA)		1

[87] There are two NCAs responsible for sampling in Greece.

MS	The lack of harmonisation impacts on the reproducibility of testing results within my MS	The lack of harmonisation impacts on the reproducibility of testing results between MSs	The lack of harmonisation does not impact on the reproducibility of testing results	Did not respond	Total respondents per MS
IT		✓ (NS)			1
LT		✓ (NSA)			1
LU			✓ (NS)		1
LV	DNP	DNP	DNP	DNP	DNP
MT		✓ (NS)			1
NL		✓ (NSA)			1
PL				✓ (NS)	1
PT				✓ (NS)	1
RO			✓ (NS)		1
SE			✓ (NSA)		1
SI			✓ (NS)		1
SK			✓ (NS)		1
UK	✓ (CS)				1
Total NCAs/ CAs	**3 (3 MS)**	**15 (13 MS)**	**15 (13 MS)**	**5 (4 MS)**	**37 (27 MS)**

NS = NCA only responsible for sampling, NA = NCA only responsible for analysis, NSA = NCA responsible for both sampling and analysis, CS = Regional CA only responsible for sampling, CA = Regional CA only responsible for analysis, CSA = Regional CA responsible for both sampling and analysis.

DNP = did not participate in the consultation

Source: ICF analysis of survey and case study responses

Table 24. Harmonisation of sampling methods - results from case studies

MS	Does the lack of harmonisation of food sampling procedures have any impact on the reproducibility of test results within your Member State and/or between Member States?	Possible benefits and negative impacts from the harmonisation of sampling protocols	Any experiences of impacts
AT	A harmonised protocol is established by the food inspectorates' quality management system, and therefore there are no impacts within Austria. Regarding potential impacts between Member States, the inspector consulted was not aware of any issues / examples.	**Benefits**: consultees agreed that harmonisation of sampling and analysis protocols would support cross-border legal compliance. **No negative impacts** were identified by consultees.	Consultees did not have experiences of impacts from the lack of harmonisation.
BE	Although a harmonised method of sampling is established in the technical information form provided to Belgian inspectors, consultees highlighted that the lack of harmonisation of sampling protocols (within Member States and between Member States) could still be a problem. The main issue highlighted was that the sampling method does not take into account the heterogeneous distribution of GMOs in the food lot.	**Benefits**: harmonisation of sampling is seen as potentially helpful, particularly through the introduction of methods that would allow for the collection of samples that are more representative of the food lot. This could help addressing the issues arising from the non-homogenous distribution of GMOs in food lots. **No negative impacts** were identified by consultees.	Consultees did not have experiences of impacts from the lack of harmonisation.
DE	There was no consensus – some consultees indicated that the lack of harmonisation in sampling protocols had no impact on the reproducibility of results, while others felt there was an impact.	**Benefits**: in very general terms, any harmonisation of methods across Member States and laboratories is seen as positive, as it increases the comparability and consistency of test results. **No negative impacts** were identified by consultees.	The lack of harmonisation impacted on the reproducibility of results for the analyses of the 2006 LL601 rice case, and the Flax FP967 case (both

MS	Does the lack of harmonisation of food sampling procedures have any impact on the reproducibility of test results within your Member State and/or between Member States?	Possible benefits and negative impacts from the harmonisation of sampling protocols	Any experiences of impacts
			asymmetric GMOs)[88].
ES	The lack of harmonisation of food sampling procedures impacts on the reproducibility of test results.	**Benefits**: harmonisation at EU level could enhance the detection of fraudulent practices **No negative impacts** were identified by consultees.	Consultees did not have experience of impacts from the lack of harmonisation.
FR	There are no impacts from the lack of harmonisation.	**Benefits**: in a framework for the overall harmonisation of procedures for the implementation of official controls, harmonisation of sampling can only provide beneficial effects. However, it was felt that the harmonisation of rules regarding asynchronous and obsolete GM material in food does not have the primary objective of addressing sampling issues, but rather of introducing a harmonised MRPL at EU level. **Negative impacts**: the harmonisation of sampling rules could have negative effects in the case that harmonised rules are too burdensome to be implemented by officials. In the case of inadequate protocols, officials may not be able to follow the harmonised rules, and this would increase the probability that food business operators may challenge the decisions made by NCAs on compliance. Additionally, harmonised rules will need to consider the different practices	Consultees did not have experiences of impacts from the lack of harmonisation.

[88] These are cases of asymmetric GMOs, that are different from asynchronous and obsolete GMOs (see definitions in Section 1.2). However, similar impacts could also concern asynchronous and obsolete GMOs.

MS	Does the lack of harmonisation of food sampling procedures have any impact on the reproducibility of test results within your Member State and/or between Member States?	Possible benefits and negative impacts from the harmonisation of sampling protocols	Any experiences of impacts
		in place along the food and feed supply chains.	
HU	Since the occurrence of GMOs in food is not homogeneous, appropriate and unified sampling is very important.	**Benefits**: sampling has a decisive influence on the outcome of the control-process, therefore it has to be done adequately. That is why the mycotoxin regulation (Regulation (EC) 401/2006) is in use at the moment. It would be useful to have detailed rules set out in one EU document in this respect. It would enhance legal certainty and make the authorities' task easier. **No negative impacts** were identified by consultees.	Consultees did not have experience of impacts from the lack of harmonisation.
NL	The lack of harmonisation of food sampling procedures impacts on the reproducibility of test results.	**Benefits**: the lack of harmonisation regarding sampling protocols and the number of analysis does have an impact. Harmonisation could avoid problems in terms of costs by allowing sampling methods that are already applied for mycotoxins and other food contaminants. It could also avoid trade problems by avoiding expensive (and unnecessary) sampling strategies. **Negative impacts** could arise if a completely new sampling protocol is introduced, as the same food samples collected for GMO analysis are also used for different kinds of analysis.	The examples of issues described by consultees related to costs of sampling, rather than impacts on the reproducibility of test results.

Source: case study interviews with NCAs

Table 25. Impacts of harmonisation of sampling methods

MS	Are there any benefits from the harmonisation of sampling methods?			Are there any negative effects from the harmonisation of sampling methods?			Respondents per MS
	Yes	No	Did not respond	Yes	No	Did not respond	
AT	✓ (NA)		✓ (NS)		✓ (NS)	✓ (NA)	2
BE[89]	✓ (NA)	✓ (2 NA)	✓ (NA)	✓ (NA)	✓ (2 NA)	✓ (NA)	4
BG	✓ (NS)				✓ (NS)		1
CY	✓ (NSA)				✓ (NSA)		1
CZ	✓ (NS; NA)			✓ (NS; NA)			2
DE	✓ (2 CSA; 2 CA; NS; NA)	✓ (4 CSA)	✓ (CS)	✓ (4 CSA; NA)	✓ (2 CSA; 2 CA; NS)	✓ (CS)	11
DK		✓ (NS; NA)		✓ (NA)	✓ (NS)		2
EE			✓ (NS; NA)			✓ (NS; NA)	2
EL[90]	✓ (NS)	✓ (NS; NA)		✓ (NA)	✓ (2 NS)		3
ES	✓ (NSA)				✓ (NSA)		1
FI[91]	✓ (NSA; NS)			✓ (NSA*; NS)	✓ (NSA)*		2
FR	✓ (NS; NA)			✓ (NS; NA)			2

[89] There are three Belgian laboratories which jointly function as the NRL. One Belgian laboratory which stated that it did not see any benefits to harmonisation, also indicated that it could not assess benefits as it did not undertake sampling activities.

[90] There are two National Competent Authorities responsible for sampling in Greece.

[91] One NSA in Finland stated both 'yes' and 'no' when asked whether it perceived there to be negative effects from harmonisation of sampling methods. The NCA stated that it did not see any negative effects insofar as harmonisation prevented diverging results, but felt that there may be issues if a completely new method for sampling is introduced.

MS	Are there any benefits from the harmonisation of sampling methods?			Are there any negative effects from the harmonisation of sampling methods?			Respondents per MS
	Yes	No	Did not respond	Yes	No	Did not respond	
HR	✓ (NS)	✓ (NA)			✓ (NS; NA)		2
HU	✓ (NS; NA)				✓ (NS; NA)		2
IE		✓ (NSA)		✓ (NSA)			1
IT	✓ (NS; NA)				✓ (NS; NA)		2
LT	✓ (NSA)	✓ (NA)			✓ (NSA; NA)		2
LU	✓ (NA)	✓ (NS)		✓ (NA)	✓ (NS)		2
LV	✓ (NA)				✓ (NA)		1
MT	✓ (NS; NA)			✓ (NS; NA)			2
NL[92]	✓ (NSA*; NA)	✓ (NSA)*		✓ (NSA; NA)			2
PL	✓ (NS; NA)				✓ (NS; NA)		2
PT	✓ (NS; NA)				✓ (NS)	✓ (NA)	2
RO	✓ (NS; NA)				✓ (NS; NA)		2
SE	✓ (NSA)				✓ (NSA)		1
SI		✓ (NS)	✓ (NA)		✓ (NS)	✓ (NA)	2
SK		✓ (NS; NA)			✓ (NS; NA)		2

[92] The Dutch NSA replied both 'yes' and 'no' to the same question regarding benefits of harmonising. The NSA explained that the 'yes' response referred to harmonisation of methods of sampling of bulk commodities, while the 'no' response referred to sampling of processed food products. The Dutch agency does not sample bulk commodities but food products. The NCA usually combines sampling for GMO analyses with sampling for other contaminants such as aflatoxins or pesticides, applying the same sampling strategies. Therefore, there is no need for a specific GMO sampling strategy for processed foods. However, harmonisation of protocols for bulk commodities could be beneficial.

MS	Are there any benefits from the harmonisation of sampling methods?			Are there any negative effects from the harmonisation of sampling methods?			Respondents per MS
	Yes	No	Did not respond	Yes	No	Did not respond	
UK	✓ (CS; NA)			✓ (CS)	✓ (NA)		2
Total NCAs / CAs	**39 (23 MS)**	**18 (11 MS)**	**6 (5 MS)**	**21 (12 MS)**	**35 (22 MS)**	**7 (6 MS)**	**62 (28 MS)**

Source: ICF analysis of survey and case study responses

NS = NCA only responsible for sampling, NA = NCA only responsible for analysis, NSA = NCA responsible for both sampling and analysis, CS = Regional CA only responsible for sampling, CA = Regional CA only responsible for analysis, CSA = Regional CA responsible for both sampling and analysis.

