JRC evaluation

IMPACT ANALYSIS of the Joint Research Centre's activities for the regulation of GMOs in the European Union

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FOREWORD by the Director General

A few months ago I asked to prepare an evaluation report on the impact from JRC activities supporting EU regulations for genetically modified organisms. The current comprehensive and detailed compilation of impacts of our work very much responds to my expectations: it gives a deeper insight into the substance and the achievements of the JRC's activities in this specific area.

I am particularly pleased that the report puts well in evidence the JRC's experience to set up a network of European laboratories to support EU food-and-feed regulations using sophisticated DNA-based test methods. The flavour of excellence from this network with Member States' laboratories contributed to the recognised quality of the control and test procedures.

Applying this experience in other fields emerges from the report as a possible challenge for the JRC. Setting up a network of highly specialised national laboratories could indeed become necessary to organise regulatory oversight in certain parts of the developing bioeconomy as well as in the domain of public health. Regulation with standardised methods and reference materials can and should improve the reliability of diagnoses in our health care systems of the future, for instance through a much higher accuracy of the growing number of molecular genetic tests carried out every day for patients and families with specific inherited conditions.

Along those lines I look forward to further developing the JRC activities in this technological field full of promises for the EU citizens in the society of tomorrow.

I am very grateful to Christine Van Broeckhoven, Tamara Lah Turnsek, Roger Wood and Joachim Schiemann, who put their expertise at our disposal in the Steering Group of this evaluation. Their experience with the JRC resulted in an effective piece of work with an objective judgement on the results achieved.

Dominique Ristori
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EXECUTIVE SUMMARY

In line with the Commission's intention to pay more attention to the European added value of its interventions, this report presents an analysis of impacts and results from the JRC's scientific and technical support for the implementation of the EU regulations for genetically modified organisms (GMO). The report is complementary to the mandatory evaluations of the EU Research Framework Programmes. A Steering Group of independent external experts accompanied the preparation of the report and helped to carry out the analysis in an objective way.

The JRC activities

Over the last 20 years the JRC has built up a specialised laboratory infrastructure to validate procedures for detecting and measuring the concentration of GMOs in food and feed, to harmonise the tests and verification methods, and to produce the necessary reference materials for the various methods. Since 2003 it operates the designated EU Reference Laboratory (EURL) for GMOs, implementing the necessary verification tasks through the European Network of GMO Laboratories (ENGL).

The JRC is also involved in a number of foresight and socio-economic research activities, such as operating the European Coexistence Bureau and building a methodological framework to define precise socio-economic indicators for monitoring the impact of the cultivation and use of GMOs in the EU together with the Member States.

These activities serve a variety of stakeholders and beneficiaries, ranging from the European Commission, the EU Member States, third countries, international standardisation bodies and industry, ultimately through to the consumers in the EU.

Impacts

During a first decade (>1991) of scientific support the JRC supported Commission services with scientific and technical tasks to underpin the content of early legislation for GMOs with a small number of staff. The intangible impact of this work is that it laid the technical foundation for the sophisticated GMO legislation and the organisational solutions to enforce the regulations later on.

The impacts of the substantial support activities in the second decade (>2001) has been analysed with the help of an evaluation matrix. This resulted in seventy-two entries of significant impacts in the policy, technical, (socio-) economic domain. They range from: quality assurance for GMO analysis achieved EU-wide, via certified reference materials, international standards, the effective protection of consumer's interest, all the way through to having kept the adverse effects of complex legislation on international trade in food and feed to a minimum.

As three most characteristic impacts the report presents:

- The existence of a technical infrastructure in the EU that allows harmonised implementation of GMO legislation and regulations, including the availability of certified reference materials
- EU-wide agreed coexistence measures in national legislation to avoid the unintended presence of GMOs in conventional and organic crops based on objective data concerning the socio-economic aspects of GMOs
- The technical clarification of the EU zero-tolerance policy; an impact of which the history is elaborated in the case study in the report.

Expert conclusions

The overall impression of the Steering Group experts is that JRC invested responsibly and adequately in this area with significant impacts of its work. Moreover the quality of the work is confirmed in a recent external assessment of all twenty-six food and feed reference laboratories in the EU, which assigned the highest performance status to the JRC's EURL for GMOs.

They support the quantitative assessment in the report showing that the JRC achieved these results at a reasonable cost with recovery of a large part of the direct expenses. Hence the work is qualified as "efficient".

The experts feel that the JRC is operating according to its institutional mandate for GMOs by not involving in risk-assessment, which is the role of EFSA. On the same note, promoting a higher public acceptance of GM (or otherwise produced) food and feed is not a subject for the JRC, even though various stakeholders express the wish that it would do so.

Bringing the various views on future use of JRC expertise in this field together, the experts encourage the JRC to develop future activities along three lines:

- **Continue on-going activities**

  Maintain the analytical capacity of the EURL-GMO fostering the global dialogue on analytical techniques for the detection of GMOs, monitoring GMOs in the pipeline for commercial use, and organising the exchange of technical and scientific information between Member States and the Commission regarding the socio-economic implications and impacts of GMOs. These JRC tasks have been arranged through EU legislation.

- **Improve strategies and methods**

  The developing bioeconomy is bringing innovation through a number of new (bio) technologies. As part of its strategy for the future the JRC should establish advanced analytical methods and verification measures for enforcement of regulatory oversight where needed.

- **Bring science to policy making**

  Having organised the EU-wide harmonisation of DNA-based testing for the implementation of GMO regulations, the JRC is in a position to bring science to other policies for the harmonisation and regulation of the increasing number of applications of genetic testing in society, most notably for public health purposes.

To release resources for developments beyond the continuation of on-going activities the experts suggest investigating possibilities for outsourcing routine parts of legally arranged technical work.

1. INTRODUCTION

In 2011 the Joint Research Centre prepared a comprehensive report[1] on the European added value and impacts of JRC activities with the help of a group of external experts as underpinning for the proposals of the Horizon 2020 Framework Programme. In their commentary the external experts encouraged the JRC to carry out also some impact analyses on specific thematic activities to give more visibility to the impact of JRC scientific support for policies and policy subjects in the EU.

Following this the Director General of the JRC decided to launch an impact analysis of the JRC's work for the regulation of genetically modified organisms (GMO) in the European Union, a well-defined support area where:

- The European Commission developed an extensive legislative framework for GMOs for the interest of the citizens and consumers in the EU since the 1990s. From the early stages in the development of this framework the JRC has invested significant resources to provide scientific and technical support to the development and implementation of this framework on a permanent basis.

- The Commission's Directorate General for Health and Consumers recently published external evaluations[2] of the above-mentioned legislative framework. The conclusions of these evaluations are generally critical regarding the current implementation of the legislation due to "a complex set of factors, both external and internal to the authorisation process". Hence it is now timely to make a comprehensive analysis of the impact of JRC's activities in the various processes required within the EU.

- Innovative developments in biotechnology require an update of the JRC's position in this field in the run-up to the Horizon 2020 Framework Programme. More specifically the Commission defined its new political priorities in a strategy for a sustainable bio-economy in Europe[3]. This should orientate JRC's activities further, in light of achieved results and established impacts.

GMOs are used in agriculture, in biological and medical research and for the production of chemicals, biofuels and pharmaceutical drugs. The applications in agriculture for food and feed are the best known and most discussed[4]. This is also the area for which JRC activities matter most.

Whilst safeguarding consumers' choice between GM or otherwise produced food, the Commission is seeking a safe and sustainable integration of this relatively new technology and its products into society. The JRC provides harmonised technical control standards and measures that can be used to enforce the regulations for this purpose. Hence, this JRC report is not about the impact of GMOs, GMO

1 http://ec.europa.eu/dgs/jrc/downloads/jrc_eval_report_2011_08_impact_analysis.pdf, Impact analysis of the Joint Research Centre and its direct actions under the EU Framework Programmes (2011), EUR 24942 EN, ISBN 978-92-79-21258-1

2 http://ec.europa.eu/food/food/biotechnology/evaluation/docs/evaluation_gm_report_en.pdf
Evaluation of the EU legislative framework in the field of GM food and feed, Final report 2010
http://ec.europa.eu/food/food/biotechnology/evaluation/docs/gmo_cultivation_report_en.pdf
Evaluation of the EU Legislative Framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) no 1829/2003, and the placing on the market of GMOs as or in products under Directive 2001/18/EC, Final Report 2011

3 COM(2012)60 final, "Innovating for Sustainable Growth: a Bioeconomy for Europe"

4 The World Health Organisation (WHO) published a comprehensive list with twenty frequently asked questions at http://www.who.int/foodsafety/publications/biotech/20questions/en/, in response to questions and concerns from member state governments with regard to the nature and safety of GMOs and GM food.

legislation or its enforcement. The report is about the JRC's support to EU policies in the field of GMOs. It addresses the impact and effects of JRC activities on relevant policies, legislation and their implementation.

To ensure an objective view on the results the JRC asked a Steering Group of external experts to accompany and assess the impact evaluation. The members of the Steering Group have a good knowledge about the organisation and its activities related to GMOs and some participated in earlier evaluations of the JRC.

In Chapter 2 the report defines the scope of the analysis, describes the framework and the methodology of the analysis. Chapter 3 describes the general setting and the relevant JRC activities. Chapter 4 introduces the various impacts and results including a case study of how the JRC's work played a role in the various stages of development and implementation of a recent GMO regulation. Chapter 5 addresses possible future orientations in view of evolving new plant and animal breeding technologies. Finally, in Chapter 6 the experts of the Steering Group comment on the findings of the impact analysis and summarise their conclusions.

2. SCOPE AND METHODOLOGY

The overall goal of the analysis is to present policy makers, budget authorities and stakeholders a comprehensive view of JRC's achievements and impacts related to the regulation of GMOs in a twenty-year retrospective time frame. The analysis also serves as input for future JRC evaluations mandatory in the EU's Framework Programme for Research and it should help orientating future JRC activities in this field.

2.1 Scope of the analysis

The analysis addresses the JRC's support to the conception, development and implementation of the GMO legislation since the early 1990s. For the first ten years EU legislation addressed GMO issues on an ad-hoc basis and the JRC provided scientific and technical support with a handful of staff. The analysis includes a qualitative assessment of the impact and results of the support during this period. As of 2002 the EU adopted new comprehensive legislation for GMOs and the JRC had and still plays a key role in the implementation of this legislation. The impact of the work in this period is the main subject of analysis.

It concerns the JRC as the European reference laboratory (EURL) for GMOs, networking those official control laboratories in the Member States, as the European Coexistence[5] Bureau and as producer of certified reference materials. These tasks have a crosscutting character:

- Involving the capacity and skills of three JRC institutes respectively in Ispra (Italy), Geel (Belgium) and Seville (Spain) to carry out the various activities in support of the European Union's GMO policies;
- Supporting GMO-related aspects in policy areas, such as Agriculture, Health and Consumers, or Environment, and to be in close contact with the responsible Directorates General of the European Commission;
- Using both theoretical and practical expertise in multiple disciplines like biotechnological analysis and engineering, as well as socio-economics.

Hence the analysis examines the impacts of all JRC activities related to GMO regulation which are described in Chapter 3.

The analysis is not about the impact of GMOs or GMO legislation, which are not produced by the JRC. It is also outside the scope of this evaluation to investigate to what extent JRC-validated test and control measures are being used in the national inspections, since the implementation of the measures is the responsibility of National Competent Authorities in the Member States' (see Figure 1 on page 16).

2.2 Methodology

The methodology for the impact report combines desk research including a case study, expert panels, interviews and questionnaires.

2.2.1 Desk research

As first part of the analysis, the regulatory environment and the various responsibilities within this environment were compiled using internal desk research. Then the specific JRC activities were identified with an indication of

[5] The term "coexistence" in the context of GMOs refers to the following issue: To meet the principle that consumers, farmers, and businesses have freedom of choice to use or not to use GM products, it must remain possible to produce foods without GM material notably on the long term. Therefore, GM plants must be grown and handled in a way to prevent uncontrolled mixing with conventional products. The European Commission has provided a set of guidelines to achieve this, based on technical advice from the European Coexistence Bureau managed by the JRC.

Intervention logic			
1	**Service delivered by the intervention**	**Output**	
2	**Initial change attributable to the intervention**	**Result**	**Impact**
3	**Further long-term change attributable to the intervention**	**Outcome**	

Table 1. Key concepts in Commission's intervention logic

the associated human and financial resources, as well as their stakeholders and beneficiaries. Since the activities related to the regulation of GMOs are spread out over different actions in the JRC Work Programme, all elements had to be brought together to allow the evaluation of this group of actions as a kind of business unit.

A JRC internal scientific knowledge management database records qualitative evidence of achievements and impacts for all its actions. This provided the necessary information to accumulate the total output, results, impacts and invested resources since 2003. The results are summarised in an impact evaluation matrix modelled on the intervention logic as applied in the Commission (see Table 1). The activities carried out in this area develop over time in interaction with policy makers as a function of their needs. Hence, this logic is not completely determined in advance, but it has to be reconstructed retrospectively with the benefit of hindsight.

