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

APPENDIX A – CONSULTATION ANALYSIS

EPEC

For DG SANCO, European Commission

March 2011

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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

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APPENDIX A

TO THE FINAL REPORT

DG SANCO

Submitted by EPEC

March 2011

EPEC

Document Control

Document Title	Annex for the *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*
Job No.	30256315
Prepared by	MP, NS
Checked by	Andrew Jarvis
Date	15 March 2011

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ABBREVIATIONS

ARM	Antibiotic resistance marker genes
EC	European Commission
JRC	Joint Research Centre
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EMEA	European Medicines Agency
ERA	Environmental risk assessment
EU	European Union
FVO	Food & Veterinary Office
GM	Genetically modified
GMM	Genetically modified micro-organism
GMHT	Genetically modified herbicide-tolerant
GMO	Genetically modified organism
GS	General surveillance
MS	Member State
NGOs	Non Governmental Organisations
NTs	Notifiers
OGs	Other groups
PMEM	Post market environmental monitoring
RASFF	Rapid Alert System for Food and Feed

1 INTRODUCTION

This Annex supplements the Final Report of the *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 marketing of their other uses under Directive 2001/18/EC*, a project commissioned by DG Environment of the European Commission from the EPEC consortium (the file was subsequently transferred to DG SANCO). The consulting team was led by GHK Consulting Ltd. GHK worked with co-consultants Technopolis and a number of individual experts in biotechnology, risk and communication from across the EU[1].

A large scale consultative exercise that engaged with governments, industry, NGOs and other interests across the EU during the summer of 2009 informed the evaluation. The consultation consisted of:

- **Detailed questionnaires** sent to authorities in all 27 EU Member State, EFSA, biotechnology companies, environmental NGOs, farming groups, trade associations, and research institutes. A standard set of 'core' questions was addressed to all Member State authorities, notifiers, research institutes and other organisations. In addition to the core set of questions which was asked to all groups, specific questions were also asked to certain groups based on their experience with the legislative framework.
- **An online survey** (referred to hereafter as the **'E-survey'**) which was open to all interested organisations in Europe. Interested organisations were given the opportunity to register themselves on a database for this survey by entering their details on a project website. This website was publicised via various news services as well as suggestions of other organisations by NGOs, notifiers and Member State authorities. All those who registered received a universal electronic survey through a web-based survey tool called 'SNAP'. The E-survey contained only the 'core' questions, and so was the shortest of all the surveys.

The Interim Report of the evaluation, which is available on the DG SANCO website, presented the results of the research. This Annex presents an updated compilation of the quantitative data resulting from the questionnaires that were sent out as part of that exercise, incorporating a small number of responses that had not been received when the Interim Report was finalised.

The questionnaires invited scaled responses to a number of questions (e.g. 'very satisfied' through to 'not at all satisfied'). The figures and charts throughout this Annex illustrate the scaled responses of the relevant consultees. The Interim Report used these quantitative data, qualitative information submitted in response to these questionnaires, and information from in-depth interviews with nine Member State authorities, seven notifiers, EFSA (the European Food Safety Authority), environmental NGOs, as well as farming and other industry associations[2].

The EPEC team would like to thank the many individuals and organisations who contributed generously to the consultation in time, effort and information. The views expressed by the authorities and officials who were consulted are not necessarily the same as the formal positions of the national governments concerned.

[1] Professors Erik Millstone and Andy Stirling of the University of Sussex, Huib de Vriend of LISConsult, Dr. Armin Spoek of IFZ-Interuniversity Research Centre for Technology, Work and Culture, and Piet Schenkelaars of Schenkelaars Biotechnology Consultancy

[2] For more information on the methodology on which the interviews were based, see Annex A of the Interim Report.

This Annex is structured to complement the Interim Report so that the appropriate data can easily be cross-referenced to match each of the main components of the legislative framework, i.e.

- The **objectives** of the legislation (section 2);
- The **scope** of the legislation (section 3)
- **Risk assessment** as defined and practised in the legislative framework (section 4);
- The implementation of Part B of the Directive governing **field trials** (section 5);
- **Risk management**, covering both the authorisation 'decision' and the measures deployed to monitor and mitigate the risks of an authorised deliberate release (section 6);
- **Risk communication** covering both the communication activities of risk assessors and risk managers to and from the public (section 7); and
- **Other discrete issues** which covers confidentiality, the zero tolerance policy on the presence of unauthorised GMO seeds, and other relevant national legislation which impacts on the cultivation of GMOs (section 8).

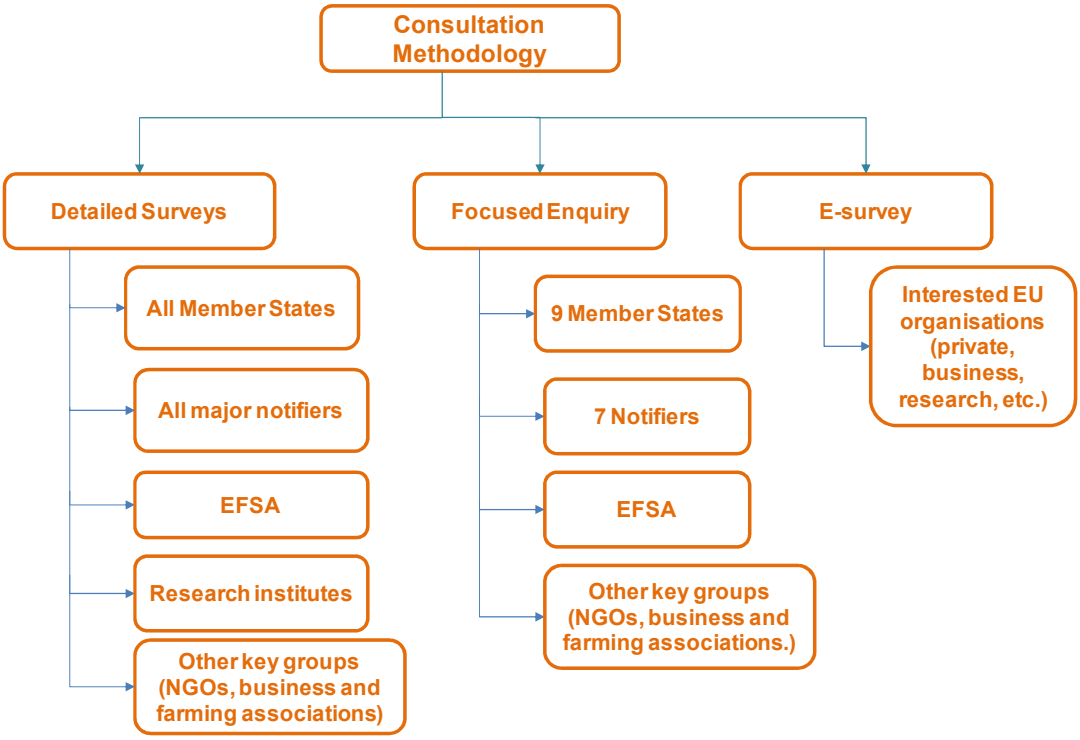
Where sub-sections are missing in this Annex, it is because the corresponding sub-sections of the Interim Report do not have any supplementary figures (e.g. Section 4.1).

1.1 Detailed Methodology

The breakdown for each group of consultees is given in Table 1.1. Figure 1.1 provides an overview of the consultation methodology. As mentioned above, this Annex presents the responses to the quantitative results of the detailed survey and the E-survey. Not all questionnaires were returned in time for inclusion into the Interim Report. Since then, additional responses were returned from Portugal and Luxembourg, which have been incorporated in this Annex to provide an updated version of the data.