Where separate sampling and analysis surveys were submitted by the same competent authority (with responsibility for both functions), the response was only counted once.

** In a few cases, NCAs responsible for both sampling and analysis gave different responses for equivalent questions in the respective sampling and analysis surveys. In these cases, both responses have been logged. Reasons provided by the authorities can be found in the relevant footnotes.*

Table 26. Types of screening elements/constructs targeted regarding asynchronous and obsolete GM material in food

MS	Types of screening elements/constructs targeted										
	Cauliflower Mosaic Virus p35S	**Agrobacterium tumefaciens tNOS**	**PAT**	**BAR**	**PFMV**	**CTP2-CP4 EPSPS**	**Cry1Ab/Ac**	**p35S-PAT**	**Other**	**Other - description**	**Comments**
AT	✓	✓	✓	✓					✓	CTP2-EPSPS.	
BE	✓	✓	✓	✓ (1 NRL)	✓ (2 NRLs)		✓ (1 NRL)		✓	pNOS, Cry1Ab/Ac, CP4 EPSPS, and Cry3Bb1. Other screening markers gat-pin and t35S_pCAMBIA, t35S are also applied, but not routinely used.	Three laboratories are organised as a consortium and jointly function as the NRL for GM analyses. Two of these laboratories carry out analyses for the presence of asynchronous and obsolete GMOs. This table presents the responses submitted by these two laboratories.
BG	DNT	DNT	DNT	DNT	DNT	DNT	DNT	DNT	DNT	DNT	DNT
CY	✓	✓	✓	✓	✓	✓		✓	✓	Cry1Ab	
CZ	✓	✓		✓		✓	✓	✓	✓	P35S-pat, CP4 EPSPS, nptII, PAT-BAR, PLA, P-NOS, P-rAct and P35S-PAT.	

MS	Types of screening elements/constructs targeted										
	Cauliflower Mosaic Virus p35S	**Agrobacterium tumefaciens tNOS**	**PAT**	**BAR**	**PFMV**	**CTP2-CP4 EPSPS**	**Cry1Ab /Ac**	**p35S-PAT**	**Other**	**Other - description**	**Comments**
DE	✓	✓	✓ (3 official Länder labs)	✓ (5 official Länder labs & 1 NRL)	✓ (4 official Länder labs)	✓ (5 official Länder labs & 2 NRLs)	✓ (3 official Länder labs & 1 NRL)	✓ (5 official Länder labs)	✓	P35S/pat (2 NRLs and 4 Länder labs) pNOS-nptII (1 NRL and 3 Länder labs) p35S-nptII (3 Länder labs) pSAMS-gm-hra (2 Länder labs) 35S-neo (2 Länder labs) pNOS (1 NRL) cryIAb/cryIAc (1 Land lab) nptII (1 Land lab) epsps (1 Land lab) T-nos-dfr (1 Land lab) Epsps (1 land lab)	Responses were received from two German NRLs and seven official Länder laboratories.
DK	✓	✓	✓	✓		✓	✓	✓	✓	35S-pat, cry1-AB.	

MS	Types of screening elements/constructs targeted										
	Cauliflower Mosaic Virus p35S	Agrobacterium tumefaciens tNOS	PAT	BAR	PFMV	CTP2-CP4 EPSPS	Cry1Ab/Ac	p35S-PAT	Other	Other - description	Comments
EE	✓	✓									Official laboratory does not carry out quantitative analyses for presence of asynchronous/obsolete GMOs as these are done by laboratories in another Member State.
EL	✓	✓							✓	Cry, pFMV34S.	
ES	DNT	DNT	DNT	DNT	DNT	DNT	DNT	DNT	DNT	DNT	DNT
FI	✓	✓							✓	CP4EPSPS	
FR	✓	✓	✓	✓		✓	✓		✓	Pubi-cry, 35S-hpt and cpti-nos.	
HR	✓	✓	✓	✓			✓		✓	nptII.	
HU	✓	✓				✓	✓	✓	✓	pNOS-nptII, p35S-pat, bar-Tg7, SAMS	
IE	✓	✓							Did not indicate use of other methods		
IT	✓	✓				✓		✓	✓	nptII	

MS	Types of screening elements/constructs targeted										
	Cauliflower Mosaic Virus p35S	Agrobacterium tumefaciens tNOS	PAT	BAR	PFMV	CTP2-CP4 EPSPS	Cry1Ab/Ac	p35S-PAT	Other	Other - description	Comments
LT	✓	✓							✓	EPSPS	
LU	✓	✓					✓	✓	✓	CTP2-EPSPS; p35S-pat	
LV	✓	✓									
MT	NR	NR	NR	NR	NR	NR	NR	NR	NR		
NL	✓	✓	✓ (1 NRL)	✓	✓ (1 NRL)	✓ (1 NRL)	✓ (1 NRL)	✓ (1 NRL)	✓ (1 NRL)	P-nos, P-Rice actin, P-SSuAra, P-TA29, P-Ubi, T-35S, T-E9, T-g7, T-OCS, cp4-epsps, Cry1A(b), Cry1A.105, Cry1Ac, Cry1F, Cry2Ab2, Cry3A, Cry3Bb1, Vip3a, nptII, I-rAct1, Barnase, Barstar, CaMV, Adh1_cry1Ab, Cry1Ab_intron, CTP2_CP4EPSPS CONSTRUCT, Ctp4_cp4epsps, RRS CONSTRUCT. hsp70_cry1Ab, OTP_mepsps, P-35S_BAR CONSTRUCT, Pat_T-35S, P-UBI_CRY CONSTRUCT.	Responses were received from two Dutch laboratories carrying out analyses for the presence of asynchronous and obsolete GMOs: the Dutch NRL and one official laboratory.

MS	Types of screening elements/constructs targeted										
	Cauliflower Mosaic Virus p35S	Agrobacterium tumefaciens tNOS	PAT	BAR	PFMV	CTP2-CP4 EPSPS	Cry1Ab/Ac	p35S-PAT	Other	Other - description	Comments
PL	✓	✓	✓	✓	✓	✓			✓	NptII and P-nos-npt II	NRL carries out analyses for presence of asynchronous/obsolete GMOs but they do not make the distinction between general GM presence and asynchronous/obsolete GM in their day-to-day work.
PT	✓	✓		✓							
RO	✓	✓		✓		✓		✓	✓	35S-pat	
SE	DNT (✓)	DNT (✓)	DNT (✓)	DNT (✓)	DNT	DNT	DNT	DNT	DNT	DNT	Sweden indicated that it does not carry out sampling and analysis of asynchronous and obsolete GMOs. The screening elements reported here refer to analysis of other GMOs. This response is therefore not included in the totals at the bottom of this table.

MS	Types of screening elements/constructs targeted										
	Cauliflower Mosaic Virus p35S	Agrobacterium tumefaciens tNOS	PAT	BAR	PFMV	CTP2-CP4 EPSPS	Cry1Ab/Ac	p35S-PAT	Other	Other - description	Comments
SI	✓	✓	✓	✓		✓					
SK	✓	✓		✓		✓		✓	✓	35S-pat	
UK	✓	✓		✓	✓		✓				
Total	**24**	**24**	**12**	**22**	**10**	**18**	**13**	**14**	**27**		

Blank cells indicate where respective options within a question were not selected.

DNT = Member State does not test for the presence of asynchronous and obsolete GM events, NR = No response (to entire question)

Source: ICF analysis of survey and case study responses

Table 27. Use of qualitative and quantitative PCR in the identification of GM events

MS	Qualitative PCR is applied	Limit of detection for laboratories applying qualitative PCR	Quantitative PCR is applied	Limit of quantification for laboratories applying quantitative PCR
AT	✓	0.01 rel. %: cotton-MON88913; OSR-MON-88302-9; soybean-87708; soybean-DAS44406; soybean-DAS-81419-2; soybean-MON87705 0.02 rel. %: cotton-MON15985; cotton-GHB614; maize-3272; maize-4027; maize-Bt176; maize-MIR162; maize-MIR604; maize-MON88017;maize-MON89034; maize-NK603; OSR-DP0734964; OSR-GT73; OSR-T45; rice-LL62; soybean-305423; soybean-68416; soybean-MON87769; soybean-FG72soybean-CV127 0.03 rel. %: maize-MON87460	✓	0.02 rel. %: soybean-DAS44406 0.03 rel. %: soybean-DAS-81419-2 0.09 rel. %: OSR-DP0734964; OSR-MON-88302-9; soybean-87708; soybean-MON87705 0.1 rel. %: cotton-GHB614; cotton-MON15985; cotton-MON88913; maize-3272; maize-40278; maize-Bt176; maize-MIR162; maize-MIR604; maize-MON88017; maize-MON89034; maize-NK603; OSR-GT73; OSR-T45; rice-LL62; soybean-305423; soybean-68416; soybean-CV127; soybean-FG72 0.14 rel. %: soybean-MON87769 0.16 rel. %: maize-MON87460
BG	DNT	DNT	DNT	DNT
BE	✓ (2 NRLs)	1 NRL: stated that Limit of detection (LOD) is below 0.1% if product consists entirely of the plant species to which the event belongs. LOD of the event-specific method is determined for each method. 1 NRL: stated that it has at present 49 event-specific and 2	✓ (2 NRLs)	One NRL stated that about 0.1% - however if less than 100 copies of the endogenous reference are measured then the result is automatically considered as below the limit of quantification (LOQ). Another NRL stated that quantitative PCR methods could be applied depending on the concentration of the target (quantifiable or not). The LOQ of the methods is determined during the method verification. The LOQ for events falling under the scope of Regulation 619/2011