The resulting evaluation table (given in Annex 1) displays a comprehensive view of the JRC's overall impact related to the regulation of GMOs, distinguishing different kinds of impacts tailored on the JRC with its mission of scientific support to EU policies:

- **Policy impact**, e.g., specifications or study results are used in official EU policy documents or contributions to the implementation of EU policy or legislation[6].
- **Technical impact**, e.g., delivering of more effective tests, more accurate measurements, user innovation and service innovation, new scientific insight or technical knowledge.
- **Economic impact**, e.g., direct through outsourcing and spin-off, or through the development or purchase of special products; indirect by savings through more precise measurement methods and systems.
- **Intangible impact**, e.g., enhanced European cooperation; exchange of staff; learning, training of non-JRC staff; enhanced science and scientific knowledge in policy proposals.

The same four impact categories have been used in the general impact study1 of JRC activities. The report quantifies technical and economic impacts where possible, respectively with technical performance statistics and financial estimates. Other impact categories relating to environment, health or social consequences are not considered here. For the JRC impacts in these categories are usually indirect.

2.2.2 Survey

The analysis used the survey technique to verify the impacts. In total 108 stakeholders/ partners in JRC's activities related to the regulation of GMOs received the following three questions:

Q1: Do you know one or more examples of where and how JRC's GMO-related activities had an important impact in your area over the last 10 years? If yes, please give a short description.

Q2: Could you attribute European added-value and/or scientific benefits to JRC activities related to GMOs? If yes, please give a short description.

[6] Policy impact usually denotes consequences and effects from the implementation of a policy. The JRC uses the term in a different sense: "policy impact" is achieved when JRC activities strongly interact with the EU policy-making process and leave verifiable traces.

Q3: Please describe your possible expectations or ideas for future JRC activities related to GMOs or novel biotechnologies in general?

It is noted here that 83 of the addressees are associated with the JRC's laboratory-based "analytical GMO network", whilst 25 of the addressees are linked with the JRC's "socio-economic GMO network". The two networks gave completely non-overlapping responses to the open-ended questions, which corroborated a dichotomy of JRC work related to GMO regulation in "laboratory-based" and "non-laboratory-based" activities.

In total 33 addressees returned responses:

- 21 through the "analytical network" of national GMO laboratories (ENGL);
- 12 through the "socio-economic network" of the European Coexistence Bureau, including EuropaBio (the European biotechnology industry association), the European Plant Science Organisation (EPSO) and the European Consumers Organisation (BEUC - Bureau Européen des Unions de Consommateurs).

The responses for the first two questions confirmed and complemented desk-study results in the impact evaluation table, substantiating and validating references for the impact of the work. The most important aspects of the JRC's main impact are given in Chapter 4. The responses to the third question have been incorporated in Chapter 5.

2.2.3 Case study

The Steering Group agreed that a more detailed study to highlight different impacts should focus on "the JRC's role in the establishment of a regulation to implement zero-tolerance policy in practical terms for GM material for which an authorisation is pending or has expired in the EU". The narrative of this case study is presented in Chapter 4.3.

2.3 Discussion on future activities

The motivation for this impact analysis was primarily to establish an ex-post account for policy makers, budget authorities and stakeholders. Nevertheless, the analysis was also meant to include a prospective element to contribute towards the seven-year research agenda of JRC under the Horizon 2020 Framework Programme.

Therefore the future of JRC's activities in this field is discussed along scenarios that followed from the responses to the third survey question. The need to project technological developments into the future required some desk research to mark the trends in new plant and animal breeding technologies as well as in biotechnology in general.

Further explanations from colleagues in the customer Directorates-General in the Commission, private communication with stakeholders and the guidance of the Steering Group experts helped to identify societal and policy needs and to focus the discussion on the key issues.

3. THE JRC'S ACTIVITIES FOR THE REGULATION OF GMOs

This Chapter presents the context of the JRC's support to the regulatory environment, the various responsibilities within this environment, the specific JRC activities with an indication of the associated human and financial resources, as well as the stakeholders and beneficiaries of the JRC activities.

3.1 The context

Biotechnology nowadays permits the characteristics of an organism to be changed in a controlled way by directly inserting new genes or by modifying the way in which existing genes operate. The resulting genetically modified organisms (GMOs), combine desired traits from often-unrelated species and may bring for instance a higher yield, a higher nutritional value or have a stronger resistance to certain diseases.

International protocols[7] address the global requirement that new GM crop varieties should be safe for use as food or feed and should not harm the environment. Thus, throughout the world a GMO requires explicit authorisation to enter the market under broadly similar regulatory frameworks and with equivalent recommended biosafety assessments. However, the effective working of the GM-authorisation systems is the combined result of the consumers', industry's, food-control authorities' and government's approaches to GMOs. These approaches may be quite different and so the regulation and authorisation systems are not uniform throughout the world.

The regulation of GMOs in the European Union serves three main objectives:

- To respect tight, i.e. cautious safety standards for health and the environment.
- To safeguard consumers' choice between GM, organic and traditionally-produced food.
- To ensure the functioning of the internal market, i.e. once authorised, GM products can be placed on the market anywhere in the EU.

Within the EU the risk-assessment and risk-management tasks associated with the introduction of GMOs in the agro-food chain and the verification of compliance with the stringent regulation is distributed according to the diagram in Figure 1. It gives an overview of key players in the regulation of GMOs in the EU with their main responsibilities.

The full set of regulations addresses the development of GMOs (the laboratory part of which is not addressed here), the stepwise introduction into the environment, the general cultivation and seed production and the whole agro-food chain, up to the consumption by humans and animals.

When GM crops are cultivated physically near to conventional crops, natural cross pollination between the two may cause mixing. To ensure the availability of GM-free conventional crops also in the future (see footnote 5 on coexistence), such unintentional mixing should be avoided. For this purpose the European Commission has drawn up guidelines for the development of national strategies and best practices to ensure the coexistence between GM crops and conventional and organic farming.

Individual Member States are responsible for organising official inspections to verify compliance with the legal requirements. This includes compliance with labelling legislation

[7] The Cartagena Protocol on Biosafety annexed to the UNEP's Convention on Biological Diversity obliges UN members the safe handling, transport and use of GMOs. Since 2008 the Codex Alimentarius Commission joint FAO/WHO Food Standards Programme is trying to elaborate guidelines on the labelling of food derived from modern biotechnology.

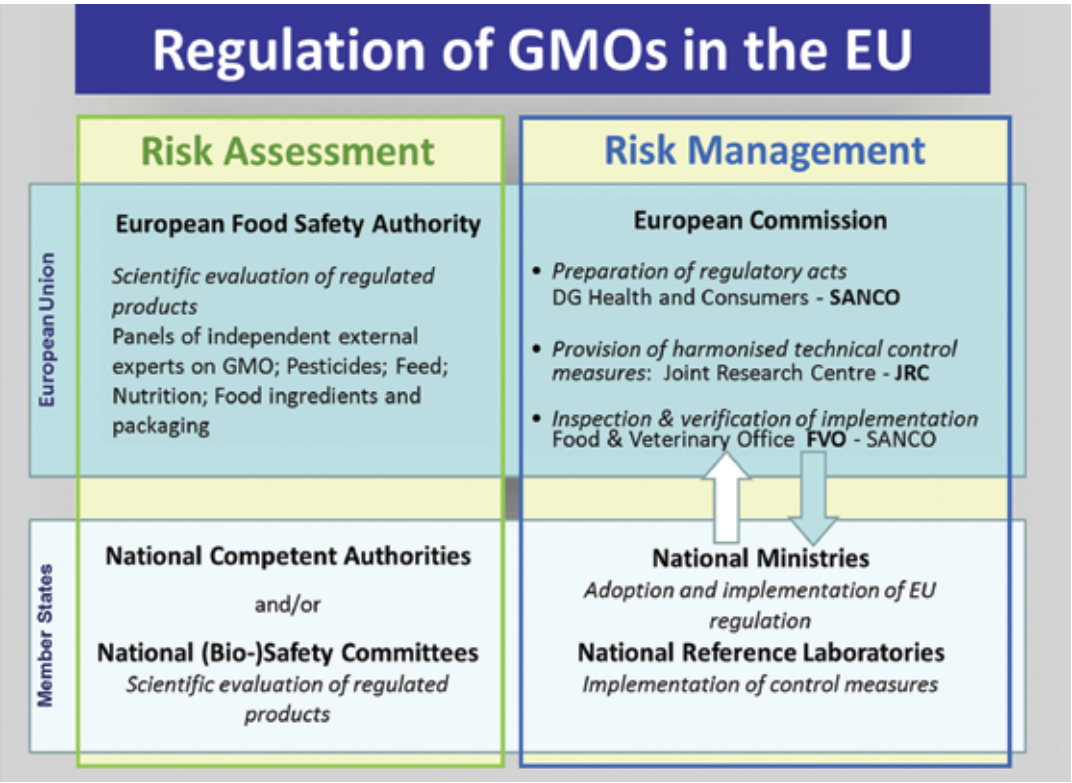

Figure 1. Overview of key players in the regulation of GMOs in the EU with their main responsibilities

and detection of not-yet-authorised and non-authorised GMOs on the market (see text box on the different authorisation statuses on page 17). Initially, there were no effective instruments available for an EU-wide enforcement of GMO regulations. However, since the adoption of the first legislation twenty years ago, the JRC has gradually developed a control-laboratory infrastructure with validated techniques and tools that would allow the regulations to be satisfactorily enforced.

Whilst the regulatory environment continued to develop, the JRC received and assumed responsibilities to bridge the crucial gap between the existing regulations and the technical ability and capacity to enforce them[8].

3.2 Responsibilities

With the advent of GMOs in the 1990s the JRC proactively supported the European Commission with the establishment of EU policies for GMOs. With its direct-research activities, it helped shaping, amending and streamlining the regulatory system to make the technical aspects of its implementation feasible. In this process the JRC received some well-defined responsibilities as EU reference laboratory (EURL), laid down in different regulations. The JRC has clustered the EURL responsibilities (described in the textbox on page 18) under one common denominator: EURL-GMO.

Thus the EURL-GMO has to take special care that the best test methodologies are available for official inspections in the Member States' National Reference Laboratories (NRLs). Via their Competent Authorities these NRLs also report anomalies (e.g. non-conformities) to the EU Rapid Alert System for Food and Feed (RASFF). This alert system has existed since 1979 to exchange information between Member States' Authorities in case of food and feed incidents.

Of the approximately eight thousand alerts per year, well over one hundred cases[9] are related to the detection of GMOs. The JRC follows the alerts, acts as referee in dispute settlements between Member States concerning the results of inspections and plays a mitigating role in case of the release of non-authorised GMOs on the market.

Whereas the JRC is responsible for developing and putting the standards in place, it is not responsible for enforcement within individual Member States. The National Authorities implement an enforcement strategy through their nominated National Reference Laboratories using methods validated by the JRC according to international standards (see also Figure 1).

[8] The JRC compiled all EU legislation on GMOs from the beginning of the 1990s until 2010: "The EU legislation on GMOs, An Overview", 2010, JRC Report EUR 24279, ISBN 978-92-79-15224-5

[9] The rapid alert system for food and feed (RASFF): Annual Report 2010

Different authorisation statuses of GMOs from an EU perspective

Authorised

Authorised GM material is allowed on the EU market. Authorisation mostly concerns the import of GMOs and their use in food and feed. The EU rarely grants authorisation for the cultivation GM crops.

Non-authorised

Four different cases can be distinguished for GM material not authorised on the EU market.

- **Asynchronous authorisation:** one or more food and feed exporting countries (e.g. USA, Brazil, Argentina) authorised a new GMO for commercial use, while a decision for authorisation in the EU is pending.
- **Authorisation expired:** the time-limited authorisation period of the GMO has passed the expiry date without renewal.

  If analytical tests indicate traces of GM material with a concentration below 0,1%, then the feed shall not be rejected from the market (cf. Commission Regulation (EU) 619/2011 and case study in Ch. 4.3).
- GMOs that are **not subject of any official procedure in the EU.**
- GMOs **authorised for laboratory experiments or field trials** are typically not authorised on any market.

  If analytical tests indicate the smallest trace of a GMO belonging to these two categories then the feed is not allowed on the EU market.

Certified reference materials are essential for the enforcement of legislation as they are required in the GMO authorisation process and to be used in conjunction with the detection and inspection methods. The JRC produced the world's first certified reference materials for GMO quantification in food and feed in 1999, and today is one of the leaders in the preparation and production of certified GMO reference materials for food and feed analysis.

Regarding the socio-economic aspects of GMOs, the JRC operates the European Coexistence Bureau. The Bureau is responsible for the definition of commonly agreed, EU-wide technical segregation measures between GM, conventional and organic agriculture to assist Member States in the development or refinement of their approaches to coexistence. In this context there is also a growing need to capture the socio-economic consequences of the cultivation of GMOs, from seed production to consumers, across the European Union. Together with Member States' representatives the JRC is building a methodological framework to define precise socio-economic indicators for long-term monitoring with the appropriate rules for data collection.