All groups, including those in Table 1.1 as well as those who registered for the E-survey, were asked about 40 core questions. For the detailed questionnaires, which were sent all the above groups listed in Table 1.1, each group was sent these core questions as well as further questions which were specifically tailored to their experience with the legislation. The group of 'Other' key consultees (Table 1.1), were asked between 70 to 90 questions. The key 9 MS authorities and 7 notifiers were asked a further 40 to 50 questions.

Figure 1.1 Overview of the consultation methodology



Source: GHK Consulting Ltd.

Table 1.1 Main groups of consultees and the means of consultation

✓ - Interviewed (Focused enquiry)
◆ - Returned survey

Member State authorities		Other key consultees		Notifiers	
Austria	◆✓	European Food Safety Authority (EFSA)	◆✓	AVEBE	◆✓
Belgium	◆✓				
Bulgaria		EuropaBio	✓	BASF	◆✓
Cyprus	◆	COCERAL	◆✓	Bayer	◆✓
Czech Republic	◆✓	COPA-COGECA	✓	Dow	◆✓
Denmark	◆	European Centre for Nature Conservation (ECNC)	✓	Monsanto	◆✓
Estonia	◆				
Finland	◆	European Environmental Bureau (EEB)	✓	Pioneer	◆✓
France	◆✓				
Germany	◆✓	European Seed Association (ESA)	◆✓	Syngenta	◆✓
Greece		Friends of the Earth (FOE)	◆✓	KWS	◆
Hungary	◆✓	Greenpeace	◆✓		

Ireland	◆	International Federation of Organic Agriculture Movements (IFOAM)	◆
Italy	◆		
Latvia	◆		
Lithuania	◆		
Luxembourg	◆		
Malta			
Netherlands	◆✓		
Poland	◆		
Portugal	◆		
Romania	◆		
Slovak Republic	◆		
Slovenia	◆		
Spain	◆✓		
Sweden	◆		
UK	◆✓		

E-Survey

We surveyed the opinions of interested EU industry, farming groups, research organisation non-governmental organisations and other stakeholders who registered on the GHK website. 208 institutions registered for the E-survey and were given log-in details. The analysis that follows is based on the 53 complete or near-complete responses that were received.

NGOs and business representatives accounted for 34% and 26% of all responses respectively (Figure 1.2). Most of the responses came from Member State authorities in whose Member State there has been GMO cultivation or GMO field trials. Stakeholders from Germany, UK and Spain accounted for bulk of the E-survey responses (Figure 1.3).

Figure 1.2 There was a total of 53 responses to the E-survey; most respondents were affiliated to NGOs and business representative groups

Respondents' affiliation

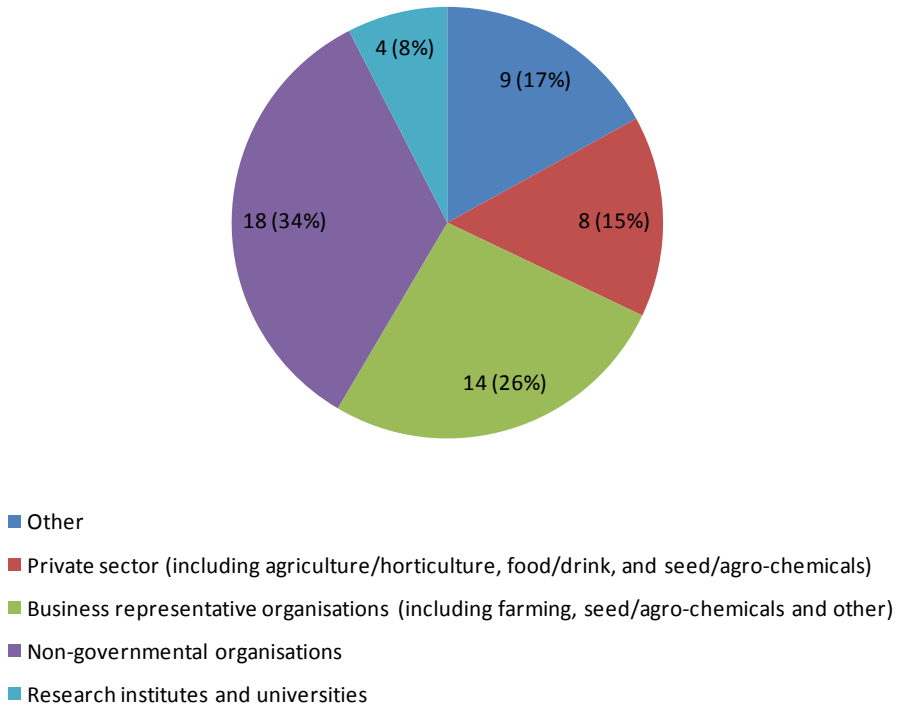
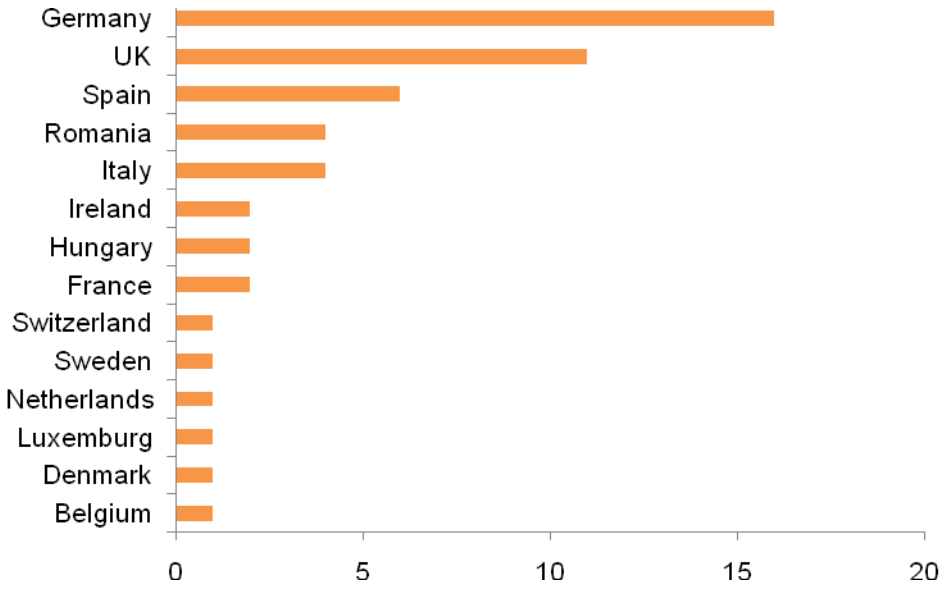


Figure 1.3 Most respondents were from Germany and the UK

Respondents' country of origin



1.2 Combining the results of the detailed enquiry with the E-survey

As mentioned above, a core set of questions was asked to all consultees, including those who registered for the E-survey. For this core set of questions, the responses of the E-survey respondents were combined with those of the relevant groups who received detailed questionnaires (i.e. answers to the core questions from NGOs who responded to the E-survey were combined with answers to the core questions of NGOs who responded to the detailed questionnaire, etc). The revised numbers for groups responding to the core questions are shown are shown in Table 1.2. The number of MS respondents and main notifiers naturally remain the same.