MS	Qualitative PCR is applied	Limit of detection for laboratories applying qualitative PCR	Quantitative PCR is applied	Limit of quantification for laboratories applying quantitative PCR
		construct specific qualitative PCR methods under accreditation. These methods cover authorised and events falling under EC/619/2011 (LLP). The LOD for most of them is ~10 Haploid Genome Equivalents (HGE). The LOD varies between 1 and 32 and is determined in the laboratory during the method verification.		is 0.1%. NRL uses 30 event-specific and 2 construct-specific methods for quantification under ISO17025 accreditation. These methods cover mostly authorised GM events. One method for LLP event is also under accreditation. The LOQ is 0.1% for most of the methods. LLP events can be also analysed out of accreditation ≥ no LOQ is determined in house. The LOQ of the methods as validated in the EURL ring trial is given in the validation dossier of each method published on the EU-RL GMFF website. Only events with available method and Certified Reference Materials can be analysed.
CY	✓	For all screening elements/constructs and GM events LOD is 0.1.	✓	LOQ is 0.03 for GTS 40-3-2 LOQ is 0.2 for following events: Bt11, Bt176, MON863, MON810, MON87460, MON88017, MON87708, MON89788, MON87705, GA21, NK603, MIR604, TC1507, A2704-12, DP 305423-1, DAS 40278-9, DAS 59122, DAS 6841 6, A5547
CZ	✓	LOD is specific for each method applied, and range between 0.0125% - 0.03%.	✓	Limit of quantification is specific for each method applied, in the range between 0.02 – 0.05%.
DE	✓ (7 official Länder labs & 2 NRLs)	LODs varied between different Länder laboratories. Limits include: Depending on plant species, for unprocessed materials: 0.001-0.02 % (mass/mass)	✓ (5 official Länder labs)	LOQs varied between different Länder laboratories. Limits include: 50-100 haploid genome copies (0.1 % depending on amount and quality of DNA extracted) 0.1%

MS	Qualitative PCR is applied	Limit of detection for laboratories applying qualitative PCR	Quantitative PCR is applied	Limit of quantification for laboratories applying quantitative PCR
		0.04 to 0.05 depending on the method 10 haploid genome copies (< 0.1% depending on amount and quality of DNA extracted) 3-10 copies of target sequence depending on GM event		The LOQ is 0.08 to 0.1 depending on the method Due to the lack of certified reference material at low level concentration (≤ 0.1%) for reliable LOQ-determination, only the practical LOQ is determined during quantification. The range depends on the matrix and on the amount of the corresponding reference gene.
DK	✓	LOD depends on the sample, but in pure material it is normally below 0.1 % measured from the copy number of the reference gene.	✓	The limit of detection depends on the sample, but in pure material it is normally below 0.1 % measured from the copy number of the reference gene.
EE	NR		NR	
EL	✓	0.1% mass/mass (PCR) or 20 copies (Real Time PCR)		
ES	DNT	DNT	DNT	DNT
FI	✓	< 0.045 %	✓	< 0.1 %
FR	✓	LODs can be considered as comparable [across laboratories]. For example, the limit of detection for the 305423 Soybean event is 0.01 per cent, based on reference material.	✓	The utilisation of quantitative PCR depends on the availability of reference material and reference EURL methods. The limits of quantification therefore are those reported within the EURL validation reports.
HR	✓		✓	0.1%
HU	✓	Use methods validated by the EU-RL GMFF. LOD for each method		

MS	Qualitative PCR is applied	Limit of detection for laboratories applying qualitative PCR	Quantitative PCR is applied	Limit of quantification for laboratories applying quantitative PCR
		can be found in its validation report.		
IE	✓	LOD is based on the Certified reference materials currently available. This currently varies from 0.1% to 0.5% (Mon810). Detection limits are based on the lowest percentage of a specific target commercially available.		Quantitative work is sub contracted to an ISO accredited commercial laboratory.
IT	✓	LOD is by definition method/laboratory dependent. All methods comply with the requirements established in the document "Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing".		
LT	✓	5 copies: MON88017 maize, MIR604 maize, LL62RICE, GT73 rapeseed, Bt176 maize 10 copies: T45 rapeseed 11 copies: NK603 maize	✓	0.1% (e.g. the concentration of the lowest certified reference material available)
LU			✓	
LV			✓	LOQ is 0.1% for all methods.

MS	Qualitative PCR is applied	Limit of detection for laboratories applying qualitative PCR	Quantitative PCR is applied	Limit of quantification for laboratories applying quantitative PCR
MT	NR		NR	
NL	✓ (1 NRL)	In pure reference material the LOD will be in between 0.1 and 0.5%.	✓ (2 NRLs)	NRL: 10 copies on average, it varies between 5 and 20 copies depending on the method. Official laboratory: Same method is used for both qualitative and quantitative methods. Difference is the use of a calibration curve for quantitative methods.
PL	NR		NR	
PT	✓	The methods are not all in-house validated as the accreditation process was suspended for some years. The LOD varies from 0,02-0,03% (m/m) and 35 copies.		
RO	✓	0.04% for every qualitative method	✓	0.1% for every quantitative method.
SE	DNT	DNT	DNT	DNT
SI			✓	50 copies of target sequence per reaction.
SK	✓	The absolute LOD is usually up to 10 copies.		
UK	✓	Depends on the sample matrix.		Again, it is matrix dependent.
Total NCAs/ CAs	**28** **(19 MS)**		**21** **(15 MS)**	

DNT = Member State does not test for the presence of asynchronous and obsolete GM events, NR = No response (to entire question)

Source: ICF analysis of survey and case study responses

Table 28. Measurement of uncertainty in quantitative tests

MS	In case of quantitative tests, is measurement uncertainty estimated?		Method used to perform measurement uncertainty
	Yes, in all cases	Yes, sometimes	
AT	✓		In general harmonized methods are applied according to Regulation (EU) 619/2011 to calculate measurement uncertainty on data derived from real samples entering the laboratory. For those events for which there is not enough quantitative data from real samples the approach recommended by Joint Research Centre (JRC) guidelines is followed. This uses ring trial information to calculate an overall measurement uncertainty. However, on test reports we generally use 30% as worst case model if measurement uncertainty does not exceed this level.
BE		✓ (2 NRLs)	NRL: based on prescriptions of the Institute for Reference Materials and Measurements (IRMM). Generally measurement uncertainty is not provided. However it is done sometimes for instance in the proficiency tests of the EURL-GMFF where it is asked. It could also be delivered for LLP events but in practice never had to do it. NRL: based on the RSDr % during the method verification (Technical guidance document from the EURL GMFF on the implementation of Commission Regulation (EU) NO 619/2011). Uncertainty is measured during the verification of the quantitative event-specific method in the laboratory.
BG	DNT	DNT	DNT
CY	✓		
CZ	✓		
DE	✓ (4 official Länder labs)	✓ (1 official Land lab)	Criteria for when uncertainty is typically measured by Länder labs included: • Quantitative methods are only applied for authorized events. • Uncertainty is calculated when measured value is near labelling level of 0.9 %. • Confidence interval 95 %

MS	In case of quantitative tests, is measurement uncertainty estimated?		Method used to perform measurement uncertainty
	Yes, in all cases	Yes, sometimes	
			• NRL: When measured value is near labelling level of 0.9 %. Methods used by Länder labs to measure uncertainty include: • Expanded measurement uncertainty obtained through the estimation of the repeatability standard deviation. (U=(standard deviation of independent test results x k-factor)/ square root of number of replica) • Horwitz with HORRAT • Method for estimating the uncertainty is based on the relative repeatability standard deviation.
DK	✓		
EE	N/A	N/A	
EL	N/A	N/A	
ES	DNT	DNT	DNT
FI		✓	
FR		✓	The estimation of measurement uncertainty is only possible when 0.1 % reference material is available. Since 2009, there were no cases of detection of asynchronous and obsolete GM material in food and feed. Therefore we have limited experience regarding the estimation of measurement uncertainty.
HR		✓	
HU		✓	
IE	NR	NR	

MS	In case of quantitative tests, is measurement uncertainty estimated?		Method used to perform measurement uncertainty
	Yes, in all cases	Yes, sometimes	
IT	N/A	N/A	
LT	✓		
LU		✓	
LV	✓		Guidance Document on Measurement Uncertainty for GMO Testing Laboratories (ENGL-Net adopted document)
MT	NR	NR	
NL	✓ (NRL)	✓ (official lab)	
PL	N/A	N/A	
PT	✓		Described by IRMM, Geel, Belgium
RO	✓		
SE	DNT (✓)		EUR 22756 - Guidance on measurement uncertainty for GMO Testing Laboratories. Sweden indicated that it does not carry out sampling and analysis of asynchronous and obsolete GMOs. The response reported here refer to analysis of other GMOs. This response is therefore not included in the totals at the bottom of this table.
SI	✓		
SK	NR	NR	
UK	N/A	N/A	

MS	In case of quantitative tests, is measurement uncertainty estimated?		Method used to perform measurement uncertainty
	Yes, in all cases	Yes, sometimes	
Total NCAs/ CAs	**14 (11 MS)**	**10 (8 MS)**	

DNT = Member State does not test for the presence of asynchronous and obsolete GM events, NR = No response (to entire question)

Source: ICF analysis of survey and case study responses

Table 29. Criteria used to assess compliance of food samples with regards to presence of asynchronous and obsolete GM materials

MS	The food lot is not compliant if		Other	Comments
	any content of asynchronous or obsolete GMOs is detected based on the application of qualitative methods of analysis.	**asynchronous / obsolete GM material exceeds a specific limit, based on results from quantitative methods of analysis.**		
AT			✓[93]	No specific limits are applied. For unauthorised GMOs with positive safety assessment published by EFSA, when the amount of GM material is above the detection limit the lot is considered not compliant. This case is considered to be non-compliant based on Article 4 (2) Reg. (EC) 1829/2003, which states that unauthorised GMOs cannot be placed on the market.
BE	✓			
BG	DNT	DNT	DNT	DNT
CY	✓			
CZ	✓			
DE	✓			
DK	✓			
EE	✓			
EL	✓			
ES	DNT	DNT	DNT	DNT

[93] The Austrian NCA reported that no specific limits are used to establish compliance, but selected the 'other' option as they do not apply the definition of asynchronous and obsolete GMOs established for this study.