The JRC is involved in the dissemination of information related to GM cultivation and international trade, which are Commission responsibilities under different regulatory acts. Examples are the on-going publication of all field trials[10] carried out in the EU and its role as focal point for the Biosafety Clearing House (BCH) established under the Cartagena Protocol on Biosafety (cf. ref. 7). The clearing house facilitates the world-wide exchange of scientific, technical, environmental and legal information on, and experience with GMOs.

The JRC does not carry out basic or applied research for the development of new GMOs. GMO risk assessments and biosafety assessments are beyond its direct remits. GM pharmaceuticals are addressed by the European Medicines Agency (EMA).

[10] http://gmoinfo.jrc.ec.europa.eu/

JRC laboratory-based activities support two major elements of GMO regulation in the EU

Authorisation for marketing of GM food and feed

Here the JRC's prime responsibility is to validate an analytical method for measuring the concentration of the GM products for which the notifier has submitted an authorisation request to the competent authorities in the EU.

Regulation (EC) No 1829/2003 nominates the JRC as "European Union reference laboratory" to be assisted by the "European Network of GMO laboratories", a consortium of national reference laboratories. Annex 3 presents a schematic view of the authorisation procedure with the JRC's tasks in this; today it has validated and published 72 methods.

Compliance with labelling and zero-tolerance policy in the EU

Here the JRC's prime responsibility is to coordinate and supervise all technical aspects in the control of food and feed concerning the presence of GMOs. This includes the detection of GMOs that are not authorised in the EU.

Regulation (EC) No 882/2004 lays down the general tasks, duties and requirements for all (currently twenty-six) EURLs for official controls performed to ensure the verification of compliance with feed and food law. The regulation nominates the JRC as EU reference laboratory for GMOs and Member States appoint their National Reference Laboratories (NRLs).

Like EURLs in the other areas, major tasks of the EURL-GMO are to:

- Provide national reference laboratories with details of analytical methods, including reference methods,
- Organise comparative tests with the National Reference Laboratories (NRLs) appointed by individual Member States,
- Organise training and advanced courses for NRL staff.

3.3 JRC capacity and activities

With a total number of staff around 3000 people and an annual budget of the order of EUR 400 million the JRC provides scientific and technical support to EU policies across the board. It has supported aspects of GMO legislation since the mid-1990s using the scientific and technical capacity and skills at the different sites of the JRC.

This report distinguishes two kinds of scientific support activities relate to GMOs, depending on the nature of the work:

- **Laboratory-based activities** to undertake the role of the EU-reference-laboratory with its responsibilities for test validation, analytical-data quality assurance, including development of methods for inspection, as well as all the work associated with the production of certified reference materials as stipulated in the EU legislation (see text box on this page).

- **Non-laboratory-based activities** consisting of socio-economic analysis and foresight related to the cultivation and use of GM crops in general and the European Coexistence Bureau in particular (see text box page 19).

Many of the tasks are carried out in conjunction with networks of technical representatives and/or laboratories in the Member States.

Over the years the JRC has made the investment to develop accredited laboratory facilities in the GMO sector with the appropriate specialised equipment, infrastructure and staff. Specifically,

JRC non-laboratory-based activities support socio-economic aspects of GMO regulation in the EU

Coexistence measures for GM and non-GM crops

Here the JRC acts as European Coexistence Bureau. The Bureau collects and coordinates relevant information based on on-going studies at EU and national level and to offer technical advice to assist interested Member States in establishing national approaches to co-existence.

The activity initiated following Commission Recommendation 2003/557/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming and was recently confirmed in Commission Recommendation 2010/C 200/01.

- The JRC is running the EU Reference Laboratory for GMOs in Ispra, which validates analytical test methods for detecting, identifying and measuring the concentration of GM products. Through the NRLs it ensures that official control laboratories in the Member States have available to them and use the same state-of-art methods and achieve comparable levels of proficiency with their tests for the presence of GMOs.

- The EURL-GMO has to carry out laboratory-based in-house research work to underpin its validation and verification activities, whilst most EU reference laboratories mainly operate as an administrative unit. Therefore the JRC employs much more staff than the average EU reference laboratory.

- The EURL-GMO organises and coordinates a network of Member States laboratories, the European Network of GMO Laboratories (ENGL), which implements the control tasks. The network is an indispensible part of the EURL's resources. The EURL-GMO reimburses the NRLs for the participation in interlaboratory trials and supports the NRLs fully for their costs incurred for participation in method validation exercises.

- In its metrology laboratories in Geel the JRC produces certified reference materials according to strict ISO criteria for certified reference materials (CRM) producers (i.e. to ISO Guide 34 "General requirements for the competence of reference material producers"). They are amongst the few laboratories in the world capable of producing and certifying GMO reference materials according to the demanding standards of this Guide.

- The socio-economic research aspects of the JRC's activities are much less resource intensive, since they do not require in-house laboratory work. A few staff is operating the European Coexistence Bureau at the JRC in Seville, overseeing research, studies and foresight related to the cultivation and use of GM crops and building a methodological framework to define precise socio-economic indicators that should be monitored.

3.4 Resources, output, results, stakeholders and beneficiaries

The average annual direct costs for the JRC's activities for the regulation of GMOs calculated during the period 2007-2011, are:

- Direct expenses of around EUR 1,7 million per year from the JRC institutional budget, largely for the laboratory-based activities and EUR 0,2 million for the socio-economic work, all excluding staff cost;

    - Received revenues of around EUR 1,5 million per year almost entirely from the laboratory-based activities in the form of fees for the validation of detection methods[11] and revenues from sales of certified reference materials;

[11] The application fee for a test validation is EUR 90.000 for an industrial GMO and EUR 45.000 for an SME or for applicants from developing countries. The relevant National Reference Laboratories receive 30% of the fee as contribution for their share in the work.

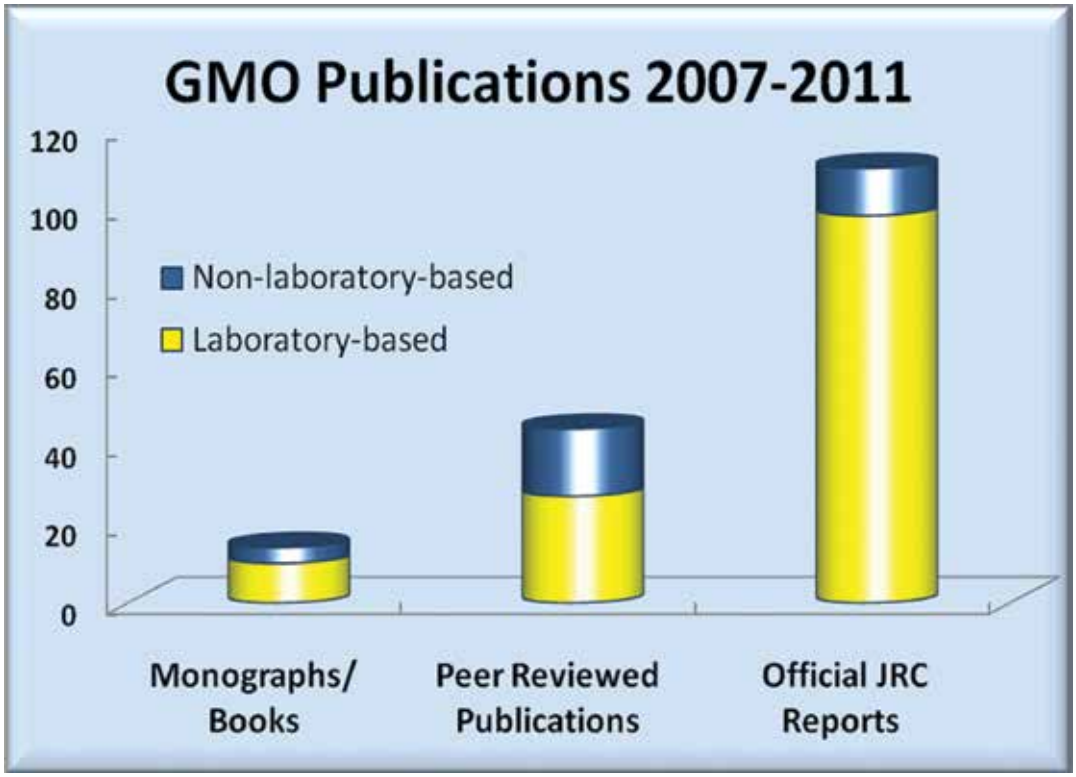

Figure 2. Number of scientific peer-reviewed publications, scientific and technical reports and books related to GMOs published by the JRC in the period 2007-2011

- A number of staff members averaging at 47 full time equivalent (FTE) persons[12] of which 41 on laboratory-based activities.

Over the last 20 years the accumulated staff total is slightly less than 400 FTE persons and these have been concentrated in the period after the adoption of the legislation in 2003 with the creation of the EURL-GMO (the total accumulated before 2003 is less than 30 FTE persons).

Currently resources to support GMO regulation represent slightly more than 1,5% of the JRC's total resources (financial, staff). The laboratory-based activities are more labour intensive with higher associated running costs than those for the socio-economic (bureau and study) activities; however, the running costs of the GMO-laboratory activities are comparable to the costs sustained for other areas using laboratory facilities. All together, these activities constitute a significant effort for the JRC for which the revenues from the laboratory activities cover the variable cost of the operations.

The collective output and results from the relevant activities are given in Annex 1 in an evaluation table with the JRC's key objectives, achievements and results together with selected major impacts.

The JRC has published several hundred scientific technical articles and reports related to GMOs. Specifically, in the five years from 2007 to 2011 it published about 49 articles in ISI-journals and 110 technical reports relating to the validation of a specific method, the production of a reference material, new approaches to (test) methods, cultivation methods, or about new technologies and trends in plant biotechnology. Figure 2 shows the distribution between the laboratory-based and the non-laboratory-based activities. Annex 2 lists the scientific papers in peer-reviewed journals during 2007-2011; these to offer an impression of the JRC's activities in this sector.

A broad range of stakeholders benefit from JRC activities related to GMOs schematically represented in Figure 3 with EU citizens in the background as ultimate beneficiaries. Besides the European Commission services, the European Food Safety Authority (EFSA), the EU Member States and third countries, the JRC also supports international standardisation, i.e., notably the "Codex Committee on Methods of Analysis and Sampling (CCMAS)" of the Codex Alimentarius Commission, established by the FAO and the WHO as well as the European and the international standard development organisations CEN and ISO[13].

[12] Number of full-time equivalent (FTE) persons, as distinguished from the (usually higher) number of persons assigned to the various actions (head counts)

[13] CEN, the European Committee for Standardisation and ISO, the International Standardisation Organisation

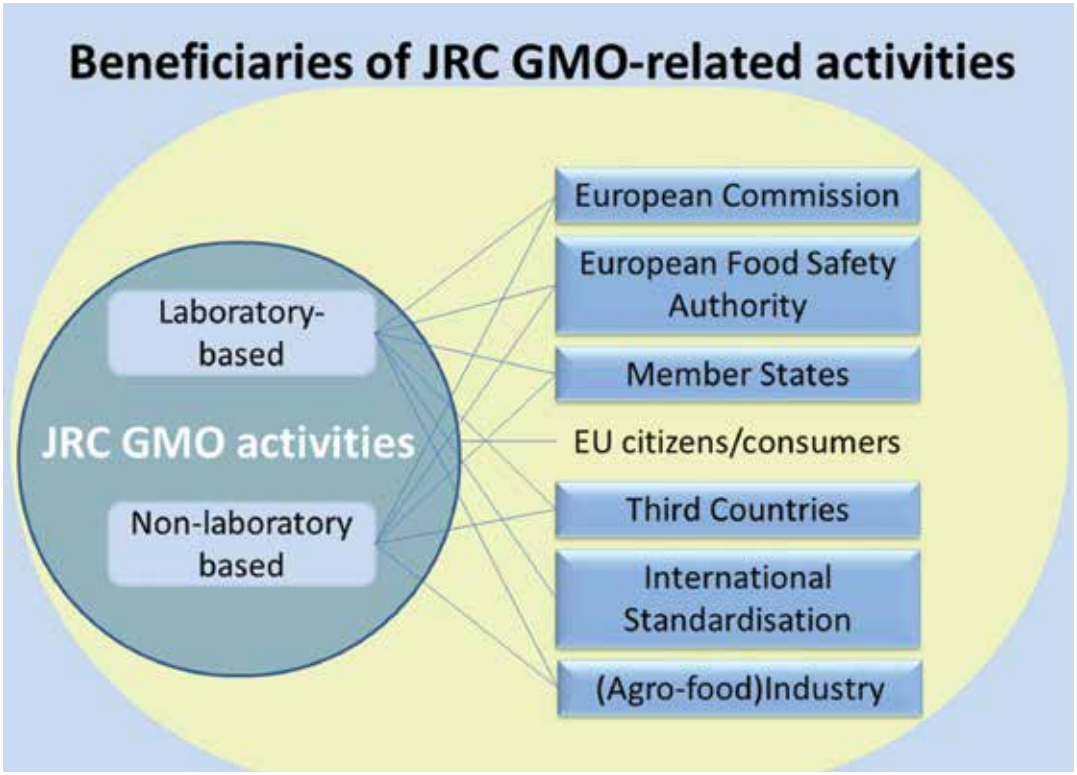

Figure 3. Stakeholders and beneficiaries of JRC's GMO activities

In the EU authorisation process, all applicants need to include a detection method for the relevant GM-product in their application file. It is a regulatory requirement, which takes precedence over any intellectual property considerations and is mandatory to enable the JRC to validate the submitted detection method and to allow NRLs to use them. Industry cooperates with the JRC to achieve validation, which has led to a fruitful relation with the agro-food industry. Similarly, the JRC prepares certified reference materials meeting the requirements of the legislation from materials provided by the biotech companies, whilst fully respecting their intellectual property right.