Table 1.2 Revised groups for figures representing responses to core questions (based on combining responses from the E-survey with similar groups responding to the detailed questionnaires)

Revised groups for core questions	Respondents of which are from E-survey	Respondents of which are from the detailed questionnaires	**Revised Total**
EFSA	-	1	**1**
Member States	-	24	**24**
Notifiers	-	8	**8**
Research Institutes	4	5	**9**
Private sector	22	3*	**25**
NGOs	18	2**	**20**
Other	9	-	**9**
TOTAL	53	43	**96**

* COCERAL, IFOAM, ESA

** Friends of the Earth, Greenpeace

Core questions which correspond to the format shown in Table 1.2 above are marked with a '**C**', i.e. **Figure 1.1C.** All other figures (i.e. those which do not overlap with questions asked in the E-survey) adopt the format shown in Table 1.3.

Table 1.3 Revised groups for figures representing responses to core questions (based on combining responses from the E-survey with similar groups responding to the detailed questionnaires)

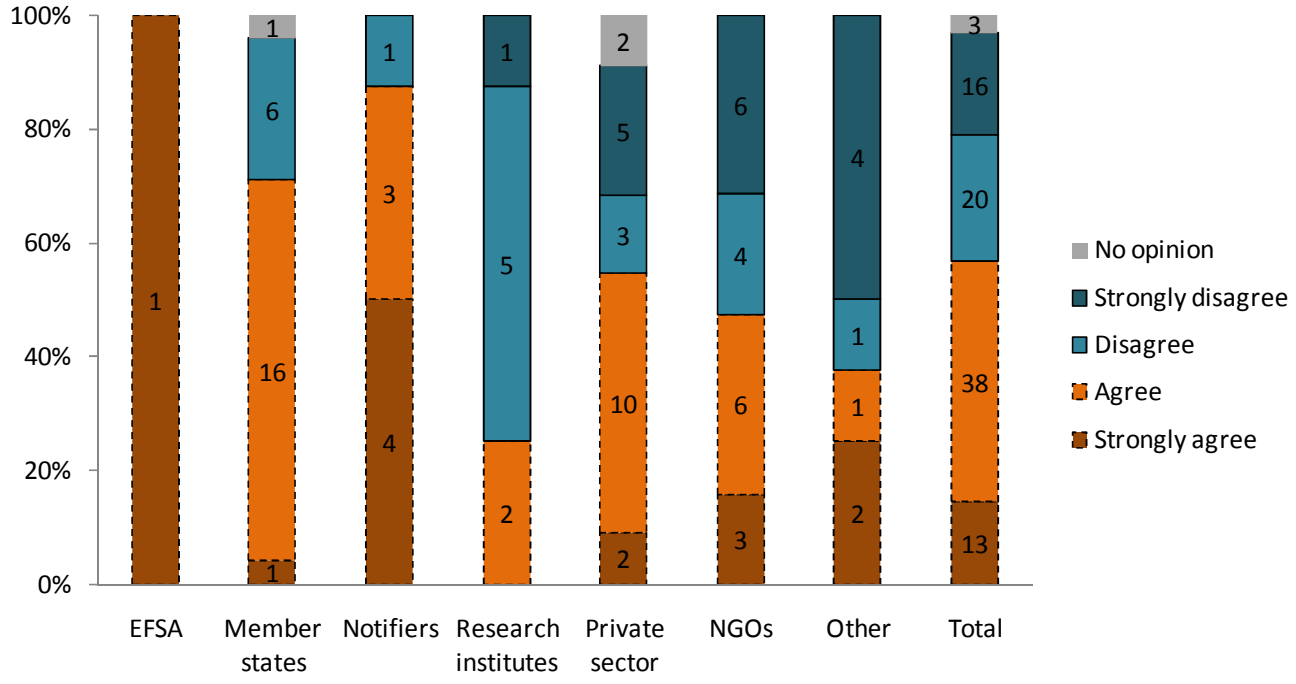
Consultee groups for questions which do not overlap with the E-survey	Number of respondents
EFSA	1
Member States	24
Notifiers	8
Research Institutes	5
Other (including industry representatives* and NGOs*)	5
TOTAL	43

* COCERAL, IFOAM, ESA
** Friends of the Earth, Greenpeace

2 OBJECTIVES OF THE LEGISLATION

The following figures supplement the text in Section 2 of the Interim Report.

Figure 2.1C To what extent do you agree that the current objectives of the EU legislation as it relates to cultivation of GMOs are in line with the needs of society?



3 SCOPE OF THE GMO LEGISLATION

Consultees were asked no quantitative questions on the scope of the GMO legislation, therefore no figures are presented here.

4 RISK ASSESSMENT

The following figures supplement the text in Chapter 4 of the Interim Report.

4.3 Figures corresponding to Section 4.3 of the Interim Report: On transparency and efficiency of the Risk Assessment procedures

Figure 4.1C To what extent are the current procedures for risk assessment transparent (i.e. the process, and the basis of the decision) clear to those outside it?

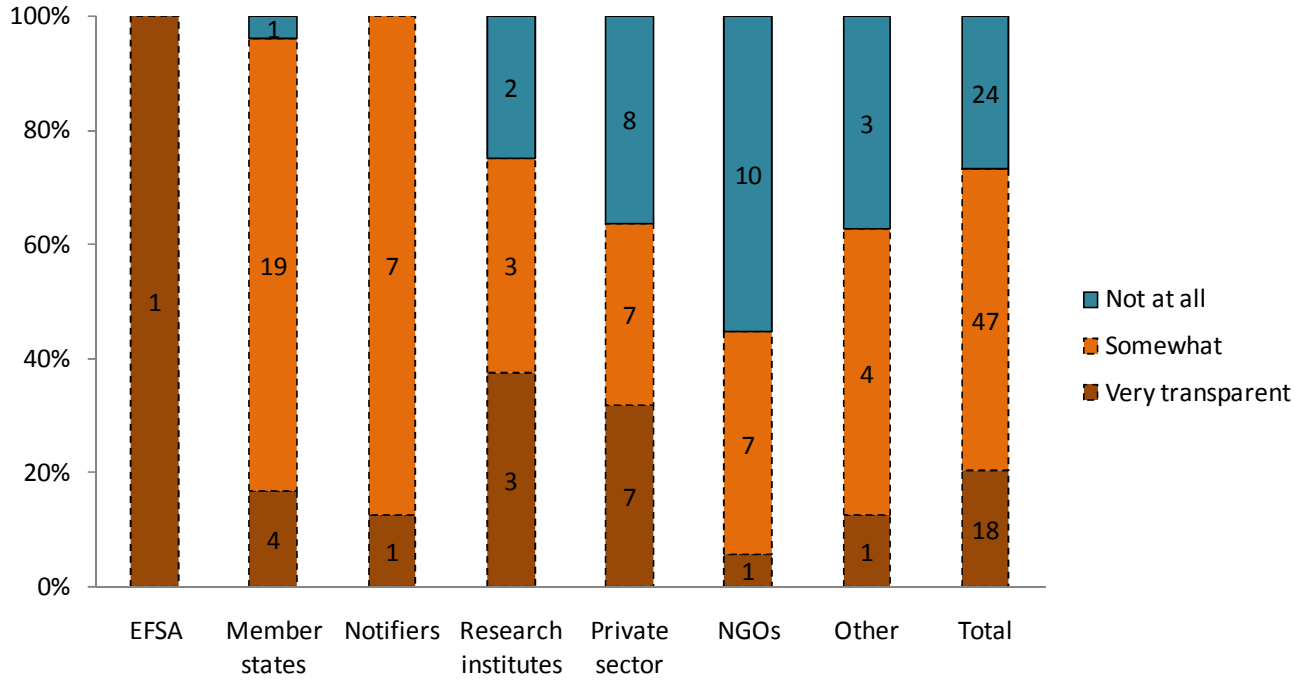


Figure 4.2C To what extent are the current procedures for risk assessment efficient?