MS	The food lot is not compliant if		Other	Comments
	any content of asynchronous or obsolete GMOs is detected based on the application of qualitative methods of analysis.	asynchronous / obsolete GM material exceeds a specific limit, based on results from quantitative methods of analysis.		
FI	✓			
FR	✓			
HR	✓			
HU	✓			
IE	✓			Control plans are not specifically targeted at asynchronous and obsolete GMOs.
IT	✓			
LT	✓			
LU	✓			
LV				No response was provided to the survey on sampling; the consultee who responded to the survey on analysis declared she was not in charge of assessing compliance.
MT	✓			
NL	✓			
PL		✓		In Poland, official laboratories in charge of GMO analyses perform quantification of GM content and apply a 0.1% limit. Results obtained below that level are burdened with a high uncertainty and therefore can lead to false results. Hence,

MS	The food lot is not compliant if		Other	Comments
	any content of asynchronous or obsolete GMOs is detected based on the application of qualitative methods of analysis.	**asynchronous / obsolete GM material exceeds a specific limit, based on results from quantitative methods of analysis.**		
				laboratories which performed analysis of the same sample of food could give a different interpretation.
PT	✓			
RO	✓			
SE	DNT	DNT	DNT	DNT
SI	✓			
SK	✓			
UK		✓		Although there is legally no maximum permitted limit for asynchronous/obsolete GM material in food, there is always some uncertainty of measurement when quantifying GMOs detected at very low levels and it is not always possible to determine precisely whether a GM material is present or not if the amount detected is very close to the limit of detection of the method, which is always higher than zero. The practical (technically achievable) limit applied is therefore 0.1% which is in line with the limit for feed and is therefore considered to be suitable for food too.
Total	**21**	**2**	**1**	

DNT = Member State does not test for the presence of asynchronous and obsolete GM events

Source: ICF analysis of survey and case study responses

Table 30. Does the lack of harmonisation of methods for analysis and interpretation of results have an impact on compliance assessment within Member States and/or between Member States?

MS	The lack of harmonisation impacts on compliance assessment within my MS	The lack of harmonisation impacts on compliance assessment between MSs	The lack of harmonisation does not impact on compliance assessment	Not applicable	Did not respond	Total respondents per MS
AT		✓ (NA)			✓ (NS)	2
BE[94]	✓ (NA)	✓ (NS)	✓ (NA)	✓ (NA)		4
BG			✓ (NS)			1
CY				✓ (NSA)		1
CZ		✓ (NS; NA)				2
DE	✓ (CSA; CA)	✓ (3 CSA)	✓ (CSA)	✓ (NS; NA; 2 CSA)	✓ (CS)	11
DK			✓ (NS; NA)			2
EE				✓ (NS; NA)		2
EL[95]			✓ (NA)	✓ (2 NS)		3
ES		✓ (NSA)				1
FI		✓ (NSA; NS)				2
FR		✓ (NS; NA)				2
HR	✓(NA)			✓ (NS)		2
HU		✓ (NS; NA)				2
IE			✓ (NSA)			1

[94] There are three Belgian laboratories which jointly function as NRL.

[95] There are two NCAs responsible for sampling in Greece.

MS	The lack of harmonisation impacts on compliance assessment within my MS	The lack of harmonisation impacts on compliance assessment between MSs	The lack of harmonisation does not impact on compliance assessment	Not applicable	Did not respond	Total respondents per MS
IT		✓ (NS; NA)				2
LT		✓ (NSA; NA)				2
LU		✓ (NS)	✓ (NA)			2
LV				✓ (NA)		1
MT				✓ (NS; NA)		2
NL			✓ (NSA)		✓ (NA)	2
PL	✓ (NS; NA)					2
PT	✓ (NS)	✓ (NA)				2
RO	✓ (NA)		✓ (NS)			2
SE				✓ (NSA)		1
SI			✓ (NS)	✓ (NA)		2
SK		✓ (NA)	✓ (NS)			2
UK	✓ (NA)			✓ (CS)		2
Total NCAs/ CAs	**9 (7 MS)**	**21 (13 MS)**	**12 (11 MS)**	**17 (11 MS)**	**3 (3 MS)**	**62**

NS = NCA only responsible for sampling, NA = NCA only responsible for analysis, NSA = NCA responsible for both sampling and analysis, CS = Regional CA only responsible for sampling, CA = Regional CA only responsible for analysis, CSA = Regional CA responsible for both sampling and analysis.

Where separate sampling and analysis surveys were submitted by the same competent authority (with responsibility for both functions), the response was only counted once.

Source: ICF analysis of survey and case study responses

Table 31. Impacts of harmonisation of methods of analysis

MS	Are there any benefits from the harmonisation of methods of analysis?			Are there any negative effects from the harmonisation of methods of analysis?			Total respondents per MS
	Yes	No	Did not respond	Yes	No	Did not respond	
AT		✓ (NA)	✓ (NS)		✓ (NA)	✓ (NS)	2
BE[96]	✓ (CA; 2 NA)	✓ (NA)		✓ (NA)	✓ (CA; 2 NA)		4
BG	✓ (NS)				✓ (NS)		1
CY	✓ (NSA)				✓ (NSA)		1
CZ	✓ (NS; NA)			✓ (NS; NA)			2
DE[97]	✓ (5 CSA*; NS; NA)	✓ (3 CSA*; 2 CA)	✓ (CS)	✓ (NA)	✓ (6 CSA; NS; 2 CA)	✓ (CS)	11
DK	✓ (NS; NA)				✓ (NS; NA)		2
EE			✓ (NS; NA)			✓ (NS; NA)	2
EL[98]	✓ (NS)	✓ (NA)	✓ (NS)	✓ (NA)	✓ (NS)	✓ (NS)	3
ES	✓ (NSA)				✓ (NSA)		1
FI	✓ (NSA; NS)				✓ (NSA; NS)		2

[96] There are three Belgian laboratories which jointly function as NRL.

[97] Two German Länder selected both 'yes' and 'no' to benefits of harmonisation of methods of analysis. Consultees explained that in the 'no' response, the answer related to the benefits of introducing a new harmonised protocol for analysis. The consultees believed that introducing a new harmonised protocol that is specific to asynchronous and obsolete GMOs could create some issues, as when the analysis starts it is not known what type of GM event will be found in the sample and therefore it would be better to have the same approach for all GM analyses (rather than a different approach for asynchronous and obsolete events). In the 'yes' response, reference was to the potential benefits from the harmonisation of rules for the interpretation of testing results.

[98] There are two National Competent Authorities responsible for sampling in Greece.

MS	Are there any benefits from the harmonisation of methods of analysis?			Are there any negative effects from the harmonisation of methods of analysis?			Total respondents per MS
	Yes	No	Did not respond	Yes	No	Did not respond	
FR		✓ (NS; NA)			✓ (NS; NA)		2
HR		✓ (NS; NA)		✓ (NA)	✓ (NS)		2
HU		✓ (NS; NA)		✓ (NA)	✓ (NS)		2
IE		✓ (NSA)		✓ (NSA)			1
IT	✓ (NS; NA)				✓ (NS; NA)		2
LT	✓ (NSA)	✓ (NA)			✓ (NSA; NA)		2
LU	✓ (NA)		✓ (NS)	✓ (NA)		✓ (NS)	2
LV	✓ (NA)				✓ (NA)		1
MT	✓ (NS; NA)			✓ (NA)	✓ (NS)		2
NL	✓ (NA)	✓ (NSA)		✓ (NSA; NA)			2
PL	✓ (NS; NA)				✓ (NS; NA)		2
PT	✓ (NS; NA)				✓ (NS)	✓ (NA)	2
RO	✓ (NS; NA)				✓ (NS; NA)		2
SE		✓ (NSA)			✓ (NSA)		1
SI	✓ (NA)	✓ (NS)		✓ (NS)	✓ (NA)		2
SK		✓ (NS; NA)			✓ (NS; NA)		2
UK	✓ (NA)		✓ (CS)		✓ (NA)	✓ (CS)	2
Total NCAs	**36 (20 MS)**	**21 (13 MS)**	**7 (6 MS)**	**13 (11 MS)**	**41 (23 MS)**	**8 (7 MS)**	**62 (28 MS)**

MS	Are there any benefits from the harmonisation of methods of analysis?			Are there any negative effects from the harmonisation of methods of analysis?			Total respondents per MS
	Yes	No	Did not respond	Yes	No	Did not respond	
/ CAs							

Source: ICF analysis of survey and case study responses

NS = NCA only responsible for sampling, NA = NCA only responsible for analysis, NSA = NCA responsible for both sampling and analysis, CS = Regional CA only responsible for sampling, CA = Regional CA only responsible for analysis, CSA = Regional CA responsible for both sampling and analysis.

Where separate sampling and analysis surveys were submitted by the same competent authority (with responsibility for both functions), the response was only counted once.

** In one case, a CA responsible for both sampling and analysis gave different responses for equivalent questions in the respective sampling and analysis surveys. In these cases, both responses have been logged. Reasons for divergent response are provided in the relevant footnote.*

Table 32. Impacts of harmonisation of Minimum Required Performance Limit for food as it already exists for feed

MS	Are there any benefits from the harmonisation of MRPL for food as it already exists for feed?			Are there any negative effects from the harmonisation of MRPL for food as it already exists for feed?			Total respondents per MS
	Yes	No	Did not respond	Yes	No	Did not respond	
AT	✓ (NA)		✓ (NS)	✓ (NA)		✓ (NS)	2
BE[99]	✓ (NSA; 2 NA)	✓ (NA)		✓ (NSA; NA)	✓ (2 NA)		4
BG	✓ (NS)				✓ (NS)		1
CY	✓ (NSA)				✓ (NSA)		1
CZ	✓ (NS; NA)			✓ (NS; NA)			2
DE	✓ (2 CSA; 2 CA)	✓ (4 CSA; NS; NA)	✓ (CS)	✓ (4 CSA; NS; NA)	✓ (2 CSA; 2 CA)	✓ (CS)	11
DK	✓ (NS; NA)			✓ (NS)	✓ (NA)		2
EE			✓ (NS; NA)			✓ (NS; NA)	2
EL[100]	✓ (NS)	✓ (NA)	✓ (NS)	✓ (NA)	✓ (NS)	✓ (NS)	3
ES	✓ (NSA)				✓ (NSA)		1
FI	✓ (NSA; NS)				✓ (NSA; NS)		2
FR	✓ (NS; NA)			✓ (NS; NA)			2
HR	✓ (NS; NA)			✓ (NA)	✓ (NS)		2

[99] There are three Belgian laboratories which jointly function as NRL.

[100] There are two National Competent Authorities responsible for sampling in Greece.