Through its non-laboratory-based work, notably through socio-economic impact assessments the JRC covers the whole chain, namely farmers (households), consumers, upstream and downstream sectors (seed, feed, food industry) as well as the trade sector.

4. IMPACTS OF JRC ACTIVITIES FOR THE REGULATION OF GMOs

4.1 Results and impact from the early activities

Since the 1990s the JRC tracked scientific progress in the field of GMOs and followed their stepwise arrival on the market in close contact with Commission policy makers, who framed the regulatory environment.

As early as 1991 the JRC developed a GMO Register with information on all field trials of specific GMOs carried out in the EU. This register is maintained even today and can be accessed via the Internet[10]. From these days also stems the JRC's role as the Commission's focal point for the Biosafety Clearing House (BCH) under the Cartagena Protocol on Biosafety (see Ch. 3.2).

These technical administrative tasks of the JRC developed into more technical support tasks when the labelling of GM food became mandatory by the time that some GMOs had been authorised on the market. It then became clear that technical measures to enforce the regulations were not initially available and GMO legislation needed further refinement to keep pace with the developments in the field.

Around the year 2000 the range of technologies used for the production of agro-food included mainly traditional technologies used for selective breeding and a few new biotechnologies with a focus on the new GM-technology placed under strict regulatory oversight (cf. Figure 4).

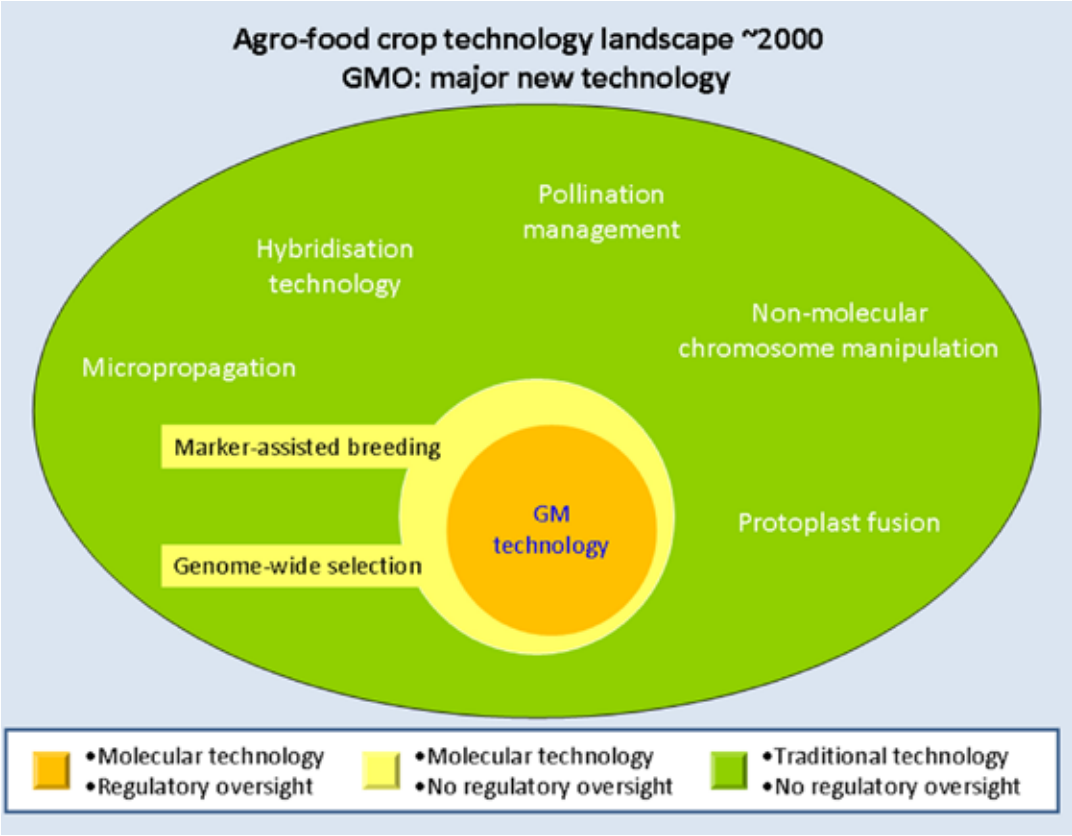

Figure 4. The agro-food technology landscape around 2000 with the introduction of strict regulatory oversight for products obtained with GM technology.

JRC started a state-of-the-art study[14] in 2000 at the request of the Commission's Agricultural Directorate General. In view of the increasing commercial cultivation of GMO crops it concluded on some important needs, i.e.:

- To make analytical determinations of GMO presence in food and agricultural products possible and reliable by the use of internationally validated and approved methodologies and standards,

- To find appropriate measures at the farm level to minimise the chances of the adventitious or technically unavoidable presence of GM crops in non-GM crops and in the environment,

- To develop procedures to monitor and verify the presence and the amount of GMOs in crops for food and feed.

As of 2001 the Commission put in place new authorisation procedures that confirmed the JRC's technical mandate to support the policy process. Whereas several national and international organisations were involved in developing harmonised guidelines and standards for sampling strategies and GMO detection methods, the legislation appointed the JRC to organise the technical coordination of the key law-enforcement instrument in this field.

The involvement of the JRC with a small number of staff from the early days that GMOs entered on the market, helped policy makers to develop sophisticated GMO legislation predicated on the use of advanced technologies, some of which had not even been fully demonstrated or yet available. Thus with a small team the JRC influenced the technical content of the proposed regulatory system and laid the foundation for continued effect later on.

At the same time the JRC was working on the technical and organisational solutions to enforce new legislation, together with a network of reference and official control laboratories in the Member States and an EU-wide availability of validated methods and certified reference materials. These intangible aspects of providing indispensable technical contributions to the definition of complex regulations characterise the first decade of JRC's activities related to GMOs.

4.2 Survey results and consolidated impacts

Since the adoption of new comprehensive legislation for GMOs between 2001 and 2003 the JRC has some well-defined roles as the European reference laboratory (EURL) for GMOs, as the European Coexistence Bureau with its foresight and socio-economic activities and as producer of certified reference materials. All output and impact records of this work have been stored systematically in internal performance databases, which are the basis of the impact evaluation-table in Annex 1. This evaluation table is at the heart of the analysis and is constructed on the model of the intervention logic applied in the Commission (cf. Table 1 on page 12).

Major impacts from the work have been verified through a survey amongst key stakeholders. The survey responses have been analysed using the dichotomy of the laboratory-based "EURL-GMO network" and the non-laboratory-based "socio-economic network", which introduces a pragmatic distinction, i.e. the former is associated with a large, resource-intensive and complex technical system, whereas the non-laboratory-based socio-economics and foresight requires a much smaller effort in terms of resources.

The results of the survey are given in Table 2 presenting the Top-10 impacts identified in the responses from the analytical network. Harmonisation of the test methods (70%) and the existence of the underlying network of GM laboratories (61%) were mentioned most frequently. This high frequency of occurrence in responses to the open-ended questions supports the reliability of the identified impacts.

The survey responses explicitly refer to the model role of the EU in GMO detection and analysis, with the EURL leading in GMO detection and global capacity building. Of the EU respondents 60% identified the JRC's key roles in technical guidance and 33% in training. The presence of enough laboratories with high competence in this field is undoubtedly linked to the technically advanced requirements of GMO legislation in the EU and the accompanying quality assurance system put in place by the EURL-GMO with its various interlaboratory and training activities.

[14] Report EUR 20394: Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture (2002), http://ftp.jrc.es/EURdoc/eur20394en.pdf

Top-10 Impacts of JRC's activities Survey "analytical network" 23 responses (15 from the EU)	Percentage of all responses	EU only
Harmonised test methods for implementation of official control	70%	67%
ENGL, networking, and usefulness of background documents	61%	80%
International capacity building, including 1st global conference	48%	40%
Comparative testing and support to accreditation	48%	40%
Technical discussions and guidance	43%	60%
Certified reference materials and/or control samples	39%	47%
Training	39%	33%
Participation in research projects	22%	33%
Compendium of reference methods	17%	27%
Direct support to NRLs	17%	27%

Table 2: Top-10 impacts of laboratory-based activities related to GMOs

The high-performance status of the EURL-GMO has been confirmed in a recent external assessment of the twenty-six EU reference laboratories in the field of food and feed[15]. Here the JRC's EURL-GMO was one in the top three EURLs assessed as "A", because of its excellent performance on all the assessed criteria. The other twenty-three all received a lower performance level.

The survey had a high return from the socio-economic network with twelve responses on an open-ended questionnaire, i.e. from more than half the surveyed population. Although the diversity in responses was high, it showed a clear impact top five, given in Table 3. The impact on national legislation comes out as the key impact with 67% of the partners in this network mentioning it. This result

Top-5 Impacts of JRC's activities Survey "socio-economic network" - 12 responses	Percentage of responses
Impact on national legislation (coexistence, new breeding technologies)	67%
Impartial studies/reports, science-based, raising awareness	42%
Reference for compilation of economic impacts	25%
Provision of an international forum for public discussions	17%
Database of field trials as reference to assess Member States' activities	17%

Table 3: Top-5 impacts of socio-economic activities related to GMOs

[15] Evaluation of the EURLs in the field of food and feed safety and animal health and live animals, Final Report, 2011, Part I: Evaluation report, Prepared for DG SANCO under framework contract for evaluation and evaluation related services - Lot 3: Food Chain

Primary impacts from JRC activities related to GMO regulations

Policy Impacts (i.e. effects on policies)

- Harmonised technical implementation of EU legislation for GMOs
- Feasibility demonstration of a technologically advanced law-enforcement system with state-of-the-art biotechnological instruments and methods
- Translation of the zero-tolerance norm into analytically meaningful significance for new GM-regulation
- Agreed coexistence measures in national legislation
- Fostering international dialogue on GM policy

Technical Impacts

- Well-developed GMO-analysis capacity in Member States
- Quality assurance for GMO analysis, resulting in a higher accuracy and precision with less false-positive and false-negative test results
- Development of international standards
- New methods and new approaches to GMO analysis

Intangible Impacts

- International recognition of JRC GMO expertise
- Open dialogue with all GMO stakeholders
- An environment of trust with policy makers, industry and the public

(Socio-) Economic Impacts

- Protection of EU consumers' interest by making the implementation of GMO legislation technically feasible
- Pragmatic and reliable implementation of the stringent regulations, minimising adverse effects on international trade in food and feed

demonstrates the complementarity of the survey, since this impact did not appear as prominently in the JRC's own impact assessment records.

Having integrated the survey results in Annex 1, the impact evaluation-table shows fifteen high-level objectives with fifty-three high-level outputs generating seventy-two consolidated impacts. The latter have been regrouped as twenty-three policy impacts, twenty-nine technical impacts, six (socio-)economic impacts and fourteen intangible impacts. Further integration of these impacts led to fourteen major impacts of the JRC's activities for the regulation of GMOs, which are listed in the charts on page 26.

The overall high-level impacts have been identified as:

- The existence of a technical infrastructure in the EU that allows harmonised implementation of GMO legislation and regulations, including the availability of certified reference materials
- The existence of agreed coexistence measures in national legislation to avoid the unintended presence of GMOs in conventional and organic crops based on unbiased data concerning the socio-economic aspects of GMOs
- A technical clarification of the EU zero-tolerance policy

A large number of impacts are qualitative and linked to policies as expected in view of the JRC's mission. Nevertheless, there are significant impacts of a scientific/technical, as well as socio-economic nature. The latter relates to more indirect effects of the JRC's activities. Intangible impacts concern a position of trust in the support for the development of the regulatory environment for this complex technical field.

4.3 Case study on the implementation of the zero-tolerance policy

Since 2003 the EURL-GMO and the network of National Reference Laboratories together serve the test and verification system necessary to implement the regulations for GMOs in food and feed. However, the technical constraints and analytical difficulty in detecting small concentrations of GM material continued to create uncertainties in the test and verification system, in particular because of the zero-tolerance policy regarding non-authorised GMOs.

In 2011 the Commission tackled these uncertainties in a regulation to harmonise the methods of sampling and analysis for the official control of feed, thus ensuring that comparable samples should lead to the same analytical result and conclusions in all EU countries. The regulation also fixes the lowest level of presence (LLP)[16] of GM material above which all official control laboratories can reproduce their results, if they use the prescribed methods of sampling and analysis.

