



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

Executive summary

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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 accuracy¹ 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
<p>A.1. <i>How many official food samples are tested annually for presence of asynchronous and obsolete GM material in the Member States?</i></p> <p><i>Which asynchronous and obsolete GMO events are tested?</i></p>	<p>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.</p> <p>The types of asynchronous and obsolete GM events tested vary. They include: LLRICE 62, Soy A5547-127, DP356043, DP 305423, MIR604, MON88017 and MON89034.</p>
<p>A.2. <i>What sampling procedures are implemented for the presence of asynchronous and obsolete GM material in food in the Member States?</i></p>	<p>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.</p>
<p>A.3. <i>Does the lack of harmonisation of sampling procedures have any impact on the reproducibility of test results (within and between Member States)?</i></p> <p><i>Have Member States ever had practical experience on that?</i></p>	<p>Competent authorities are split on whether the lack of harmonisation of food sampling procedures has an impact on the reproducibility of test results.</p> <p>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 States². Fifteen respondents in 13 countries indicated that there are no impacts. The remaining five consultees did not respond.</p> <p>Respondents in five Member States had practical experiences of impacts on the reproducibility of test results between or within 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.</p>

¹ 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.

² Multiple options could be selected by respondents.

Study question	Conclusions
<p>A.4. <i>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)?</i></p>	<p>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.</p>
<p>A.5. <i>Does the lack of harmonisation in the interpretation of test results have an impact on compliance assessment (within and between Member States)?</i></p> <p><i>Have Member States ever had practical experience on that?</i></p>	<p>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.</p> <p>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.</p> <p>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.</p>
<p>A.6. <i>Would the definition of a Minimum Required Performance Limit affect protocols of testing?</i></p>	<p>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.</p>
<p>A.7. <i>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?</i></p>	<p>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.</p> <p>A majority also expect that setting a MRPL would result in beneficial effects that include improved comparability of results.</p> <p>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.</p>

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
<p><i>B.1. What are the sampling, analysis and risk management strategies and protocols applied by food business operators regarding asynchronous and obsolete GMOs?</i></p> <p><i>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?</i></p>	<p>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.</p> <p>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 downgrading³ food products to feed status.</p> <p>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.</p> <p>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.</p>
<p><i>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?</i></p>	<p>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.</p>
<p><i>B.3. Does the lack of harmonisation of sampling and analysis for official controls for the presence of</i></p>	<p>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.</p>

³ 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
<p><i>asynchronous and obsolete GM material affect food business operators at EU level?</i></p> <p><i>If so, what are these impacts?</i></p>	<p>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.</p>
<p><i>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?</i></p>	<p>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.</p>
<p><i>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?</i></p>	<p>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.</p>

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
<p><i>B.6. Does the harmonisation of testing and sampling, or the lack of harmonisation thereof, affect consumers in the EU? If so, how?</i></p>	<p>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.</p> <p>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.</p>