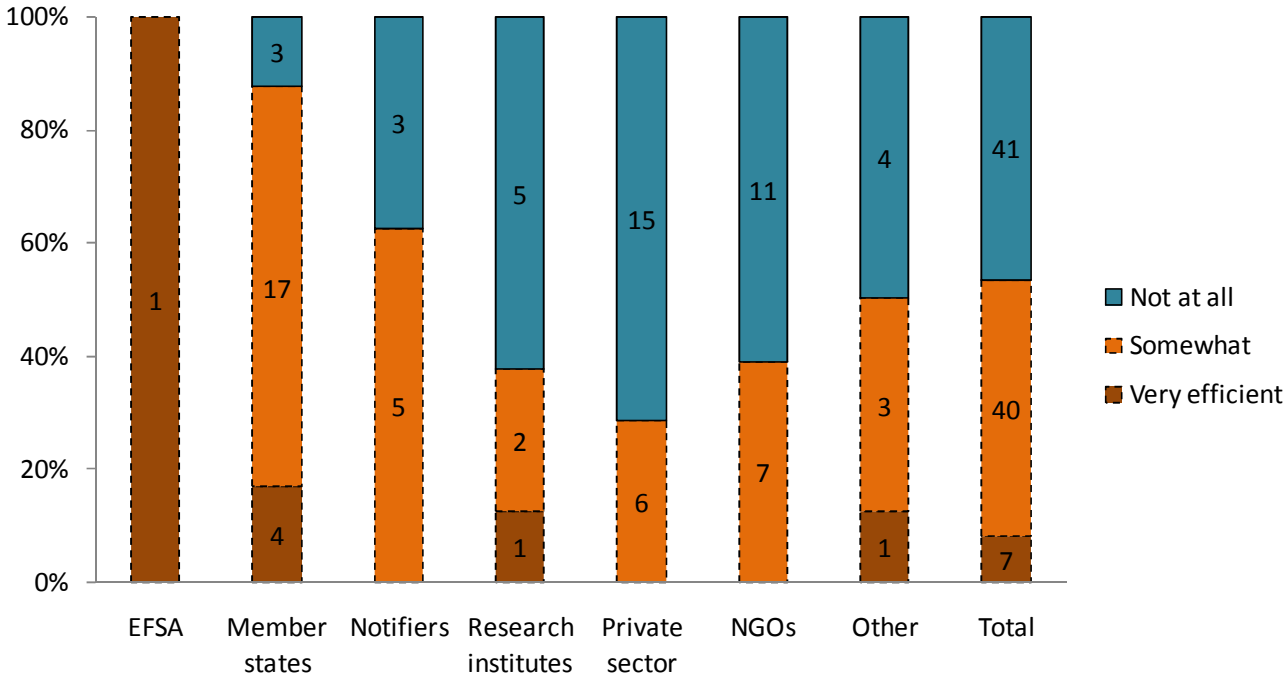


Figure 4.3C In general, how satisfied are you with the ERA requirements as specified in the legislative framework?

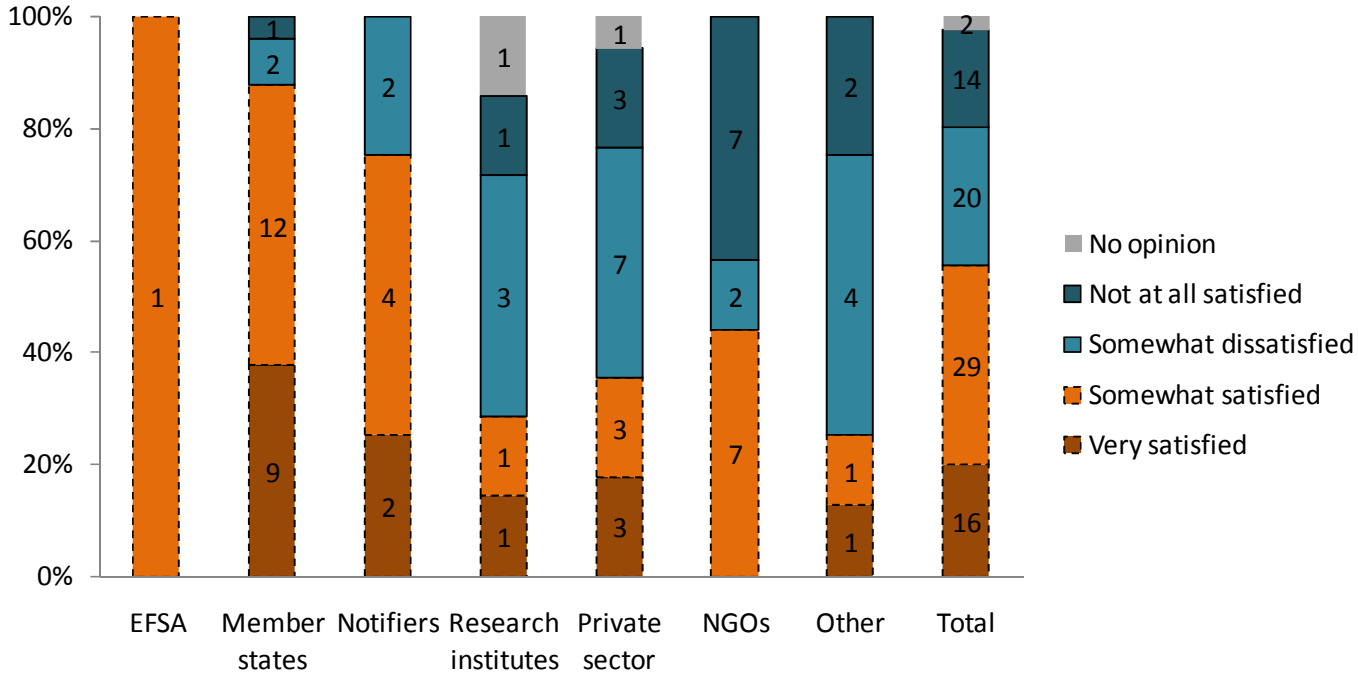
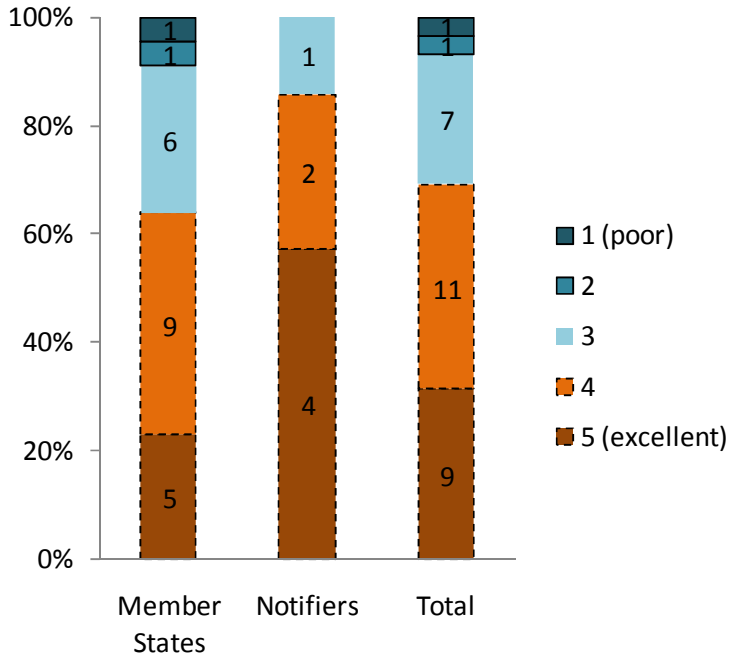


Figure 4.4 On a scale of 1 to 5 (where one is poor and five is excellent), how clear and comprehensive is EFSA's guidance for conducting an ERA?