The case study below elaborates the evolution towards this often-called "LLP regulation" in a narrative, highlighting technical contributions from the JRC.

Feed imports mixed with "non-authorised GMOs"

- The EU imports large amounts of soybean and maize products as essential supplements for its livestock sector. These imports mainly come from Brazil, Argentina and the US, third countries where GMO cultivation is authorised and widespread in addition to traditional agriculture.
- The distribution systems in these countries handle products with GM material for which the EU authorisation procedure is still pending; a case of asynchronous authorisation as explained in the textbox in Chapter 3.1. There are precautionary measures in place to avoid the presence of the locally (home) authorised GMOs in exported commodities for the EU. Nevertheless, it is practically impossible to prevent extremely small traces of a non-authorised GMO in a bulk shipment of maize or soybean.
- The asynchronous authorisation in combination with a zero-tolerance policy meant that the EU had to reject shipments of imported agricultural products from major exporting countries if the EU monitoring system detected the smallest indication of the presence of a non-authorised GMO.

Potential economic damages

- In 2007 the Commission's Directorate-General for Agriculture and Rural Development contracted a study[17] on the eco-

[16] "Low Level Presence" is jargon for the accidental presence of small amounts of GM material in an otherwise traditional agro-food commodity.

[17] Economic Impact of Unapproved GMOs on EU

nomic impact of potential interruption of soybean/meal imports from USA, Argentina, and Brazil. It calculated a rise of the feed expenditure and a longer-range risk of shortages in feed supply for the EU as important consequences of any import interruption. These shortages would also affect the pig-meat and poultry sectors with a substantial reduction in production, exports and consumption. It would lead to a strong increase in meat imports and a drop of exports down to zero.

- A report for the Confederation of the Food and Drink Industries of the EU (CIAA) studied two concrete LLP incidents, involving soy protein from the USA with traces of GM maize not authorised in the EU. It quantified costs for the food industry between EUR 2 million when the incident is contained at shipment level and EUR 400 million in a worst-case scenario where the affected ingredients have been incorporated into finished food products involving retailer and consumer recalls[18].

- The International Food & Agricultural Trade Policy Council recently published a report[19] underscoring the complexity of a full analysis of economic impact from LLP. Completed empirical studies are all ex-ante; no ex-post study could be traced in the literature. The proceedings[20] of an international workshop convened by the JRC flagged similar caveats for economic impacts of GMOs worldwide. Notwithstanding this as well as the absence of hard economic figures, LLP rejections have negative economic effects for all parties concerned.

The pipeline study

- In late 2008 the JRC convened a group of experts to establish a list of GM crops in the pipeline that may be commercialised in the short-to-medium term. The experts included national regulators, representatives of private technology providers, scientists from public research institutes, and stakeholders of the agro-food supply chain from all major countries where GM crops are developed or cultivated.

- Subsequently the JRC compiled a list of GM crops in the pipeline for marketing worldwide in the short-to-medium term up to 2015. This was done for the seven crops for which GM varieties already exist or are likely to be marketed in the near future (soybeans, maize, rapeseed, cotton, sugar beet, potatoes and rice). The ensuing report[21] counted that there are about 33 GM crops with a different transgenic background commercially cultivated during 2008. This number would grow to more than 120 by the year 2015 based on the information provided by the experts.

- The results of the pipeline study have been used to link the growing number of GMOs becoming available outside the EU with an expected increase in asynchronous authorisations. Combined with a zero-tolerance policy this could lead to an increasing number of LLP issues[22] with increasing prospects of disturbances of international trade in agro-food and negative economic consequences for the EU[23].

The uncertainty of random checks in the EU

- At least as important as this potentially increasing number of GMOs on the market was an inherent uncertainty in the measurement result of random checks. Since not every food-control laboratory achieves the same accuracy and precision when carrying out its analysis, especially at low concentrations, the same sample with small

Feed Imports and Livestock Production, 2007 http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf

18 The cost of low-level presence of GMOs in food products in Europe http://foedevarer.di.dk/sitecollectiondocuments/landmark%20llp%20study%20final%209%20oct%202009final%20dok929981.pdf

19 "The Economic Impacts of Asynchronous Authorizations and Low Level Presence: An Overview", 2011, http://www.agritrade.org/Publications/documents/LLPOverview.pdf

20 Proceedings International workshop on socio-economic impacts of genetically modified crops co-organised by JRC and FAO, EUR 25265 EN (2012) http://ftp.jrc.es/EURdoc/JRC69363.pdf

21 "The global pipeline of new GM crops; implications of asynchronous approval for international trade", 2009, JRC report , EUR 28346

22 Stein, A.J., & Rodríguez-Cerezo, E. (2010). Low-level presence of new GM crops: An issue on the rise for countries where they lack approval. AgBioForum, 13(2), 173-182.

23 Implications of Asynchronous GMO Approvals for EU Imports of Animal Feed Products, 2010, Study executed for the Directorate-General for Agriculture and Rural Development http://ec.europa.eu/agriculture/analysis/external/asynchronous-gmo-approvals/index_en.htm

traces of GM material may be tested as being positive (present) in one laboratory and negative (not present) in another. This was already creating unpredictable situations for food and feed business operators on the EU market.

- Indeed the JRC established that the test results obtained by the application of the Regulation (EC) No 1829/2003 on GM food and feed were not sufficiently comparable. Inspectors were using different methods of taking test samples for the detection of GMO traces in batches of feed material and laboratories reported results with different accuracy and sensitivity, thus resulting in different interpretations of analytical results. Small differences in sampling technique or analytical characteristics could generate opposite conclusions as regards the compliance of a product with the regulation.

- The European Commission noticed at the highest level that unpredictable outcomes of random checks by the competent authorities in the Member States exposed the EU and its internal market. Commissioner Fischer Boel for instance confirmed this in 2009 in a public speech[24] showing understanding for the problems of European importers of soybeans who repeatedly could not get approval for their soya to be released from the docks. The EU needed to harmonise random checks with consistent quantitative measurements at the levels of presence for legally unambiguous rejection.

The conception and development of the Regulation

- In these circumstances Commission services started to sharpen up rules for checking feed imports on the containment of traces of not yet authorised GMOs. JRC experts elaborated technical elements of these proposals, defining how to measure quantities of GM material different from zero in a consistent manner. This resulted in standardised methods for sampling, standardised analytical procedures, certified reference materials and rules for the interpretation of results from the analytical tests.

- As a result the JRC specified a numerical level at which there is sufficient technical and analytical certainty that feed material contains a certain GMO. This level was set at a mass fraction of 0,1%. This means that measured mass fractions smaller than 0,1% do not prove the presence of the GM material with certainty and that the inspected product complies with EU rules to be allowed on the market.

- The 0,1% threshold is a clarification of the Commission's zero-tolerance policy where this is possible, i.e. for non-authorised GMOs for which an authorisation is pending and for which the EURL (JRC) completed the validation of the quantification method.

- The Commission's proposal was formally adopted[25] on 24 June 2011 and clarified the technical specifications in legal requirements as follows:

  - It sets a numerical threshold at 0,1% for GM material in feed for which an authorisation procedure is pending or the authorisation of which has expired;

  - It takes the measurement uncertainty in consideration when assessing compliance and specifies that it should be calculated according to the guidelines issued by the JRC;

  - Measurements may only be made with methods validated by the EURL-GMO;

  - The proposed legislation only applies to GM material for which certified reference material is available.

- JRC Guidance document[26] on Measurement Uncertainty for GMO testing laboratories is the basis for an annex to the Regulation on the interpretation of analytical test results.

- Currently eight GMOs fulfil the requirements laid down in the regulation and since the adoption in 2011 there have been no alerts about the presence of these GMOs.

[24] "GMOs: letting the voice of science speak", speech Mariann Fischer Boel, Member of the European Commission responsible for Agriculture and Rural Development http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/09/474

[25] Commission Regulation (EU) No 619/2011 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.

[26] http://www.irmm.jrc.be/html/reference_materials_catalogue/user_support/EUR22756EN.pdf

5. FUTURE SUPPORT RELATED TO GM/BIOTECH-CROPS LEGISLATION

For the past twenty years, JRC support to the regulation of GMOs in the EU steadily grew into an activity of around 50 FTE persons[12] operating at a cost of around EUR 1,7 million per year largely recuperated from Nºtification fees and revenues from certified reference materials. This chapter adds a prospective view to the analysis, which projects possible scenarios for exploitation of JRC's expertise in this field for the seven-year research agenda under the Horizon 2020 Framework Programme.

GM crops are of considerable socio-economic interest. At global scale the area of cultivated GM crops has progressively increased to 160 million hectares[27] in 2011. This represents around 10% of the global land area used for crop production and has a commercial value of the order of EUR 100 billion. Whilst GM crops rarely receive authorisation for cultivation in the EU, their import is significant.

Hence GM crops have their place in the agro-food sector and GM technology keeps its place amongst the fast evolving agro-food crop technologies. However, this is no longer the place as a dominant new technology of ten years ago (Figure 4). The landscape of currently available technologies (Figure 5) is much more complex with a variety of new molecular technologies.

Current legislation and control measures focus on GM technology and its products, but a key

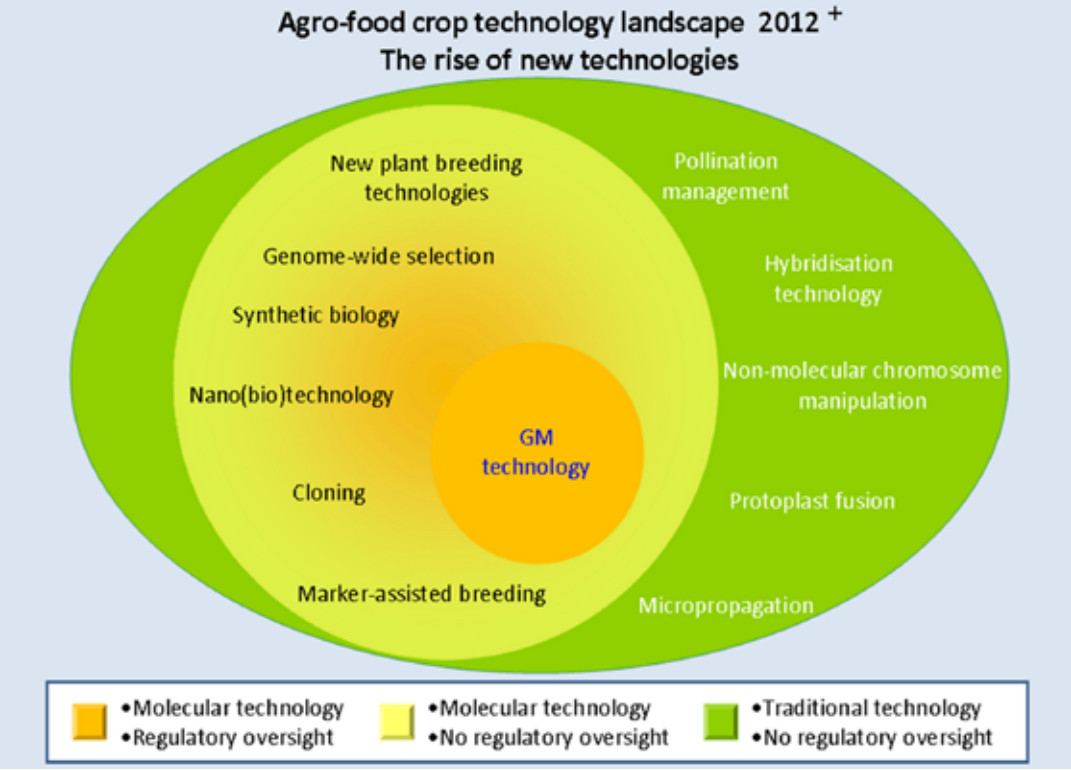

Figure 5. The developing technology landscape shows a steadily growing number of molecular technologies. Only GM technology has a clear regulatory oversight, whereas the situation for other molecular technologies becomes increasingly blurred.

[27] ISAAA Brief 43, Global Status of Commercialized Biotech/GM Crops: 2011

Future appliance of JRC competence in this field Survey Q3: 33 responses	Mentioned in percentage of the responses
Continue on-going activities: coordination, networking, training; maintain leadership, organise conferences	52%
Improve strategies and methods including for non-authorised GMOs; consider new technologies including new plant breeding technologies	36%
Communication; bring science to policy making	15%

Table 4. Suggested future directions in the responses to the survey

question for the future is what will happen to these new molecular technologies and their products in terms of governance also in the broader perspective of the bioeconomy. Today practically every new technology and every new product is submitted to regulation, not only in the agro-food sector. Therefore crops produced with the new techniques - in the blurred zone of Figure 5 - may also require (or merit) some form of regulatory oversight plus an enforcement system with methods to detect the new products in food and feed[28].

When the distinction between GM and other plant biotechnological techniques becomes blurred, it is no longer clear whether the products of these techniques are, or should be subject to new regulations or to GMO legislation (indicated by the fading colour in Figure 5). Detection of these new products will require analytical methods and instruments more powerful than the first-generation instruments currently deployed to support GM regulations. A strategic question is to what extent the JRC should be involved in the development of second-generation analytical instruments.