MS	Are there any benefits from the harmonisation of MRPL for food as it already exists for feed?			Are there any negative effects from the harmonisation of MRPL for food as it already exists for feed?			Total respondents per MS
	Yes	No	Did not respond	Yes	No	Did not respond	
HU	✓ (NS; NA)			✓ (NS; NA)			2
IE		✓ (NSA)		✓ (NSA)			1
IT		✓ (NS)	✓ (NA)		✓ (NS)	✓ (NA)	2
LT	✓ (NSA)	✓ (NA)			✓ (NSA; NA)		2
LU	✓ (NA)		✓ (NS)	✓ (NA)		✓ (NS)	2
LV		✓ (NA)			✓ (NA)		1
MT	✓ (NS; NA)			✓ (NS; NA)			2
NL[101]	✓ (NSA)*	✓ (NSA)*		✓ (NS; NA)			2
PL	✓ (NS; NA)				✓ (NS; NA)		2
PT	✓ (NS; NA)			✓ (NA)	✓ (NS)		2
RO	✓ (NS; NA)				✓ (NS; NA)		2
SE		✓ (NSA)			✓ (NSA)		1
SI	✓ (NA)		✓ (NS)	✓ (NA)		✓ (NS)	2
SK		✓ (NS; NA)			✓ (NS; NA)		2
UK	✓ (CS; NA)				✓ (CS; NA)		2

[101] One Dutch NSA explained its divergent position on the benefits of harmonisation of MRPLs. To be beneficial, a MRPL should not be too low. The NL had issues with the 0.1 per cent limit for feed: in the NL, testing is done on processed foods (and not raw commodities) where it is difficult to meet the 0.1 per cent limit.

MS	Are there any benefits from the harmonisation of MRPL for food as it already exists for feed?			Are there any negative effects from the harmonisation of MRPL for food as it already exists for feed?			Total respondents per MS
	Yes	No	Did not respond	Yes	No	Did not respond	
Total NCAs / CAs	**38 (22 MS)**	**16 (10 MS)**	**8 (7 MS)**	**26 (15 MS)**	**28 (18 MS)**	**8 (7 MS)**	**62 (28 MS)**

Source: ICF analysis of survey and case study responses

NS = NCA only responsible for sampling, NA = NCA only responsible for analysis, NSA = NCA responsible for both sampling and analysis, CS = Regional CA only responsible for sampling, CA = Regional CA only responsible for analysis, CSA = Regional CA responsible for both sampling and analysis.

Where separate sampling and analysis surveys were submitted by the same competent authority (with responsibility for both functions), the response was only counted once.

** In one case, NCA responsible for both sampling and analysis gave different responses for equivalent questions in the respective sampling and analysis surveys. In these cases, both responses have been logged. Reasons for the divergent position are provided in the relevant footnote.*

Table 33. Setting of a MRPL - results from case studies

MS	Possible benefits from the setting of a MRPL	Possible negative effects	Other comments
AT	A MRPL for food would facilitate the interpretation of a quantitative result, compared to the current 'zero tolerance', as tested through qualitative analysis. A MRPL would also allow comparison of test results between laboratories.	The introduction of a MRPL would represent a significant additional cost. Compared to qualitative methods, additional resource would be needed: To verify a quantitative method. This is laborious and more expensive, as additional performance criteria are required. To run and maintain a quantitative method. This is much more expensive due to the need for Certified Reference Material, calibration curves in each single PCR run, and more extensive evaluation of results. To carry out quality management procedures, as quantitative proficiency testing schemes, and control charts are needed. The additional cost may be less significant in laboratories that are also establishing the MRPL for feed. Furthermore, specific methods and certified reference material, including at MRPL level, would have to be available in order to allow the introduction of a MRPL.	A MRPL should correspond to at least the LOQ of 0.1 % (mass fraction) or even a lower limit.
BE	The introduction of a MRPL could ensure that all laboratories are able to achieve the same limit for quantitative analyses and therefore achieve the same level of performance. This would solve potential issues in terms of comparability of test results and provide a better foundation to compliance assessment	Additional resources in terms of costs and time would be needed for the validation of the laboratories. Additionally, the introduction of a MRPL for food would mean that quantification of GM content is necessary when asynchronous and obsolete GMOs are detected through screening. Interviewees stated that the introduction of a MRPL for feed already increased the complexity of analysis and interpretation rules. In feed, sometimes asynchronous events were detected, but their presence was too low (not quantifiable): in these cases, the MRPL represents a big burden, as it implies that quantification of the GM event is necessary. It was also reported that there	Consultees also noted that analyses are time consuming and costly, and asynchronous and obsolete GMOs are rarely detected in food. Consultees concluded that they are not in favour of the introduction of a MRPL for food as negative impacts would be far

MS	Possible benefits from the setting of a MRPL	Possible negative effects	Other comments
		are significant differences between 'real' samples collected for official controls and reference samples: while it may be possible to measure uncertainty for the reference sample, the same may not be possible with the official sample when GM material is at very low levels. Some steps of the analysis (such as grinding and DNA extraction) are performed on the official sample, but not on the reference material: for this reason, uncertainty measurement for official samples is more difficult than for reference material. These issues were faced with the quantification of GM presence close to the MRPL in feed.	higher than the benefits obtained.
DE	Consultees viewed the potential introduction of a MRPL for food with caution, although some welcomed that a MRPL would increase the comparability of results between Member States / laboratories.	Consultees pointed to the costs arising from the setting of a MRPL, from availability of appropriate instrumentation to additional staff time / staff and reagents. There were also concerns that the introduction of a MRPL would signal acceptance of low level presence of unauthorised GMO events, and allow food products with trace amounts of this material (below the MRPL) to enter the market.	It was unclear to consultees how the issue could be addressed
ES	The introduction of a MRPL for food could imply: An easier application of methods for analysis; The possibility to compare results of analysis Easier and harmonised interpretation of results	No negative impacts are foreseen, granted that the limit is used for non-authorised GMOs.	
FR	When products for processing are imported, the final destination of these products (food or feed) is not always	The only possible concern regarding the setting of a MRPL for food is that this could lead to a lower sensitivity towards the issue of the low level presence of GMOs yet to be authorised.	

MS	Possible benefits from the setting of a MRPL	Possible negative effects	Other comments
	known. In case of detection asynchronous GMOs below the 0.1 per cent limit, the marketing of products destined to feed would be accepted, but products destined to food would be deemed not compliant although they came from the same lot.	Food business operators reported that the introduction of the MRPL for feed will have no benefits in terms of trade in the absence of a similar solution for food. It is therefore necessary to ensure that a food MRPL will not indirectly lead operators to be less vigilant regarding the import of raw materials.	
HU	No benefits were mentioned during case study interviews.	According to one interviewee quantification is too costly, time-consuming and results in high uncertainty. There should rather be emphasis on harmonising qualitative methods. Another interviewee stated that the use of any MRPL system would enhance costs without adequate justification.	
NL	Technically, a zero per cent limit cannot be achieved, and therefore it is technically necessary to regulate / harmonise controls for asynchronous and obsolete GM material. There is no reason to apply different approaches for food and feed do this differently than the regulation for feed.	If the MRPL is too low, then it might be difficult for laboratories to achieve validation. The MRPL of 0.1 per cent that has been set for feed would be too low for use in food: official controls for feed generally deal with raw material in a pure form, whereas in the case of food controls usually deal with a processed product. For processed foods it is more difficult to use a level as low as 0.1 per cent within a reasonable range of uncertainty.	A MRPL which is not considered too low could be for instance a level of 0.9 per cent.

Source: case study interviews with NCAs

A5.2 Impacts on food business operators and on the market

Table 34. Sampling protocols applied by businesses

Consultee type	Where sampling takes place	Who applies these protocols	Food product sampled	Description of protocols and strategies applied for bulk commodities	EU or other guidance followed	Description of protocols applied for packaged food
EU multinational business (food ingredients processor)	Not specified	Internal audit processes and external assurance schemes	Maize; sometimes raw material is sampled and tested, and in other cases the semi-processed food product to be further processed	The company uses auto-sampling or statistical sampling both of which are dependent on the lot size.	GIPSA guidance is followed (Grain Inspection, Packers and Stockyards Administration)	Not applicable
EU multinational business (food producer)	At the premises of food processors	Internal audit process	A broad range of raw materials is tested; the main products tested for the presence of GMOs are soy derived products, rice, maize, soy lecithin, corn starch	Internal protocols for sampling are used; they are not specifically tailored to asynchronous and obsolete GMOs.	ISO norms for cereal sampling	Not applicable
EU multinational business (food producer)	Samples are collected by suppliers of raw commodities and food ingredients; sometimes, the	Suppliers of raw commodities and food ingredients; internal audit process	Main commodities are maize, wheat, soybeans, soy lecithin	Suppliers are requested to follow existing EU guidance for sampling, but the consultee was not aware of the exact protocols followed. When sampling is done internally, EU guidelines	EU guidance is followed; the exact protocols were not specified	Not specified

Consultee type	Where sampling takes place	Who applies these protocols	Food product sampled	Description of protocols and strategies applied for bulk commodities	EU or other guidance followed	Description of protocols applied for packaged food
	business also does spot-sampling			are not always followed although the protocols used aim at ensuring representativeness of the sample.		
FEDIOL and COCERAL	Exporting countries; points of import	Some testing is undertaken by suppliers in third countries and other testing may be done by importers	Mainly bulk commodities. Sampled products include soybeans.	Not specified	Not specified	Not specified
FoodDrinkEurope	Not specified	Often sampling and analysis protocols are applied by external parties and/or suppliers	Sampling focusses on raw materials and food ingredients	Usually no fixed sampling protocols are applied. Sampling schemes may differ by material type, origin of materials, and type of delivery (bulk or bags). Samples must be representative of the lot.	No EU/other guidance is followed	Not specified
Starch Europe	Cultivation, transportation, plant intake by starch producer	Mandated by starch producer as part of sourcing contract, plus testing at plant intake by starch producer	Waxy maize and finished starch products produced in Third Countries where GM maize varieties (i,e, regular corn) are cultivated	Members apply statistics based protocol to ensure representativeness.	No EU/other guidance is followed	Not applicable

Table 35. Does the lack of harmonisation of sampling for official controls for the presence of asynchronous and obsolete GM material affect food business operators at EU level?

Type of respondent	Yes	No	Did not respond	Total
Businesses - multinational	3			3
Commercial laboratories	1	1		2
EU Business Associations	5	1		6
National business			1	1
National business associations	1	2	1	4
NGOs		1		1
Third countries	2	3		5
Total	**12**	**8**	**2**	**22**

Source: ICF analysis of consultation results

Table 36. Does the lack of harmonisation of analysis for official controls for the presence of asynchronous and obsolete GM material affect food business operators at EU level?