4.4 Figures corresponding to Section 4.4 of the Interim Report: On the characteristics of the application of the Risk Assessment requirements in practice

Figure 4.5C On a scale of 1 to 5 (where one is poor and five is excellent), to what extent do you think the way ERAs are currently conducted and assessed are achieving the objective of an ERA to, on a case by case basis, identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have?

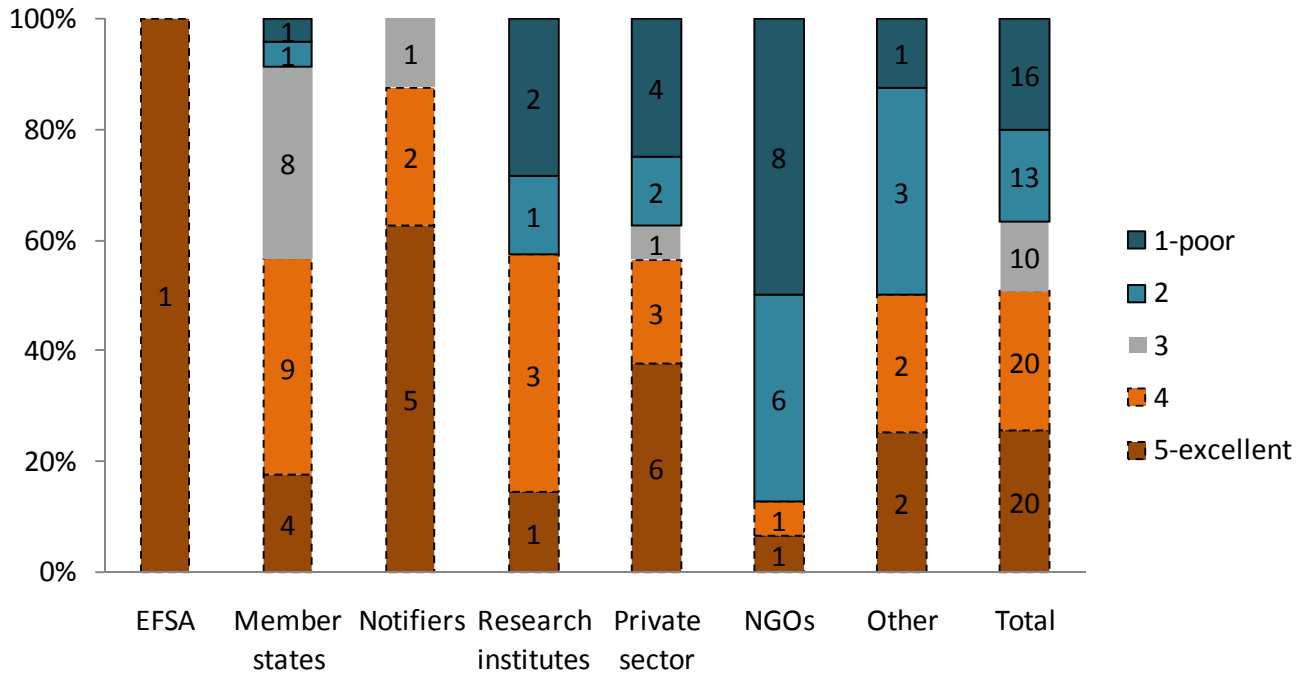


Figure 4.6C On a scale of 1 to 5 (where one is poor and five is excellent), to what extent do you think the way ERAs are currently conducted and assessed are achieving the objective of an ERA to identify if there is a need for risk management and if so, the most appropriate methods to be used?

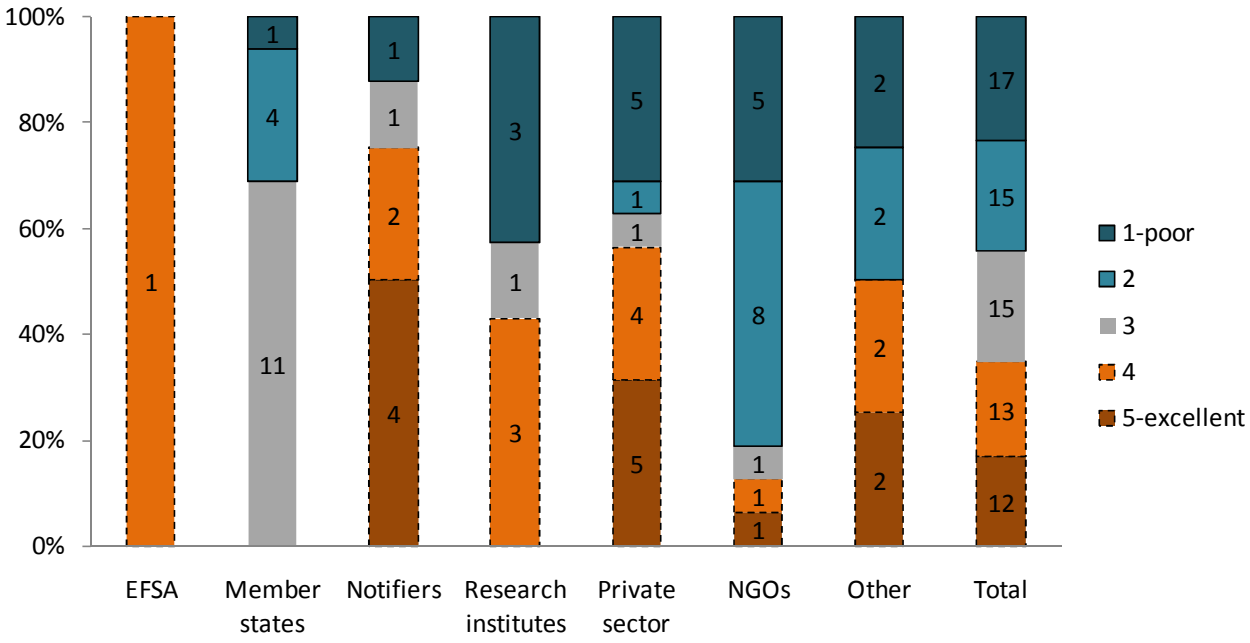


Figure 4.7C On a scale of 1 to 5 (where one is poor and five is excellent), how well is the preparation and assessment of ERAs following the principle of Annex II of the Directive 2001/18/EC (as supplemented by Decision 2002/623/EC) that identified characteristics which have the potential to cause adverse effects should be compared to those of the non-modified organism and its use?