When an analytical test cannot distinguish products produced by certain new molecular technologies from products produced by conventional breeding techniques or by natural genetic variation, then it will be impossible to detect their presence. Such products are likely to exist in the future and it will be *de facto* impossible to regulate them on the market.

Against this background the stakeholder survey included a last question concerning possible expectations or ideas for future JRC activities related to GMOs or novel biotechnologies. Table 4 shows the headlines of the responses, which are used to structure reflections on the future and addressed below as lines of action.

"Business as usual": continue on-going activities

Continuation of current JRC activities is the direction most frequently quoted by those presently involved with the various JRC networks. Half of the respondents expects a "business as usual" scenario as baseline for the JRC.

An extrapolation of the average workload over the last eight years (included in Annex 3) indicates a stable number of new GMOs notifications per year[29] for which the EURL validates the analytical test methods. In addition the need for trustworthy socio-economic information on GMO/biotech crops continues. Those two points (should) constitute the baseline for the planning of the JRC. It means the intention to

- Maintain the analytical capacity of the EURL-GMO with scope to foster a global dialogue on analytical techniques for the detection of GMOs and monitor GMOs in the pipeline for commercial use;
- Continue the organisation and exchange of technical and scientific information between Member States and the Commission regarding the socio-economic implications and impacts of GMOs.

Improve strategies and methods, including for non-authorised GMOs

More than one third of the respondents suggested the JRC to prepare for future developments, improving strategies in view of the arrival of new technologies. Products of these technologies challenge governments and their regulatory oversight, which will require more-advanced analytical methods and control measures for enforcement. This line of

[28] Lusser, M., C. Parisi, D. Plan and E. Rodríguez-Cerezo (2012). Deployment of new biotechnologies in plant breeding. Nature Biotechnology, Vol. 30, 231–238.

[29] The number of new GMOs notifications per year is an indicator to measure the workload for the regulatory system and should not be confused with the much higher numbers in the pipeline study (cf page 30) which concern possible new GMO varieties that may or may not come on the market.

action involves novel thinking primarily in the approach to laboratory-based work, but it would also require a broader approach to prospective socio-economic analysis.

Several issues emerged from the survey and the various discussions, leading to the following listing of points, which need to be elaborated to anticipate the effects from on-going technological developments:

- New (often proprietary) technology platforms are bringing fast, versatile, highly automated technologies. Key-enabling technologies arrive on the market at ever increasing speed and lower cost[30]. The use of these platforms for GMOs is just one of their applications in the regulation of biotechnological products.

- The technologies will benefit advancement in completely new areas and generate new possibilities for industrial crops, where GM technology applications turn plants into production platforms for industrial and pharmaceutical products.

- The application of new plant breeding techniques has increased considerably over the last twenty years (see Figure 5) and nowadays most seed is harvested from crops that have gone through a passage in a molecular laboratory. Some of these techniques involve biochemical steps in which part of or whole genomes are synthesised. These crops may present new – yet unsolved – challenges for traceability.

Indeed, the landscape of plant and animal breeding technologies will change quickly and significantly. Adaptation of the regulatory framework will be needed to keep pace with these developments that affect detection limits, traceability and other requirements for enforcement of the regulations.

The increasing share of GM crops on the world market combined with the ever-higher sensitivity of detection methods is likely going to make it rare, difficult and costly to achieve complete absence of GM traces in certain crops. Improved strategies could deal with the ensuing question whether it is meaningful to check for the presence of GM material below 0,1% and address the need for and the consequences of setting different levels of impurity.

The survey mentioned a few times that the JRC could start working on non-authorised GMOs. It could for instance monitor the developments world-wide and recommend appropriate methods for their detection and identification. Still the responsibility to check their presence is with Members States' control laboratories, which prioritise their work to detect them.

From a more political, socio-economic angle the proposed focus on detection of non-authorised GMOs would benefit from a sound ex-ante impact assessment investigating the consequences for trade and food/feed supply chains and with proper assessments of risks from other unknown traces in feed/food commodities. There is room for proper modelling and socio-economic research related to GMOs and a view on practical implications for the introduction of screening methods for detecting the presence of non-authorised GMOs.

The desk research for this impact analysis produced several examples of conclusions from the use of statistical data with represent confusing socio-economic indicators (see annex 4). This report is not the place to elaborate the issue, but there is scope for clearing out inaccurate conclusions about the position of GM in the EU. An improved strategy needs to use meaningful indicators for the proper positioning of GMOs and other new biotechnologies in the context of the developing smart, sustainable and inclusive bioeconomy.

Communicating the facts, bringing science to policy making

15% of the responses with expectations for future JRC activities mentioned the communication of unbiased information on GMOs. The same message came across as a strong point of the JRC in related interviews. This choice was usually linked with an expectation that JRC's interventions could lead to a higher public acceptance of GMOs. However, the JRC has to play its proper role[31] and this is not engaging in socio/political processes that try to influence public acceptance of a specific technology.

Indeed, the JRC takes no position regarding safety assessments, which is the responsibility of others (Figure 1) and it does not promote one technology solution over others. Moreover, competent organisations like FAO, WHO or EFSA

[30] As an illustration: the first sequencing of a full human genome took several billion Euros and thirteen years (until 2003) in the Humane Genome Project http://www.genome.gov/11006943. In 2012 bench-top sequencers entered the market, designed to decode a human genome in a few hours for less than EUR 1000.

[31] JRC Guideline towards integrity and veracity in scientific support and advice, October 2006

provide ample communication about the safety of GMOs and there is a wealth of information on the subject in the scientific literature.

Hence, the JRC's well-defined responsibilities in the support of regulations (Chapter 3.2) are acceptable to both sides of the GMO debate. Work on socio-economic statistics is more susceptible to bias. Since the smallest departure from an objective presentation is perceived as bias, communication of unbiased information requires an additional effort.

Against this background communication efforts from the JRC can clarify issues within the realm of its responsibilities and the impact analysis revealed a number of them, i.e.:

- The need to **broaden the debate to cover the full bioeconomy.** The evolving technologies require a horizon beyond one technology for one application, here GM for crop improvement. There are many traditional and new molecular biotechnologies to improve crops. Similarly GM technology has many applications other than in the food sector. The JRC has the capacity to address the full spectrum of issues in the context of Commission's bioeconomy strategy with the possibility to communicate on regulatory and socio-economic aspects.
- The **importance of DNA-based diagnostics for law enforcement** related to biotechnologies (products). DNA-based diagnostics is the key instrument for the implementation of current and future regulations. The main impact of JRC's work (i.e. to make it possible to enforce the GMO regulations) completely depends on it. This delicate diagnostics has to be used by highly trained analysts in a consistent manner. Today this concerns the verification of food labelling by checking for the presence of GMOs. However, the emerging bioeconomy will need this expertise for the regulation of many other issues like the use of living organisms as production plants, food security, plant and animal health and in human health such as for medical diagnostics and personalised medicine. The EURL experience lends itself for communication to policy makers and to national enforcement bodies for application in this wide range of applications.

6. CONCLUSIONS BY THE STEERING GROUP

In accordance with our Terms of Reference (cf. Annex 5), we have accompanied the JRC's work preparing this Impact Analysis report and summarise our comments and conclusions regarding the various aspects of the analysis as follows.

6.1 The impact

As high-level impacts from the JRC's activities in the field of GMO regulation we retain:

- The current existence of a technical infrastructure in the EU that allows harmonised implementation of GMO legislation and regulations, including the availability of certified reference materials;
- The existence of agreed coexistence measures in national legislation to avoid the unintended presence of GMOs in conventional and organic crops based on unbiased data concerning the socio-economic aspects of GMOs;
- The technical clarification of the EU zero-tolerance policy.

In line with the mission of the JRC these impacts are mainly technical and policy related. They have been achieved thanks to the constructive relationship between JRC scientists and EU policy makers to create an environment of collegial trust within one public administration.

The value of this policy-support work is at the level of its enabling capacity for enforcement strategies. Such achievement is much more policy than economy oriented and we steered the analysis away from estimates of supposed economic impact. The economics of cost-benefit analyses cannot attribute a monetised value to these impacts.

Having seen the output and impact of the various activities, we judge the four assessment criteria that were proposed in our Terms of Reference as being:

- **European added value:** very positive. The JRC is running several European networks. Its EURL-GMO appointment is the driving force behind the EU control system. Its position within the Commission as being independent of national and private interest is key for bringing the benefits at EU level.
- **Scientific added value:** overall very positive. The science in the articles published is innovative, useful and well received by the scientific community. The expertise of the JRC is also useful in academic consortia that conduct research on GMO analysis and/or study coexistence measures as well as socio-economic modelling. We believe that the JRC expertise should help setting priorities in calls for the Commission's Research Framework Programme with a role for the JRC in certain projects.
- **Customer demand:** very positive. The activities respond to clear needs from the policy makers in the Commission. Member States and Third countries receive tools, training and assistance to be in a position to organise efficient controls and to manage effectively GMO cultivation along organic and traditional cultivation.
- **Relation with EU priorities:** mixed, but overall positive. Positive, because the activities are crucial for achieving the technical implementation of EU legislation. Mixed, because there are also many experts who consider that the successful implementation of this legislation is slowing down the work on another EU priority, i.e. innovation in agro-food production. We feel that any such effect should be attributed to the legislation, not to the JRC.

We notice that there is no information about the extent to which Member States carry out controls and use the array of test methods validated by the JRC. Although this absence is intentional, we believe that such information would be relevant and helpful to the JRC so that it may gain an indication of how the value of its work; it is also a measure for the effectiveness of the enforcement system as a whole. Such assessment would require the cooperation and the consent of the various parties in this system, i.e. the Commission with its Food and Veterinarian Office (FVO) and the Member States with their NRLs[32].

6.2 Efficiency considerations

Based on the resource analysis for the twenty-years of JRC support to EU policy and legislation related to GMOs, we make the following efficiency considerations.

- The laboratory-based activities are labour intensive and require specialised infrastructure. The investment in this work is proportionate compared to other efforts needing a laboratory infrastructure.

- Notification fees for test validation and revenues from certified reference material cover most of the direct project expenditure for the work.

- The JRC's non-laboratory-based activities related to socio-economic aspects of GMOs have a proportionally high impact in Member States and in the literature in view of the modest resources for this work.

The overall conclusion from this is that the JRC invested responsibly and adequately in this area.

The clustering of GMO/biotech activities fits in a policy-based prioritisation of JRC activities in the lead to the Horizon 2020 programme. A periodic analysis and reporting of the integrated GMO/biotech activities would benefit both the JRC and its stakeholders for better-informed decision-making during operations. Such reports would also facilitate future general evaluations and impact analyses of the JRC.

To position the JRC in line with the Commission's strategy for a sustainable bioeconomy in Europe, a further integration of the relevant JRC's activities and interaction with other molecular technology domains like for instance nano(bio)technology could be beneficial.

6.3 The survey

Regarding the outcome of the survey we note that many respondents have referred to a world-leading position for the EU in GMO analysis, measurement and detection. We share this observation and the JRC can take full credit for an instrumental role in achieving this position. The major push behind this success comes from the GMO regulations of the EU. As these are the world's most detailed and most stringent regulations, their enforcement also requires the best-developed technological support.

In the survey several disadvantages were attributed to the EU regulations for GM material, but these are unrelated to the work of the JRC.

We feel that the JRC should take advantage of its current global reputation to promote further dialogue in this area between the major organisations responsible for GMO analysis, and particularly within organisations such as the Codex Alimentarius Commission.

6.4 Future scenarios

The scenarios for developing JRC activities related to GM/biotech crops (Chapter 5) offer a useful framework to structure reflections and we recommend including the following ideas in this process.

"Business as usual"

This is a compulsory scenario as long as EU legislation prescribes the JRC's tasks in this field.

Regarding the test validation activities of the EURL-GMO we note that the common prospect of - at best - constant resources may not allow any significant change in direction. Since the workload involved with the notification of GMOs is not expected to change and the

[32] Note added in proof: The FVO regularly caries out audits in Member States to evaluate the control systems in place for food, feed and seed containing, consisting of, or produced from GMOs. To date the FVO completed five such audits, with the last report being published in October 2012. Although the audits have not investigated the efficiency of the control systems, all the audits concluded that an (adequate) control system is in place regarding GM food and feed. These systems use tests validated by the JRC.

responsibility for proper execution of routine control procedures continues, there will be no resources for activities at the forefront of science, which require consideration of any new developments.

Therefore we propose to investigate possibilities for outsourcing technical routine work to release resources to contribute to new developments in the two other scenarios.

"Improve strategies and methods"

- Products of new biotechnologies will challenge governments and their regulatory oversight. This concerns detection limits, traceability and other requirements for enforcement of regulations. With its experience as EURL-GMO, the JRC can investigate and report on these challenges.

- The regulatory framework will need adaptation to keep pace with the quickly changing technology landscape. It will also require more advanced analytical methods and control measures for enforcement. For this purpose the JRC should monitor new applications for the bioeconomy, as well as the development of new (often proprietary) technology platforms. The JRC could prepare novel thinking primarily on the approach to laboratory-based work, but it would also require a broader approach to prospective socio-economic analysis of GM/biotech crops.