Type of respondent	Yes	No	Did not respond	Total
Businesses - multinational	2	1		3
Commercial laboratory	1	1		2
EU Business Associations	6			6
National business			1	1
National business associations	1	2	1	4
NGOs		1		1
Third countries	3	2		5
Total	**13**	**7**	**2**	**22**

Source: ICF analysis of consultation results

Table 37. Potential impacts from the harmonisation of sampling

Type of respondent	Consultees who identified potential benefits	Consultees who had mixed views	Consultees who identified negative impacts	Did not comment on potential impacts	Total
Businesses - multinational	2	1			3
Commercial laboratories	1			1	2
EU Business Associations	5	1			6
National business				1	1
National business associations	1			3	4
NGOs				1	1
Third countries	2	2		1	5
Total	**11**	**4**		**7**	**22**

Source: ICF analysis of consultation results

Table 38. Potential impacts from the harmonisation of analysis

Type of respondent	Consultees who identified potential benefits	Consultees who had mixed views	Consultees who identified negative impacts	Did not comment on potential impacts	Total
Businesses - multinational	1	1		1	3
Commercial laboratories	2				2
EU Business Associations	5	1			6
National business				1	1
National business associations	1			3	4
NGOs		1			1
Third countries	2	1	1	1	5
Total	**11**	**4**	**1**	**6**	**22**

Source: ICF analysis of consultation results

Table 39. Potential impacts from the setting of a MRPL

Type of respondent	Consultees who identified potential benefits	Consultees who had mixed views	Consultees who identified negative impacts	Did not comment on potential impacts	Total
Businesses - multinational	1	1		1	3
Commercial laboratories	1			1	2
EU Business Associations	5	1			6
National business				1	1
National business associations	1			3	4
NGOs			1		1
Third countries[102]	3	1	2		5
Total	**11**	**3**	**3**	**6**	**22**

Source: ICF analysis of consultation results

[102] One of the third country respondent identified both benefits (legal certainty for trade) and negative effects (potential additional costs from certification and quantitative analyses) from the setting of a MRPL for food.

Annex 6 List of asynchronous and obsolete GMOs

This annex presents the lists of asynchronous and obsolete GMOs considered in the scope of this study.

Table 40. Asynchronous GMOs (2009-2015)

	Application: statement of validity	Adoption by Commission	Year in which the GMO was considered to be asynchronous						
			2009	2010	2011	2012	2013	2014	2015
T45 Rapeseed	13 April 2007	10 March 2009	x						
MON 88017 Maize	11 January 2007	30 October 2009	x						
59122 x NK603 Maize	20 June 2007	30 October 2009	x						
MON 89034 Maize	24 August 2007	30 October 2009	x						
MIR604 Maize	16 September 2005	10 November 2009	x						
MON863xMON810 Maize	26 November 2004	02 March 2010	x	x					
MON 863 x NK603 Maize	14 January 2005	02 March 2010	x	x					
MON 810 x MON 863 x NK603 Maize	14 January 2005	02 March 2010	x	x					
MON 88017 x MON 810 Maize	21 February 2007	28 July 2010	x	x					
59122 x 1507 x NK603 Maize	20 June 2007	28 July 2010	x	x					
1507 x 59122 Maize	13 July 2007	28 July 2010	x	x					

	Application: statement of validity	Adoption by Commission	Year in which the GMO was considered to be asynchronous						
			2009	2010	2011	2012	2013	2014	2015
MON 89034 x NK603 Maize	24 August 2007	28 July 2010	x	x					
Bt11 x GA21 Maize	19 February 2008	28 July 2010	x	x					
GHB614 Cotton	11 March 2008	14 June 2011	x	x	x				
MON 89034 x MON 88017 Maize	20 September 2007	17 June 2011	x	x	x				
281-24-236 x 3006-210-23 Cotton	03 August 2005	22 December 2011	x	x	x				
Bt11 x MIR604 Maize	11 March 2008	22 December 2011	x	x	x				
MIR604 x GA21 Maize	12 March 2008	22 December 2011	x	x	x				
Bt11 x GA21 x MIR604 Maize	19 August 2008	22 December 2011	x	x	x				
356043 Soybean	28 September 2007	10 February 2012	x	x	x	x			
A5547-127 Soybean	18 July 2008	10 February 2012	x	x	x	x			
MON 87701 Soybean	11 June 2010	10 February		x	x	x			

	Application: statement of validity	Adoption by Commission	Year in which the GMO was considered to be asynchronous						
			2009	2010	2011	2012	2013	2014	2015
		2012							
MON 87701 x MON 89788 Soybean	08 December 2009	09 July 2012	x	x	x	x			
MIR162 Maize	24 August 2010	18 October 2012		x	x	x			
MS8 x RF3 Rapeseed	05 October 2011	25 June 2013			x	x	x		
MON89034x1507xMON88017x59122 maize	03 March 2009	06 November 2013	x	x	x	x	x		
1507 x MON 89034 x NK603 Maize	06 August 2009	06 November 2013	x	x	x	x	x		
LLRICE62 Rice	14 January 2005		x	x	x	x	x	x	x
MON 1445 x MON 531 Cotton	12 July 2005		x	x	x	x	x	x	x
3272 Maize	06 July 2007		x	x	x	x	x	x	x
MON 88913 Cotton	19 October 2007		x	x	x	x	x	x	x
305423 Soybean	22 October 2007		x	x	x	x	x	x	x
MON 15985 x MON 88913 Cotton	28 January 2008		x	x	x	x	x	x	x
305423 x 40-3-2 Soybean	19 February 2008		x	x	x	x	x	x	x

	Application: statement of validity	Adoption by Commission	Year in which the GMO was considered to be asynchronous						
			2009	2010	2011	2012	2013	2014	2015
MON 15985 Cotton	20 August 2008		x	x	x	x	x	x	x
MON 1445 x MON 15985 Cotton	26 August 2008		x	x	x	x	x	x	x
BPS-CV127-9 Soybean	13 July 2009		x	x	x	x	x	x	x
Bt11 x GA21 x MIR162 x MIR604 Maize	13 July 2009		x	x	x	x	x	x	x
Bt11 x GA21 x MIR162 Maize	13 July 2009		x	x	x	x	x	x	x
MON 87460 Maize	28 January 2010			x	x	x	x	x	x
MON 87769 Soybean	15 February 2010			x	x	x	x	x	x
MON 87705 Soybean	13 August 2010			x	x	x	x	x	x
NK603 x T25 Maize	12 October 2010			x	x	x	x	x	x
MON 87769 x MON 89788 Soybean	26 November 2010			x	x	x	x	x	x
GHB614 x LLcotton25 Cotton	26 January 2011				x	x	x	x	x
281-24-236 x 3006-210-23 x MON 88913 Cotton	03 March 2011				x	x	x	x	x
DAS-40278-9 Maize	11 March 2011				x	x	x	x	x

			Year in which the GMO was considered to be asynchronous						
	Application: statement of validity	**Adoption by Commission**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
MON 87708 Soybean	13 May 2011				x	x	x	x	x
5307 Maize	21 June 2011				x	x	x	x	x
DAS-68416-4 Soybean	08 September 2011				x	x	x	x	x
T304-40 Cotton	24 October 2011				x	x	x	x	x
FG72 Soybean	24 October 2011				x	x	x	x	x
GHB119 Cotton	21 November 2011				x	x	x	x	x
GT73 Rapeseed	22 November 2011				x	x	x	x	x
1507 x 59122 x MON 810 x NK603 Maize	30 January 2012					x	x	x	x
MON 88302 Rapeseed	30 March 2012					x	x	x	x
MS8 x RF3 x GT73 Rapeseed	11 May 2012					x	x	x	x
Bt11 x MIR162 x 1507 x GA21 Maize	14 June 2012					x	x	x	x
Bt11 x 59122 x MIR604 x 1507 x GA21 Maize	14 June 2012					x	x	x	x

	Application: statement of validity	Adoption by Commission	Year in which the GMO was considered to be asynchronous						
			2009	2010	2011	2012	2013	2014	2015
MON 87708 x MON 89788 Soybean	20 July 2012					x	x	x	x
MON 87705 x MON 89788 Soybean	30 July 2012					x	x	x	x
73496 Oilseed rape	04 December 2012					x	x	x	x
MON 87427 Maize	03 January 2013		4				x	x	x
SYHT0H2 Soybean	09 January 2013						x	x	x
DAS-44406-6 Soybean	15 April 2013						x	x	x
MON 88701 Cotton	25 June 2013						x	x	x
MON87427xMON89034xNK603 maize	22 January 2014							x	x
DAS-81419-2 Soybean	07 February 2014							x	x
MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 maize	10 March 2014							x	x
3272 x Bt11 x MIR604 x GA21 Maize	11 March 2014							x	x
MON88302xMs8xRf3 oilseed rape	24 April 2014							x	x
DAS-68416-4 x MON-89788-1 Soybean	13 June 2014							x	x

	Application: statement of validity	Adoption by Commission	Year in which the GMO was considered to be asynchronous						
			2009	2010	2011	2012	2013	2014	2015
Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 Maize	18 August 2014							x	x
MON 89034 x 1507 x NK603 x DAS-40278-9 Maize	29 August 2014							x	x
MON 89034 x 1507 x MON 88017 x 59122 x DAS-40278-9 Maize	02 October 2014							x	x
MON 87751 Soybean	22 January 2015								x
FG72 x A5547-127 soybean	23 February 2015								x

Text highlighted in green: Authorised in the EU (at the time of the launch of the consultation, i.e. March 2015)

Table 41. Obsolete GMOs (2009-2015)

	Withdrawal decision*	2009	2010*	2011*	2012	2013	2014	2015
Bt176 Maize	2007/304/EC Official Journal L 117, p. 14 – 16 05/05/2007				x	x	x	x
GA21 x MON 810 Maize	2007/308/EC Official Journal L 117, p. 25 - 26 05/05/2007				x	x	x	x

** Adventitious presence in a proportion no higher than 0.9% was tolerated until 5 years after the date of notification of the Decision, i.e. until 4/05/2012*