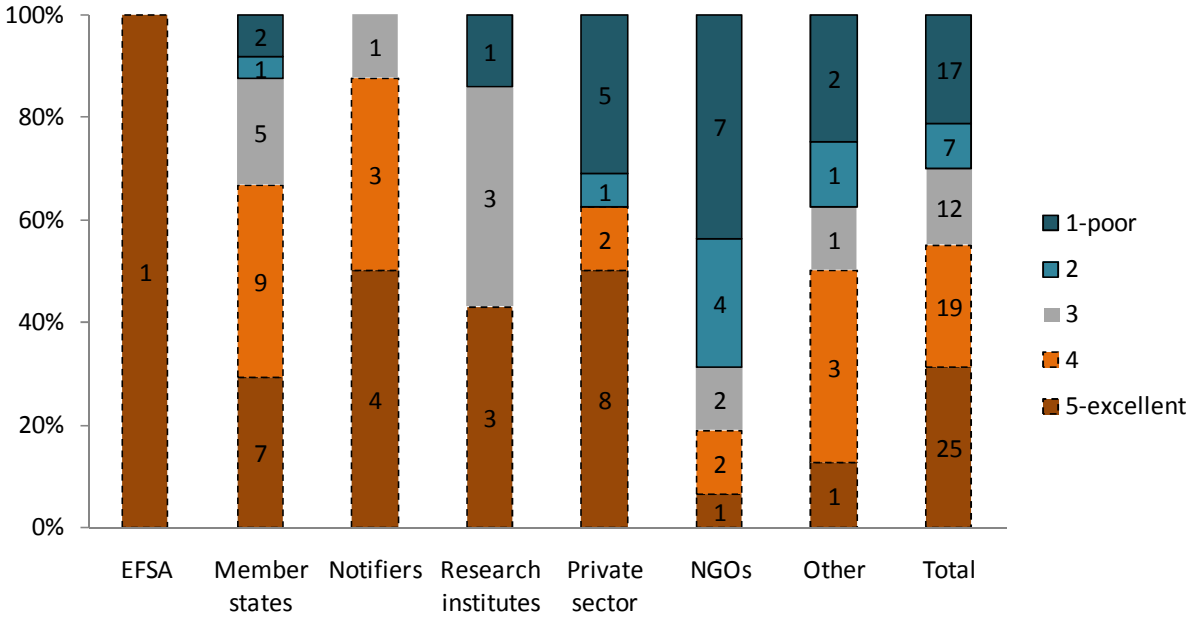


Figure 4.8C On a scale of 1 to 5 (where one is poor and five is excellent), how well is the preparation and assessment of ERAs following the principle of Annex II of the Directive 2001/18/EC (as supplemented by Decision 2002/623/EC) that an ERA is to be carried out in a scientifically sound and transparent manner based on available and scientific data?

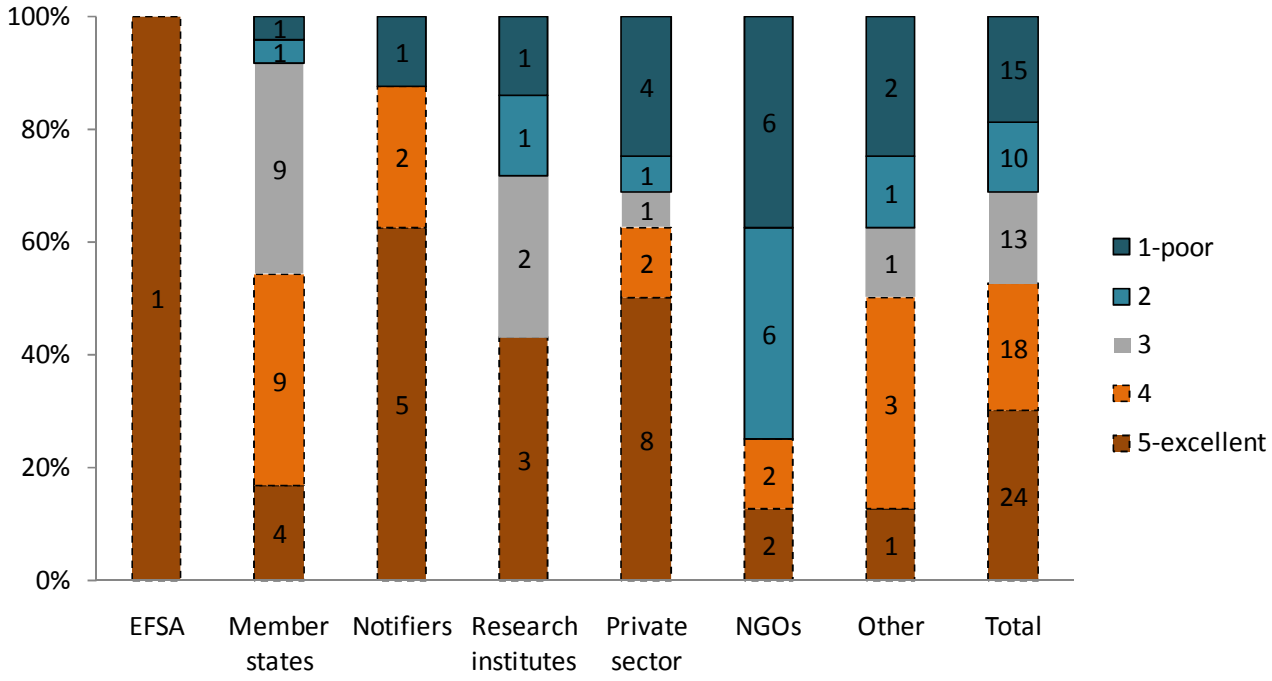


Figure 4.9C On a scale of 1 to 5 (where one is poor and five is excellent), how well is the preparation and assessment of ERAs following the principle of Annex II of the Directive 2001/18/EC (as supplemented by Decision 2002/623/EC) that an ERA is to be carried out on a case-by-case basis?

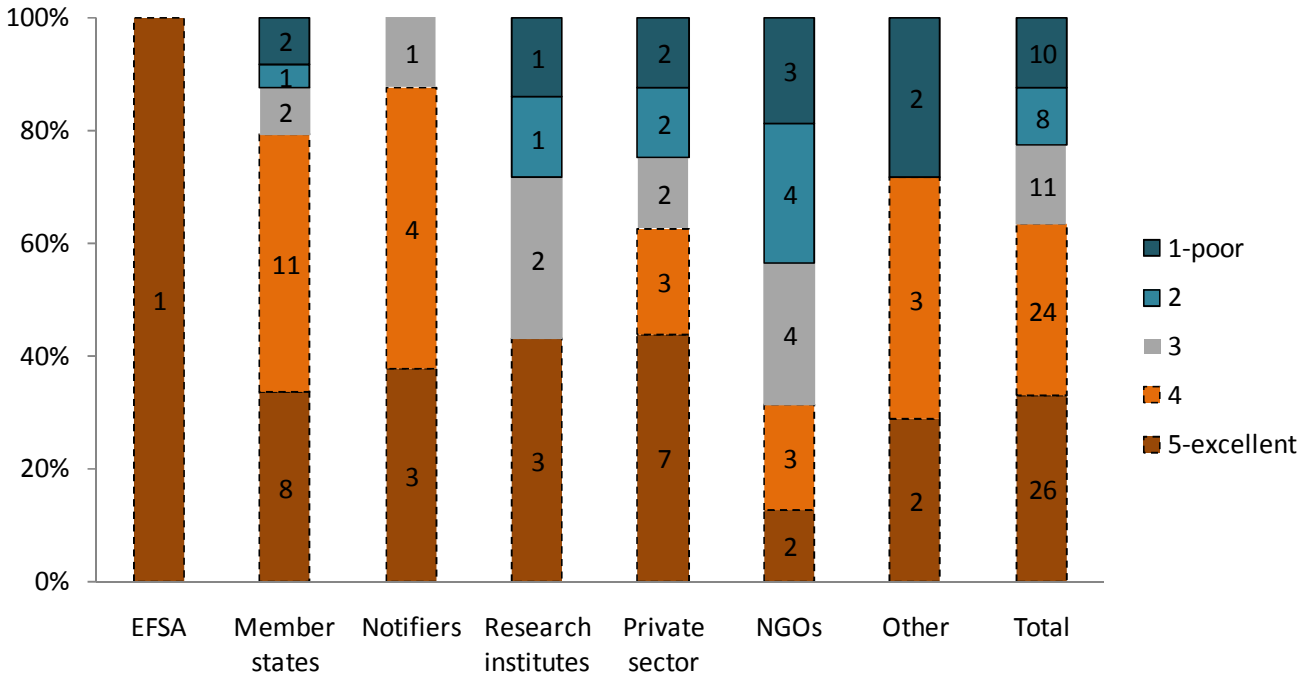


Figure 4.10 On a scale of 1 to 5 (where one is poor and five is excellent), how well are the 6 steps detailed below being properly followed during the conduct and assessment of the ERA?