- Establishing how and where the GMO-regulation experience can be applied for the benefit of the broader bio-based economy is a key challenge. We see potential for the JRC to use the EURL-GMO experience in the broader context of the bioeconomy strategy, for:

    - Transferring operational tools and technologies to other areas of biotechnological applications (e.g. clinical diagnostics, especially for genetic diseases or direct-to-consumer genetic testing)

    - Transferring operational tools and technologies to other EURLs (e.g. the EURL for meat and bone meal, or the EURL for E. coli).

    - Developing a European DNA-based diagnostics centre, covering a large analytical spectrum entirely based upon the DNA molecule as biomarker.

"Communication, bringing science to policy making"

It is understood that the JRC respects its scientific and technical responsibilities and that addressing socio/political questions of how to win the trust of the public for GM (or otherwise produced) food and feed stays outside this scope.

However, since the JRC has a highly developed competence in the field of DNA-based diagnostics, it could usefully communicate more on the use of this tool for regulatory oversight and extrapolate towards applications in the broader bioeconomy. We feel that this should be carried out using language which is readily understood by all stakeholders.

Furthermore, there is a need to use meaningful socio-economic indicators for GMOs and new biotech products to monitor the broad development of the bioeconomy. Unbiased communication of the facts from this technological innovation area, as well as the scientific arguments underlying the complex legislation, could build some bridges between the political and societal debates.

Trusted information about the development of new biotechnologies will benefit the development of a bioeconomy with new opportunities for science and innovation working for the benefit of higher goals like food security and the sustainable management of natural resources and climate.

ANNEX 1
Impact Evaluation table for JRC's laboratory-based activities for the regulation of GMOs

Objectives	Output/Achievement	Impact (result/outcome)	
Validation of GMO detection methods and provision of certified reference materials that allow for the detection, traceability and labelling of GMOs and for general market surveillance. These activities are mandatory under Regulation EC 1829/2003 and EC 882/2004	○ A set of validated detection methods for 72 GMOs all validated within the timeframe foreseen by the legislation since 2004 http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm ○ Guidance, explanations and expert advice for biotechnology companies on the exact requirements for the validation of the detection method, which made implementing procedures predictable and transparent http://gmo-crl.jrc.ec.europa.eu/guidancedocs.htm ○ "Method Acceptance Criteria" developed to ascertain that notifiers deliver a dossier that contains the necessary elements for an efficient and appropriate validation. ○ A Compendium, a Database and an Application for tablet PCs of all world-wide reference methods known for GMO-detection. http://gmo-crl.jrc.ec.europa.eu/gmomethods/ ○ Certified Reference Materials (CRMs) currently for 22 different GMOs (and for each GMO with different GMO contents), before the conclusion of the authorisation process and the marketing consent of GM products http://irmm.jrc.ec.europa.eu/reference_materials_catalogue/catalogue/Pages/index.aspx ○ Detection methods for GMOs in compound food and feed ○ Guidance document on "Measurement uncertainty for GMO testing laboratories"	○ The EU has a technical infrastructure that allows harmonised implementation of GMO legislation and regulations. ○ Practical demonstration of a biotechnological law-enforcement system with state-of-the-art instruments and methods; an example for the use of biotechnological analytical methods in support of regulations in other areas. ○ Major trade partners recognize the need for Identity Preservation in their agro food production chain and are able to apply recognised testing schemes for quality control, prior to export to the EU.	**Policy**
		○ Reliable test system enabled a large number of GM products to come on the EU market. Possible negative effects of GMO legislation on trade cannot be attributed directly to EURL activities. ○ Stakeholders have ample time to set up control procedures according to high-quality standards, thanks to timely availability of CRMs. ○ Faster control processes and therefore saving in waiting time for ships to unload; direct economic benefit for producer/trader.	**Economic**
		○ Reduction of both false-positive and false-negative test results in the EU from ~15% to 5% since 2002. ○ Control laboratories, importers and retailers have the tools and techniques necessary for the implementation of the legislative requirements. ○ The Codex Alimentarius took up the "Method Acceptance Criteria", i.e. in essence they are applied worldwide. ○ EURL guidelines are used for development of molecular DNA-based diagnostics for food-borne pathogens or for genetic testing ○ Harmonised estimation of measurement uncertainties provides the basis for correct evaluation and comparability of testing results	**Technical**
		○ A constructive dialogue with biotechnology industry that keeps them well-informed regarding the human and capital investments needed for efficient processing of their validation dossiers ○ Control laboratories operating with internationally agreed standards, and predictable and transparent procedures offer certainty to operators	**Intangible**

Objectives	Output/Achievement	Impact (result/outcome)	
Distribution of control samples (Reg. EC 1829/2003)	○ GMO plasmid control samples developed for each of the validated methods published since 2004. ○ Control samples developed for emergency measures regarding non-authorised GMOs ○ Production and distribution of control samples to National Reference Laboratories (NRLs) and to non-EU GMO control laboratories.	○ Implementation of legislation ○ Fast integration of newly published protocols in NRLs' control portfolio, as soon as detection method is validated. ○ Better implementation of Identity Preservation schemes related to exports to the EU, since many non-EU GMO control laboratories receive control samples.	**Policy**
		○ Higher precision of tests performed by NRLs.	**Technical**
Providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses (Reg. EC 882/2004)	○ Expertise and analyses of counter samples for referee purposes, i.e. so far one dispute among Member States, one court case and four second-opinion analyses. ○ Support to the Rapid alert system for food and feed (RASFF) network managed by the Commission. ○ Verified and/or validated and distributed detection methods to NRLs in case of an alert of non-authorised GMO in food. ○ Provided technical basis for all EU emergency measures issued so far (http://gmo-crl.jrc.ec.europa.eu/default.htm). ○ Scrutinised the content and quality of a large number of alerts issued by Member States through the RASFF.	○ Reduced number of false positive and negative results both from ~15% to 5% since 2002. ○ Harmonised procedures, e.g. fixed format to report for non-authorised GMOs.	**Technical**
		○ Prevention of undue product recalls, economic losses and trade disruptions.	**Economic**
		○ Proper implementation of complex regulations increases confidence in the EU regulatory system.	**Intangible**
Quality assurance of the EURL GMFF, the NRLs and the CRM production at JRC	○ ISO 17025 accredited for "General requirements for the competence of testing and calibration laboratories", is ○ ISO 17043 accredited for "Conformity Assessment - General Requirements for proficiency testing" ○ ISO 9001 certified for the global quality management standard. ○ Comparative testing rounds with ~100 labs (EU/non-EU ratio 4:1) done under JRC ISO 17043 accreditation twice per year ○ Assistance to underperforming laboratories. ○ ISO17025 training courses for and audits of NRLs. ○ GMO CRM production accredited according to ISO Guide 34 and ISO/IEC 17025 requirements ○ Annual training courses on the selection and use of reference materials	○ Accreditation enhances confidence in the operations of the EURL and of the NRLs ○ The accreditation of the dedicated reference-material production was the first demonstration in the world of a third-party competence assessment for GMO CRMs	**Policy**
		○ Harmonised GMO control laboratories throughout the EU, operating in similar facilities and meeting the required high quality standards ○ Enhanced performance of the laboratories e.g. reduced number of errors, reproducible results	**Technical**
		○ Worldwide incorporation of the JRC/EURL concept of quality assurance in the operations of GMO testing laboratories	**Intangible**

Objectives	Output/Achievement	Impact (result/outcome)	
Organise the European Network of GMO Laboratories (ENGL) as formalised in the context of Regulation 1829/2003	○ Management and chairing of the ENGL (all MS plus Norway, Switzerland, Turkey, Croatia are permanent member) since 2002, organising ○ Two plenary sessions of the network per year, two steering committee meetings per year ○ Series of working group meetings on topical technical issues. ○ Network extended with non-EU laboratories that applied for participation. Among the non-EU are important trade partners such as China, and are important Institutions such as EFSA and international associations such as the international seed association. ○ First Global Conference on GMO Analysis in 2008 attended by more than 600 international participants	○ Harmonised implementation of EU legislation	**Policy**
		○ Members of ENGL have set up joint research programmes and exchange programmes for staff. ○ New approaches, new ideas e.g. the development of a decision support systems for GM testing. ○ New technologies for ENGL members, e.g. digital PCR.	**Technical**
		○ Knowledge exchange leading to general enhancement of knowledge and enhanced capacities in the laboratories of ENGL members. ○ Leading role in GMO-analysis, example for regional networks (e.g. the South African Network of GMO laboratories, the Red Latino Americana de laboratorios de detección de OGM, and the ASEAN GM testing Network), ○ Example for networks in similar areas, e.g. the genetic testing community. ○ Prominence of the ENGL network: Enforcement laboratories have (inter)national visibility and receive support because of their recognised status.	**Intangible**
Capacity building for laboratories responsible for analysing feed and food in third countries Required under Regulation EC 882/2004	○ Fostering of regional networking through the organisation of workshops and training sessions, held in different regions of the world since 2009 ○ Participation of non-EU laboratories to JRC Proficiency Testing rounds and distribution of control samples to non-EU labs ○ Around 20 laboratories in the EU and 10 laboratories in Third Countries have been trained to achieve accreditation level	○ Global harmonisation of GMO analysis through information exchange and experience sharing with international control laboratories. ○ Targeting of EU support for instance through Commission's Technical Assistance and Information Exchange instrument (TAIEX) or the EU's Framework Programme for Research and Technological Development	**Policy**
		○ Education in complex analytical control systems. ○ Third countries set up the technical facilities of a GM control laboratory with national support because of links to EURL/JRC	**Technical**
		○ Increased awareness in third countries of the EU institutions, legislation and programmes as well as the procedures in place. ○ Motivation for third countries to set up agro-food control mechanisms based upon the same principles as used in the EU.	**Intangible**

Objectives	Output/Achievement	Impact (result/outcome)	
Conducting training courses for the benefit of staff from national reference laboratories and of experts from developing countries (Reg. EC 882/2004)	○ Various hands-on training courses in the EU as well as in other regions of the world. ○ Sizeable and extensive training material, such as ○ Laboratory manuals in several languages, ○ Audio-visual educational material e.g. on laboratory procedures or EU regulatory framework.	○ Offering relief in trade disputes (e.g. training Chinese experts in applying the necessary controls before export allows China to certify products correctly and block non-authorised export in China). ○ Raise awareness and public knowledge by training NGOs like Greenpeace and scientific journalists.	**Policy**
		○ Improved competence and skills of trainees in the field of GMO analysis and detection. ○ Satisfied a need for technical information (impact demonstrated by a large number of downloads and requests for training materials).	**Technical**
		○ Strengthening of JRC's reputation in this field. ○ Reported increased (inter)national visibility and recognition of laboratories after hosting a JRC training course.	**Intangible**
Permanent support to EU policies	○ EU regulatory framework :Oversight of all technical and technological aspects of EU legislation on GMOs during conception, development and implementation ○ Research: Underpinning innovative and exploratory research (e.g. on decision-support systems, on digital PCR, on pollen-traps, on high-resolution melting) ○ The JRC represents the EU in the assembly of national focal point for the Biosafety Clearing House established under Article 20 of the Cartagena Protocol on Biosafety, http://bch.cbd.int/ ○ Information to the public: Operation of the GMO Register foreseen under article 30 of Directive 2001/18/EC ("Summary Notification Information Format (SNIF)" database) maintaining the field trials register over a long period.	○ Legal provisions for quality management of enforcement laboratories. ○ Achievable threshold values in legislation.	**Policy**
		○ New methods and new approaches to GMO detection (e.g. multi-target PCR plates for GMO screening or DNA sequencing in addition to PCR). ○ Results incorporated in laboratories world-wide. ○ The SNIF GMO register is used in biosafety training courses and in international forums to (1) analyse the past activities in the EU, (2) identify tendencies and (3) make projections for future GM cultivations.	**Technical**
International Standardisation	○ Contributions to the functioning of relevant Working Groups and Committees of standardisation bodies ISO, CEN and Codex Alimentarius. ○ Design and proof-of-concept for new sustainable reference measurement systems for GMO quantification based on quantitative PCR and specifically tailored certified reference materials	○ Methods validated by the EURL are submitted to become international standards. ○ The expertise of the EURL and of ENGL provides a considerable contribution to the elaboration of standardisation bodies. ○ Designing and facilitating new documentary standards via chairing ISO/REMCO ○ Extension of requirement standards to GMO reference material production	**Technical**

Impact Evaluation table for European Coexistence Bureau, socio-economic and foresight studies

Coexistence's practices aim to manage the economic risk of unintentional mixing of GM and non-GM crops in farming using science-based, feasible and economically viable measures.