Annex 7 References

- ADM, 2015. ADM Europe. http://www.adm.com/en-US/worldwide/europe/Pages/default.aspx
- Anderson-Sprecher, A., Jie, M., 2014. Agricultural Biotechnology Annual, People Republic of China, http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Beijing_China%20-%20Peoples%20Republic%20of_12-31-2014.pdf.
- André, D., 2014. LLP Policy in the EU. Implementation and implications. European Commission - DG Health and Consumers. Presentation for the FAO Technical Consultation on Low Levels of Genetically Modified (GM) Crops in International Food and Feed Trade, Rome, 20-21 March 2014, http://www.fao.org/fileadmin/user_upload/agns/topics/LLP/Presentations/11_EU_Final.pdf.
- Anwaltsbüro Gaßner, Groth, Siederer & Coll, 2011. Provisions concerning sampling and analysis of animal feed for genetically modified material on the basis of Regulation (EC) No 882/2004. Legal opinion on a proposal by the European Commission, http://www.endseurope.com/docs/110208a.pdf.
- Atici, C., 2014. Low Levels of Genetically Modified Crops in International Food and Feed Trade: FAO International Survey and Economic Analysis. Food and Agriculture Organization of the United Nations, Rome 2014, http://www.fao.org/docrep/019/i3734e/i3734e.pdf.
- Babuscio, T., 2014. Almost two decades of Low Level Presence. Lessons to be learnt: turning challenges into opportunities? Presentation of COCERAL, FAO International Technical Consultation on low levels of GM crops in international food and feed trade Rome, 20-21 March 2014, http://www.fao.org/fileadmin/user_upload/agns/topics/LLP/Presentations/16_Industry_Final.pdf.
- Brookes, G., 2008. Economic impacts of low level presence of not yet approved GMOs on the EU food sector, http://www.agrodigital.com/images/estudio.pdf.
- Brookes, G., 2009. The existing and potential impact of using gm insect resistant (gm ir) maize in the European Union.
- Bunge, 2015. Bunge Europe. http://www.bunge.com/Europe
- Canadian Biotechnology Action Network, 2015. Where in the world are GM crops and foods? http://gmoinquiry.ca/wp-content/uploads/2015/03/where-in-the-world-gm-crops-foods.pdf.
- CDU, CSU and SPD, 2013. Deutschlands Zukunft gestalten.
- Central Science Laboratory, 2007. Adventitious traces of genetically modified seeds in conventional seed lots: current situation in Member States, http://www.gm-inspectorate.gov.uk/reportsPublications/documents/EUseeds_final_081007.pdf.
- Clarke, R. 2014. Low levels of GM crops in international food/feed trade. Results of the FAO technical survey and discussions at the FAO international technical consultation.
- Danube Soya, 2015. Danube Soya Declaration, http://www.donausoja.org/en-en/Pages/Erklaerung.aspx.
- Dessureault, D. and Lupescu, M. 2014. Canada. Agricultural Biotechnology Annual, 2014. USDA GAIN Report,

http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Ottawa_Canada_7-14-2014.pdf.

- DG AGRI, 2007. Economic Impact of Unapproved GMOs on EU Feed Imports and Livestock Production, http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf.
- DG AGRI, 2014. Medium-term prospects for EU agricultural markets and income 2014-2024, http://ec.europa.eu/agriculture/markets-and-prices/medium-term-outlook/index_en.htm.
- DG AGRI, 2015. Short Term Outlook for EU arable crops, dairy and meat markets in 2015 and 2016, http://ec.europa.eu/agriculture/markets-and-prices/short-term-outlook/index_en.htm.
- EC, 2014. EU Cereals Trade 2013/14 Marketing Year July - December, http://ec.europa.eu/agriculture/cereals/trade/cereals/2013-2014_en.pdf.
- ENGL, 2011. Overview on the detection, interpretation and reporting on the presence of unauthorised genetically modified materials, http://gmo-crl.jrc.ec.europa.eu/doc/2011-12-12%20ENGL%20UGM%20WG%20Publication.pdf.
- Esterhuizen, D., 2014. Agricultural Biotechnology Annual, Republic of South Africa, http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Pretoria_South%20Africa%20-%20Republic%20of_7-14-2014.pdf.
- Euromaisiers, 2013. Euromaisiers's statistics, http://www.euromaisiers.eu/data/14164938002014%20Statistics%20_year%202013__Euromaisiers.pdf.
- Euromaisiers, 2015, Official website, http://www.euromaisiers.eu/web/facts%20on%20industry/1011306087/list1187970201/f1.html.
- Europabio. 2014. Spanish farmers lead the European innovation in the cultivation of maize, http://www.europabio.org/press/spanish-farmers-lead-european-innovation-cultivation-maize.
- European Commission, 2013. Report from the Commission to the European Parliament and to the Council on the overall operation of official controls in the Member States on food safety, animal health and animal welfare, and plant health, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0681&from=EN.
- European Commission, 2015. EU Register of authorised GMOs, ec.europa.eu/food/dyna/gm_register/index_en.cfm.
- Eurostat, 2015. EU Trade Since 1988 by HS2, 4, 6 and CN8 (DS-045409), http://epp.eurostat.ec.europa.eu/newxtweb/.
- EUVEPRO, 2011. The Low Level Presence of not yet EU Authorised GM Events on the European Vegetable Protein Industry in the Absence of a Technical Solution (TS) Applicable to Food. Impact Assessment.
- FAO, 2014. Technical Consultation on low levels of genetically modified (GM) crops in international food and feed trade.
- FAOSTAT, 2015. Production quantities by country, http://faostat3.fao.org/browse/Q/*/E.

- FEDIOL, 2011a. Low level presence of not yet EU authorized GM events. Impact assessment on the EU vegetable oil industry resulting from the absence of a Technical Solution (TS) applicable to food.
- FEDIOL, 2011b. The importance of LLP technical solution for both feed and food, http://www.fediol.be/data/11GMO123_The_importance_of_the_LLP_technical_solution_for_both_feed_and_food_Compatibility_Mode.pdf.
- FEDIOL, 2014. 2013 Annual Statistics, http://www.fediol.be/data/1427965562Stat%20seeds%202013.pdf.
- FEDIOL, 2014. Impact assessment of different non-authorized GMOs crisis scenarios.
- Fernandez-Cornejo, J., Wechsler, S., Livingston, M., and Mitchell, L. J., 2014. Genetically engineered crops in the United States, http://www.ers.usda.gov/media/1282246/err162.pdf.
- FoodDrinkEurope, 2014. Data & Trends of the European Food and Drink Industry 2012, http://www.fooddrinkeurope.eu/uploads/publications_documents/Data__Trends_(interactive).pdf.
- FoodDrinkEurope, 2014. Data & Trends of the European Food and Drink Industry 2013-2014. http://www.fooddrinkeurope.eu/uploads/publications_documents/Data__Trends_of_the_European_Food_and_Drink_Industry_2013-20141.pdf
- FoodDrinkEurope, EUVEPRO and FEDIOL, 2013. Technical definition of « zero » for not yet EU authorised GM events in food. Letter to Ms Catherine DAY, Secretary General, European Commission.
- Freitag, C., Minol, K. and Stein, A. J. GMO study: Imports of conventional and GM crops in the EU. For FoodDrinkEurope Brussels. Genius GmbH – science & communication, Berlin.
- Friends of the Earth Europe, 2010. No link between animal feed crisis and EU zero tolerance policy.
- Friends of the Earth Europe, 2011. The impacts of dropping Europe's zero tolerance to gm feed imports. No legal certainty for feed and food sectors.
- Friends of the Earth Europe, ARGE, Coop Italy, EuroCoop, Greenpeace EU and VLOG, 2013. Upholding the principle of zero tolerance in GM food, http://www.eurocoop.org/en/publications/position-papers/position-papers-food-policy/495-ngos-and-food-operators-write-to-commissioner-borg-for-the-respect-of-the-zero-tolerance-principle-in-gm-food.
- FVO, 2012a. Final report of an audit carried out in Germany from 20 to 29 September 2011 in order to assess the official controls of genetically modified organisms including their deliberate release into the environment, http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2849.
- FVO, 2012b. Final report of an audit carried out in Romania from 11 to 20 September 2012 in order to evaluate the official controls of genetically modified organisms, including their deliberate release into the environment, http://ec.europa.eu/food/fvo/act_getPDF.cfm?PDF_ID=10135.
- FVO, 2012c. Final report of an audit carried out in Spain from 21 to 30 November 2011 in order to assess the official controls of genetically modified organisms including their deliberate release into the environment, http://ec.europa.eu/food/fvo/act_getPDF.cfm?PDF_ID=9949.

- FVO, 2012d. Final report of an audit carried out in Sweden from 02 to 10 August 2011 in order to assess the official controls of genetically modified organisms including their deliberate release into the environment, http://ec.europa.eu/food/fvo/act_getPDF.cfm?PDF_ID=9426.
- FVO, 2012e. Final report of an audit carried out in the Czech Republic from 18 to 22 June 2012 in order to evaluate the official controls of genetically modified organisms, including their deliberate release into the environment, http://ec.europa.eu/food/fvo/act_getPDF.cfm?PDF_ID=10060.
- FVO, 2013a. Final report of an audit carried out in Hungary from 27 November to 05 December 2012 in order to evaluate the official controls for genetically modified organisms including their deliberate release into the environment, http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=3074.
- FVO, 2013b. Final report of an audit carried out in Poland from 22 to 31 January 2013 in order to evaluate the official controls of genetically modified organisms, including their deliberate release into the environment, http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=3108.
- FVO, 2013c. Final report of an audit carried out in the Netherlands from 19 to 23 November 2012 in order to evaluate the official controls of genetically modified organisms, including their deliberate release into the environment, http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=3075.
- FVO, 2014. Final report of an audit carried out in Slovakia from 10 to 18 September 2013 in order to evaluate the official controls of genetically modified organisms, including their deliberate release into the environment, http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=3201.
- FVO, 2014b. Overview report of a series of audits carried out in member states between 2011 and 2013 to assess the official controls of genetically modified organisms including their deliberate release into the environment, http://ec.europa.eu/food/fvo/overview_reports/details.cfm?rep_id=67.
- Genetic ID (Europe) AG, 2011. Understanding Regulation EC No. 619/2011on low-level presence (LLP) of GMOs in feed imports and the implications for food business operators.
- Gwirtz, J. A. and Garcia-Casal, M. N., 2014. Processing maize flour and corn meal food products, Annals of the NY Academy of Sciences, 1312, 66-75, http://onlinelibrary.wiley.com/doi/10.1111/nyas.12299/pdf.
- Henselera, M., Piot-Lepetitb, I., Ferrarib, E., Gonzalez Melladob, A., Bansea,, M. Grethee,, H. Parisib, C. and Hélaine, S., 2013. On the asynchronous approvals of GM crops: Potential market impacts of a trade disruption of EU soy imports, http://www.sciencedirect.com/science/article/pii/S0306919213000560.
- HighQuest Partners and Soyatech, LLC, 2011. How the Global Oilseed and Grain Trade Works, http://unitedsoybean.org/wp-content/uploads/2013/07/RevisedJan12_GlobalOilSeedGrainTrade_2011.pdf.
- Hobbs, J. E., Kerr, W. A. and Smyth, S. J., 2014. How Low Can You Go? The Consequences of Zero Tolerance, http://www.agbioforum.org/v16n3/v16n3a04-hobbs.pdf.
- Holst-Jensena, A., Bertheaub, Y., de Loosec, M., Grohmannd, L., Hamelse, S., Hougsf, L., Morissetg, D., Pecoraroh, S., Plai, M., Van den Bulckek, M. and Wulff, D., 2012. Detecting un-authorized genetically modified organisms (GMOs) and derived materials, http://www.sciencedirect.com/science/article/pii/S0734975012000377.
- IUPAC, 2014. IUPAC Compendium of Chemical Terminology.