Annex II of Directive 2001/18/EC specifies six steps that must be completed for a satisfactory ERA (and supplemented by Decision 2002/623/EC):

i. identification of characteristics which may cause adverse effects;
ii. evaluation of the potential consequences of each adverse effect, if it occurs;
iii. evaluation of the likelihood of the occurrence of each identified potential adverse effect;
iv. estimation of the risk posed by each identified characteristic of the GMO(s);
v. application of management strategies for risks from the deliberate release or marketing of GMO(s);
vi. determination of the overall risk of the GMO(s)

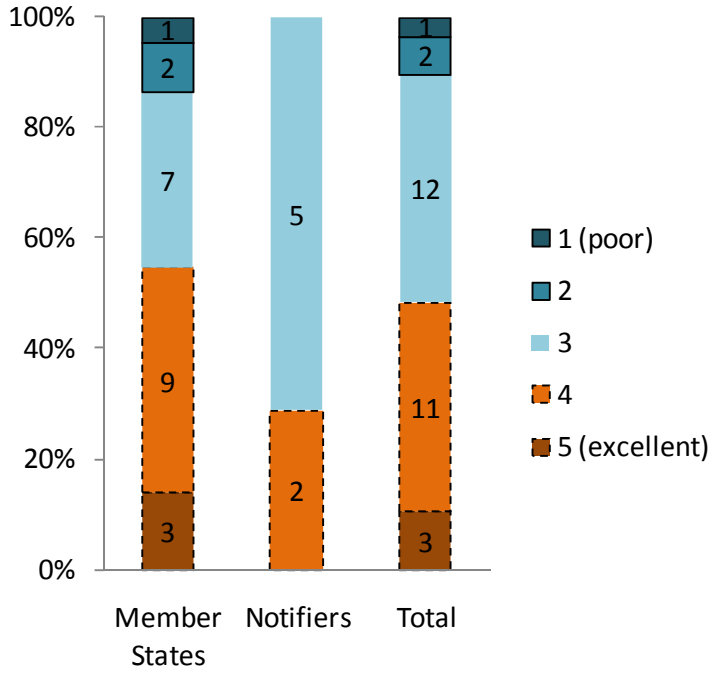


Figure 4.11C Overall, how satisfied are you with the way in which ERAs for GMOs are being conducted by notifiers?

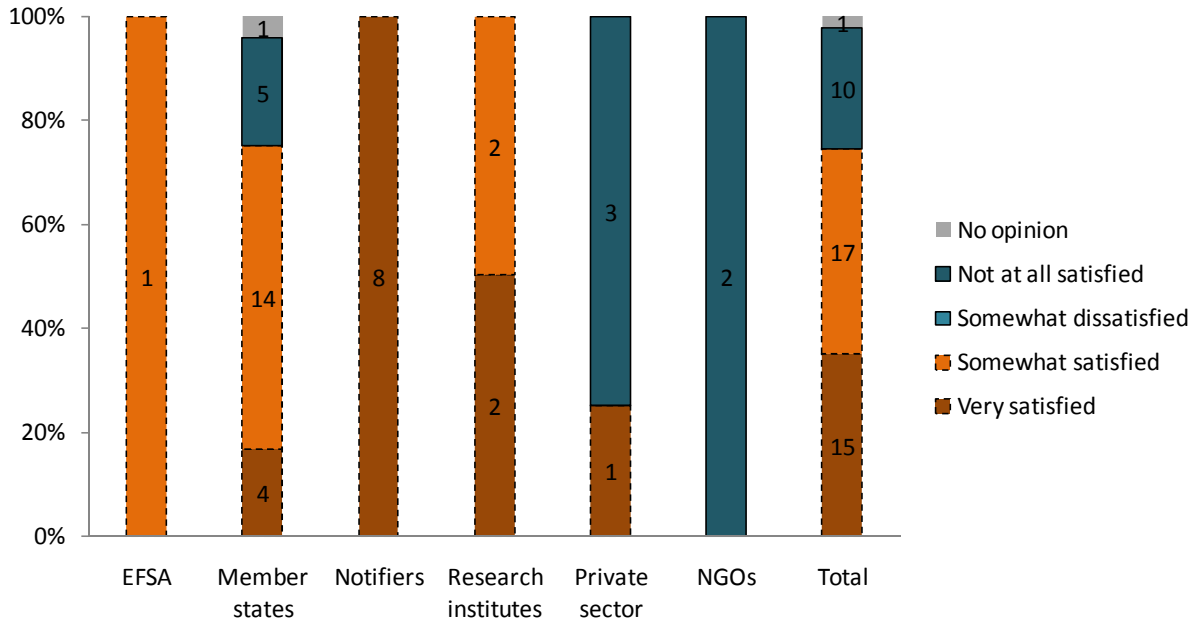


Figure 4.12C Overall, how satisfied are you with the way in which ERAs for GMOs are being assessed in Member States under the Directive and by volunteer Member States under the Regulation?

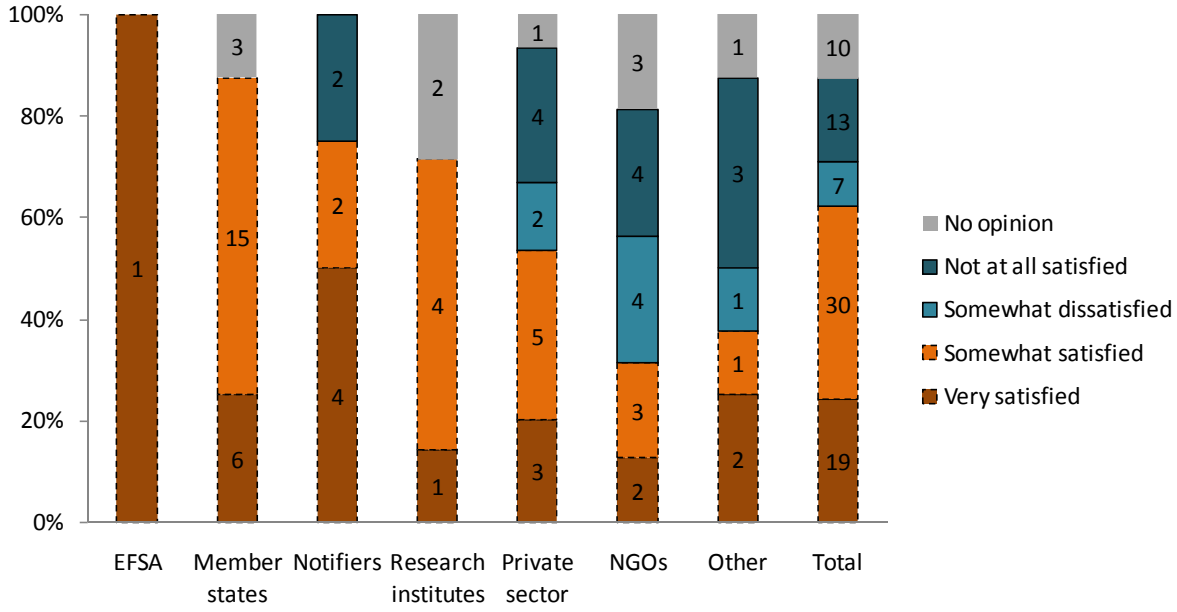


Figure 4.13C Overall, how satisfied are you with the way in which ERAs for GMOs are being assessed by EFSA?