Objectives	Output /Achievement	Impact	
Find consensus at EU level of agronomic practices for achieving co-existence between GM and non-GM farmers.	○ Establishment of the European Coexistence Bureau (ECoB), a group of EU Member States experts managed by JRC scientists http://ecob.jrc.ec.europa.eu/index.html ○ Best Practice Documents for coexistence of genetically modified crops with conventional and organic farming: http://ecob.jrc.ec.europa.eu/documents/Maize.pdf	○ Continuation of ECoB fixed by Commission Recommendation 2010/C200/01 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops ○ Impact on national legislation	Policy
		○ Best practices to manage the economic risks of the technically unavoidable mixing of GM and non-GM harvests while maintaining economic efficiency of farms ○ Standardisation, harmonisation of technical standards, single market	Economic

Economic and agronomic modelling research to develop science-based coexistence measures	○ Scientific publications (Nature Biotech)
	○ JRC Technical reports (2002 and 2006):
	  ○ http://ftp.jrc.es/EURdoc/eur20394en.pdf
	  ○ http://ftp.jrc.es/EURdoc/eur22102en.pdf
		○ High impact in scientific community (high citation index)
		○ Reports translated in several non-European languages at government request
			Technical

Capacity building for Member States and EU staff via scientific conferences	Founder of global conference on Coexistence between GM and non-GM supply chains every two years (GMCC conference series) http://gmcc-11.com/	○ Network creation ○ Leading at global level on agro-economic research to evaluate impact of coexistence policies	Intangible
Assess socio-economic ex-ante and ex-post impacts of GMOs in the EU and globally	○ Research publications in high-impact journals (cf Annex 2) ○ A report on world-wide economic impacts of GM crops with UN-FAO (2012) http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=5019 ○ Creation of a European GMO Socio-Economic Bureau on the model of the ECoB	○ Implementation of the reform of Directive 2001/18 to allow EU Member States decision on cultivation of GMOs ○ In-house production of scientific data on economic impacts of cultivation of GM crops for EU. ○ Harmonise Member States' socio-economic assessment of GM crops trough operation of European Bureau	Policy
		○ Science-based, uniform developments in the EU	Technical
Assess global commercial developments, asynchrony in authorisation, and impacts for agricultural trade.	Foresight reports (GMOs up to 2015) Impact analyses on the economic consequences of asynchronous authorisation between EU and trading partners	○ (World) policy makers' reference on global pipeline data on GM crops ○ Key reference for the implementation to EU Regulations on "low level presence" of non-authorised GMOs ○ Well-informed policy makers in the Commission	Policy
Pre-normative research on new biotechnologies applied in plant breeding, whether or not to include them in GMO legislation	"Deployment of new biotechnologies in plant breeding" Nature Biotechnology publication F1000 selected paper http://f1000.com/ Technology mapping, surveys on commercial uptake of technologies, feasibility of detection of new products	○ EU decisions on classification of new breeding techniques ○ Technological development	Technical

ANNEX 2
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ANNEX 3
The GM authorisation process in the European Union

STEP 1: Submitting an application

An application for a product that consists of, or is made from a GMO must be submitted to a Member State Authority. Supporting documents must accompany the application, including:

- Studies showing that the GM food causes no adverse effects to human and animal health or the environment
- Analyses showing that the characteristics of the GM food do not show biologically relevant differences with respect to the conventional counterpart and reference varieties with a history of safe use.
- Suggestions for product labelling
- Methods and sample material for detecting GM content
- A proposal for post-market monitoring for environmental effects
- A summary of the application dossier

The Member State then forwards the application to EFSA, which subsequently notifies the other Member States and allows them to access the application. EFSA also makes the application summary available to the public.

STEP 2: Risk assessment

Once all required documents are present, EFSA has six months to formulate an opinion. The most important part of this opinion is a scientific safety assessment for which a committee of independent scientific experts, the GMO Panel, checks and evaluates the data presented by the applicant.

Each of the following aspects is considered by EFSA for all applications:

- Molecular characterisation of the GM product, taking into account the characteristics of the donor and recipient organism.
- Compositional, nutritional, and agronomic characteristics of the GM product.
- Potential toxicity and allergenicity of the GM product.
- Potential environmental impact following a deliberate release of the GM product and taking into account its intended uses either for import, processing or cultivation.

Along with the safety assessment, EFSA's official opinion includes:

- A suggestion for product labelling
- The recommendation may include restrictions or conditions such as post-market monitoring in response to results of the safety assessment
- Detection methods validated by the EU Reference Laboratory for GMOs (Since 2003 the JRC validated 72 methods within the prescribed time.)
- Environmental monitoring plan for the GM plant

EFSA submits its opinion to the European Commission and Member States and the opinion is made available to the public on the EFSA website.

STEP 3: Final Decision

After receiving EFSA's opinion, the European Commission has three months to produce a draft decision for granting or refusing authorisation. The decision process is described in the Treaty on European Union and in other legal documents. This is not a specific process for GMO regulations; it is the general process used in all legislative decision-making.

- The Commission submits its draft for a decision to the "Standing Committee on the Food Chain and Animal Health" (SCFCAH). The committee consists of representatives from all Member States and may approve or reject the EC's draft with a qualified majority.

- If the SCFCAH does not agree with the Commission's draft, or if a decision with qualified majority cannot be reached, the Commission can either submit an amended draft to the committee (within two months) or submit the same measure for a second deliberation to the Appeal Committee (within one month).

- The composition of the Appeal Committee can be flexible, adapted to the political sensitivity and the difficulty of the negotiations. In principle it will consist of representatives appointed by the Member States and will be chaired by the Commission whilst it will not have a voting right.

- In order to reach a qualified majority, 232 out of 321 votes are needed. Additionally, a qualified majority must represent at least 62 percent of the EU population.

- If the Appeal Committee cannot reach a qualified majority, the Commission may adopt the proposal.

The EURL hosted by the JRC has a key task with the validation procedure in step 2. Since 2004 it received around 90 dossiers for validation. After two years of gradually building up the experience it processes between 7 and 12 files per year. In addition, in cases of emergency when not (yet) approved GMOs are found persistently on the EU market, it needs to assure that national enforcement laboratories have a verified test protocol available, together with appropriate control samples and adequate test procedures. This was the case for maize (BT10 and GM EVENT 32, both originating from the US), for rice (LLRice601 originating from the US and different GM rice varieties originating from China) and for CDC Triffid Flax originating from Canada[33].

[33] http://gmo-crl.jrc.ec.europa.eu/emerg-unauth.html webpage with "Emergencies / unauthorised GMOs"

ANNEX 4
An example of careful use of statistics

Europe has taken a cautious position and adopted stringent legislation regarding the authorisation for the import of GM products. Authorisation procedures in the EU take more time than for instance in the United States. That the EU has some backlog in authorisations is an obvious expectation, which feeds a general belief that the EU is lagging behind the USA regarding the authorisation of GMOs in food and feed. What are the facts?

World wide there are around twenty different GM plant species (maize, soya etc.) with a total of around 150 transgenic varieties for cultivation, and/or commercial use on the market.

A: The EU has authorised 40 out of these 150 GMO varieties on its market; the USA authorised 91 of them. These numbers alone give the impression that the EU is much more restrictive than the US in authorising GMOs on the market. They seem to confirm the image that the EU is lagging dramatically in this field.

B: Around 100 of the 150 GMOs listed worldwide are not or no longer in cultivation or cultivated for local use only. Hence the 40 GMOs authorised for the EU market today, include all major varieties commercially cultivated for international trade.

Adding A and B gives a different image of the EU, because it adds "the detail" that the EU has authorised all major GMO varieties on its market.

Using the number of authorised GMOs as indicator without proper reference leads to irrelevant conclusions. Including GMOs that are not cultivated for international trade or not commercially cultivated at all make the indicator meaningless.

The sheer number of government authorisations should not be used to assess the degree of a country's status regarding authorisations for GMOs.

Annex 5
Impact Analysis of the JRC's GMO-related activities Terms of reference for a Steering Group

Background

In line with the Commission's principles to focus on European added value, impact and results and following recommendations in the recent Impact Analysis of the Joint Research Centre the JRC is planning some dedicated impact analyses to establish impacts and cost-benefits analyses of its individual programmes and projects in more detail.

The current impact analysis concerns JRC activities related to Genetically Modified Organisms (GMO) for which recent Commission evaluations of GMO legislation and programme reviews of Commission GMO research offer an excellent point of reference. The JRC is active in the development and implementation of legislation as well as in research:

- Having set up the European Network of GMO Laboratories (ENGL) officially in 2002, today the JRC is running this active and effective network, connecting approximately one hundred laboratories specialised in GMO analysis throughout Europe.
- In Ispra (ITA) the JRC hosts the European Union Reference Laboratory for Genetically Modified Food and Feed (EU-RL GMFF) through which it is responsible for the validation of GMO-detection methods as foreseen in the EU legislation.
- In Geel (BEL) the JRC produces certified reference materials (CRMs) for GMO-testing laboratories world wide and advises on their correct use. These materials are essential for reliable calibration and quality control of quantification methods.
- In Seville (ESP) the JRC hosts the European Coexistence Bureau, which organises the exchange of technical-scientific information on best agricultural management practices for coexistence of GM crops and non-GM crops.

Against this background the JRC wants to take stock of achievements and impacts from its GMO-related activities and carry out an impact analysis guided by a Steering Group of high-level experts.

Objectives and scope

The purpose of the Steering Group is to validate the approach and the applied methodology for the impact analysis of JRC activities for the regulation of GMOs. The Steering Group ensures the evaluative character of the final report and formulates an independent commentary to the JRC's findings.

The scope of the Impact Analysis encompasses all GMO-related activities of the JRC, looking back approximately over the last ten years (2002-2011), but also looking forward with a view to the Europe 2020 strategy. Details of the scope remain subject to be decided with the Steering Group.

The various impacts of the JRC's GMO activities at the interface of the scientific, economic and social domains shall be analysed and classified as technical impacts, (environmental, societal, legal) policy impacts, economic impacts and intangible impacts.

The Steering Group

The Steering Group will consist of four high-level external experts, selected by the Director General of the JRC, who may want to appoint one person to chair the group. The Director General may invite a representative of the Steering Group to present its findings to the JRC Board of Governors.

The evaluative character of the exercise requires that the experts cover a broad range of expertise (e.g. scientific, economic, political) and be familiar with the JRC's work programmes and its operations, for instance through the participation in past external evaluations of the JRC.

Working method, deliverables and timetable

The JRC and the Steering Group set out the scope of the Impact Analysis, the working method and the issues to be addressed at the kick-off meeting. Together, these three elements provide a preliminary outline for the impact analysis report.

The JRC carries out all tasks related to the impact analyses and the preparation of the report. It will collect relevant information like historical JRC resource management data, accomplishments recorded in its scientific knowledge management data base, relevant facts in compilation reports and articles. This information may be complemented with contextual information and references from the literature and information obtained through consultations of relevant JRC stakeholders. The Steering Group will accompany the compilation of this information into the report.

During the kick-off meeting the experts may propose to provide specific deliverables as individual contributions.

The impact analysis report will identify, assess and, where possible, measure the various impacts of the JRC GMO activities at the interface of the scientific, economic and social domains, distinguishing the above-mentioned four categories of impact: policy impact, technical impact, economic impact and intangible impact.

The analysis will address immediate effects of JRC's GMO-related activities on: e.g., EU or member-state's policies, policy makers, food and feed industry, environment, trade, the public. It will also look at longer time scale impact or indirect effects from the collective effect of the relevant JRC actions. An assessment of the counterfactual situation shall be considered as a tool to quantify various impacts.

The prospective element of the analysis will project the achievements and impacts from JRC GMO-related activities in the light of the Europe 2020 strategy. The Steering Group may want to hear a number of invited exerts about the impacts of past and possible future JRC work on GMOs.

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Abstract
This report presents an analysis of impacts and results from the JRC's scientific and technical support for the implementation of the EU regulations for genetically modified organisms (GMO).
The report is complementary to the mandatory evaluations of the EU Research Framework Programmes.
A Steering Group of independent external experts accompanied the preparation of the report and helped to carry out the analysis in an objective way.
Over the last 20 years the JRC has built up a specialised laboratory infrastructure to validate procedures for detecting and measuring the concentration of GMOs in food and feed, to harmonise the tests and verification methods, and to produce the necessary reference materials for the various methods.
Since 2003 it operates the designated EU Reference Laboratory (EURL) for GMOs, implementing the necessary verification tasks through the European Network of GMO Laboratories (ENGL).
The report puts well in evidence the JRC's experience to establish a network of European laboratories to support EU food-and-feed regulations using sophisticated DNA-based test methods.

The report presents as most important impacts:
- The existence of a technical infrastructure in the EU that allows harmonised implementation of GMO legislation and regulations, including the availability of certified reference materials
- EU-wide agreed coexistence measures in national legislation to avoid the unintended presence of GMOs in conventional and organic crops based on objective data concerning the socio-economic aspects of GMOs
- The technical clarification of the EU zero-tolerance policy; an impact of which the history is elaborated in the case study in the report.

JRC Mission

As the Commission's in-house science service, the Joint Research Centre's mission is to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle.

Working in close cooperation with policy Directorates-General, the JRC addresses key societal challenges while stimulating innovation through developing new standards, methods and tools, and sharing and transferring its know-how to the Member States and international community.

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