- James, C. 2009b. Global status of commercialised biotech/GM crops: 2009. Ithaca: The International Service for the Acquisition of Agri-biotech Applications (ISAAA) , http://www.isaaa.org/resources/publications/briefs/41/download/isaaa-brief-41-2009.pdf.
- James, C., 2009a. Executive summary - Global status of commercialised biotech/GM crops: 2009. Ithaca: The International Service for the Acquisition of Agri-biotech Applications (ISAAA) , http://www.isaaa.org/resources/publications/briefs/41/executivesummary/default.asp.
- James, C., 2012. Global status of commercialised biotech/GM crops: 2012. Ithaca: The International Service for the Acquisition of Agri-biotech Applications (ISAAA) , http://www.isaaa.org/resources/publications/briefs/44/download/isaaa-brief-44-2012.pdf.
- James, C., 2013. Global Status of Commercialized Biotech/GM Crops: 2013. ISAAA Brief 46-2013: Executive Summary, http://www.isaaa.org/resources/publications/briefs/46/executivesummary/default.asp.
- James, C., 2013. Global Status of Commercialized Biotech/GM Crops: 2013. ISAAA Brief No. 46. ISAAA: Ithaca, NY. Pocket K No. 16: Global Status of Commercialized Biotech/GM Crops in 2013, http://isaaa.org/resources/publications/pocketk/16/default.asp.
- JRC, 2014. Guidelines for sample preparation procedures in GMO analysis. Prepared by the ENGL ad hoc working group on "sample preparation procedures" , http://gmo-crl.jrc.ec.europa.eu/ENGL/docs/WG-SPP-Final-Report.pdf.
- Kalaitzandonakes, N., Kaufman, J. and Miller, D., 2011. Potential Economic Impacts of Asynchronous Approvals of Biotech Crops on Latin American Countries, http://www.agritrade.org/Publications/documents/LLPLAC.pdf.
- Kalaitzandonakesa, N., Kaufmanb, J. and Miller, D., 2014. Potential economic impacts of zero thresholds for unapproved GMOs: The EU case, http://www.sciencedirect.com/science/article/pii/S0306919213000791.
- Kaphengst, Tom, et al., 2009. Assessment of the economic performance of GM crops worldwide, http://ec.europa.eu/food/plant/gmo/reports_studies/docs/economic_performance_report_en.pdf.
- Knight, S., 2015. EU-28. Grain and feed annual. USDA GAIN Report, http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Grain%20and%20Feed%20Annual_London_EU-28_3-27-2015.pdf.
- Krautgartner, R., Audran, X., Rehder, L. E., Boshnakova, M., Dobrescu, M., Flach, B., Wilson, J., Bettini, O., Guerrero, M., Bendz, K. and the group of FAS oilseeds specialists in the EU, 2014. EU-28. Oilseeds and Products Annual. Record Rapeseed Production but Sunflower Production Down, http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Oilseeds%20and%20Products%20Annual_Vienna_EU-28_3-31-2014.pdf.
- Krautgartner, R., Henard, M.-C., Rehder, L. E., Boshnakova, M., Dobrescu, M., Flach, B., Wilson, J., Bettini, O., Guerrero, M., Bendz, K. and the group of FAS oilseeds specialists in the EU, 2013. EU-27. Oilseeds and Products Annual, Ample Soybean World Supplies to Boost EU-27 Soybean Meal Consumption,

http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Oilseeds%20and%20Products%20Annual_Vienna_EU-27_4-5-2013.pdf.

- Landmark Public Policy Advisers Europe, 2009. The cost of low level presence of GMOs in food products in Europe. An impact assessment based on the recent RASFF 2009.1037 & 2009.1165, http://foedevarer.di.dk/sitecollectiondocuments/landmark%20llp%20study%20final%209%20oct%202009final%20dok929981.pdf.
- Lefebvre, L., Polet, Y. and Williams, B. 2014. EU-28. Agricultural Biotechnology Annual. Biotechnology and Other New Production Technologies. USDA GAIN Report, http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_1-9-2015.pdf.
- LEI, EMAC, PRI, 2010. Study on the Implications of Asynchronous GMO Approvals for EU Imports of Animal Feed Products. Executed on behalf of Directorate-General for Agriculture and Rural Development, European Commission, http://ec.europa.eu/agriculture/analysis/external/asynchronous-gmo-approvals/index_en.htm.
- Library of Congress, 2013. Restrictions on GMO: China, http://www.loc.gov/law/help/restrictions-on-gmos/china.php#_ftn11.
- Nábrádi, A. and Popp, J., 2011. Economics of GM crop cultivation, http://ageconsearch.umn.edu/bitstream/104659/2/1_Nabradi__Apstract.pdf.
- Paoletti et al., 2006. Kernel lot distribution assessment (KeLDA): a study on the distribution of GMO in large soybean shipment.
- PFP, 2011. Primary Food Processors call for a rapid introduction of a technical solution extending the scope from feed only to food and feed, http://www.pfp-eu.org/data/PFP%20Position_on_LLP_food_Final%20_2_.pdf.
- Promar International, n.d.a. GM-analysis project. Segregation of supply chain. Report prepared for Defra, http://archive.defra.gov.uk/environment/quality/gm/crops/documents/foodmatters-supplychain-1308.pdf.
- Promar International, n.d.b. GM analysis project. Supply chain segregation. Literature Review. Report prepared for Defra, http://archive.defra.gov.uk/environment/quality/gm/crops/documents/foodmatters-literature-review-1308.pdf.
- Renaldi, R., 2009. The cost of Low Level Presence of GMOs in food products in Europe An impact assessment based on RASFF 2009.1037 and 2009.1165. Landmark Public Policy Advisers Europe.
- Roïz, J., 2014. Limits of the current EU regulatory framework on GMOs: risk of not authorized GM event-traces in imports. FEDIOL, http://www.ocl-journal.org/articles/ocl/pdf/2014/06/ocl140037-s.pdf.
- Silva, J. F., 2014. Brazil. Agricultural Biotechnology Annual, 2014. USDA GAIN Report, http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Brasilia_Brazil_7-8-2014.pdf.
- Solae, 2010. Maintaining the EU's comprehensive and integrated approach on food and feed with regards to the low level presence (LLP) of genetically modified material in raw materials.

- Stein, A. J. and Rodríguez-Cerezo, E., 2009. The global pipeline of new GM crops: introduction to the database. European Commission, JRC-IPTS, http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=2199.
- Stein, A. J. and Rodríguez-Cerezo, E., 2010. Low-Level Presence of New GM Crops: An Issue on the Rise for Countries Where They Lack Approval. European Commission, Joint Research Centre (JRC), Institute for Prospective Technological Studies (IPTS), http://www.agbioforum.org/v13n2/v13n2a08-cerezo.htm. The Dutch Soy Coalition, 2014. Soya Barometer. http://soycoalition.org/wp-content/uploads/2014/04/Soja-Barometer2014_NL_FINAL2.pdf
- Tillie, P., and Rodríguez-Cerezo, E., 2015. Markets for non-Genetically Modified, Identity-Preserved soybean in the EU, http://publications.jrc.ec.europa.eu/repository/bitstream/JRC95457/report.pdf.
- Tillie, P., Vigani, M., Dillen, K. and Rodríguez Cerezo, E., 2012. Proceedings of a workshop on "Market for non-Genetically Modified Identity Preserved crops and derived products", http://ftp.jrc.es/EURdoc/JRC76117.pdf.
- Trapman, S., Burns, M., Broll, H., Macarthur, R, Wood, R. and Zel, J., 2009. Guidance document on measurement uncertainty for GMO testing laboratories, https://ec.europa.eu/jrc/sites/default/files/eur22756en.pdf.
- USDA, 2014. Genetically engineered varieties of corn, upland cotton, and soybeans, by State and for the United States, 2000-14, http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx.
- USDA, 2015. USDA Agricultural Projections to 2024, http://www.usda.gov/oce/commodity/projections/USDA_Agricultural_Projections_to_2024.pdf.
- Van Broeckhoven, C., Lah Turnsek, T., Wood, R. and Schiemann, J. 2013. Impact analysis of the Joint Research Centre's activities for the regulation of GMOs in the European Union, http://www.epsoweb.org/file/1436.
- Van Gelder, J. W., Kuepper, B. and Vrins, M., 2014. Soy Barometer 2014. A research report for the Dutch Soy Coalition, http://www.bothends.org/uploaded_files/document/2Background_research_report_Soy_Barometer_2014.pdf.
- Varacca, a., Boccaletti, S. and Soregaroli, C., 2014. Economic Aspects of Segregation between GM and Non-GM Crops in Italy, http://www.agbioforum.org/v17n2/v17n2a03-boccaletti.htm.
- Vogel, S., 2014. EU supply and demand: crops, origins, challenges and current questions marks. Presentation of COCERAL, Annual General Meeting, 2014.
- Yankelevich, A., 2014. Argentina. Agricultural Biotechnology Annual, 2014. USDA GAIN Report, http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Buenos%20Aires_Argentina_8-15-2014.pdf.

EW-04-15-862-EN-N

Publications Office

doi: 10.2875/762184