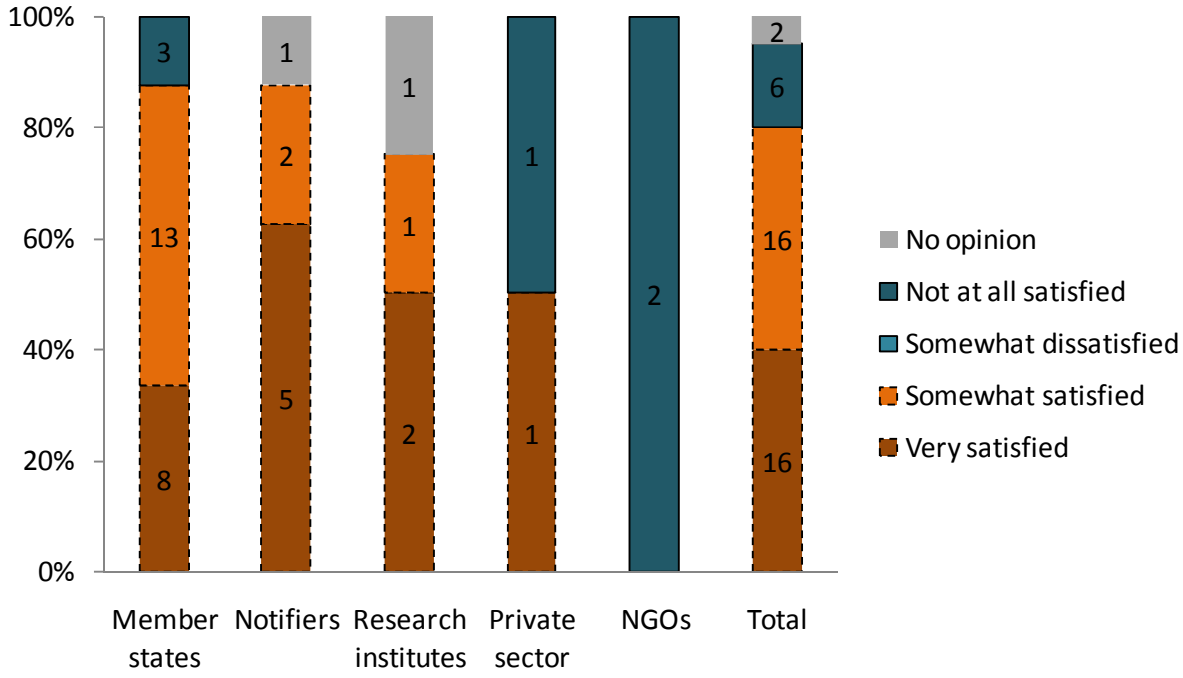


Figure 4.14 **To Notifiers only:** To what extent are procedures for submitting an application clear and easy to follow in Member States?

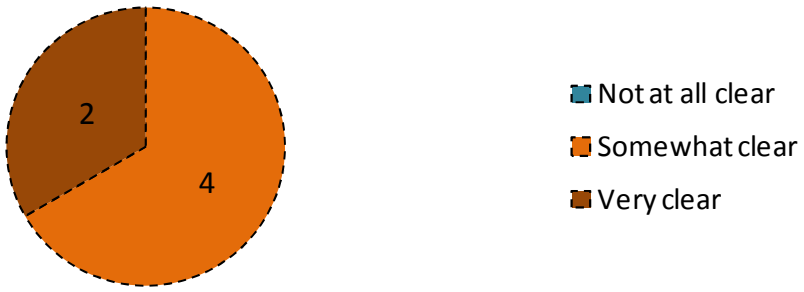


Figure 4.15 How satisfied are you with the mandate EFSA has been given?

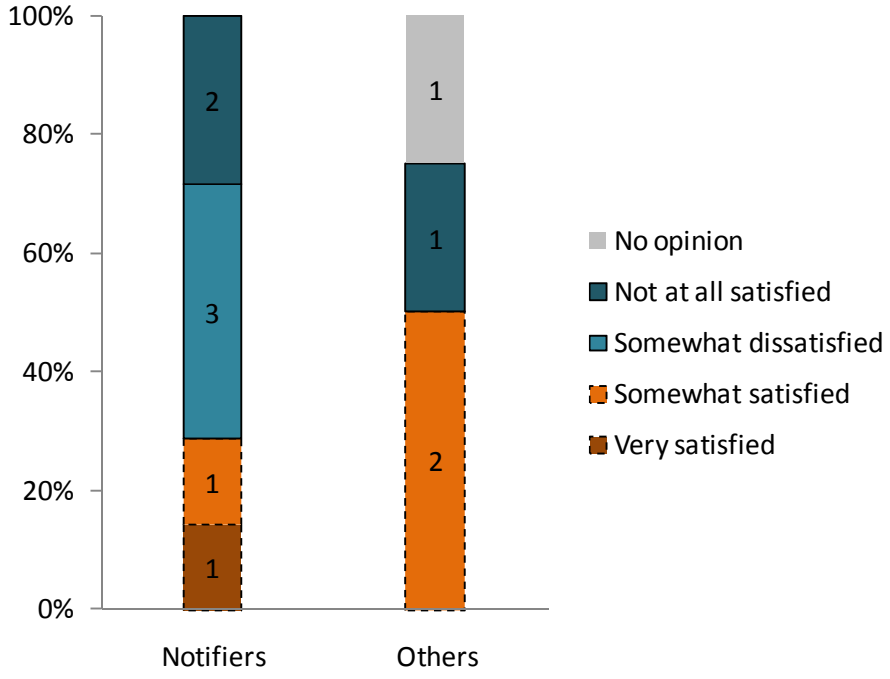


Figure 4.16 **To Notifiers only:** How useful is the guidance that MSs provide on the preparation of an application?

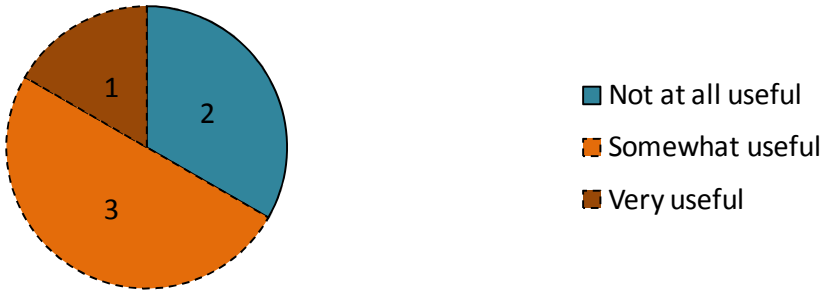


Figure 4.17C How consistent are Member States in assessing ERAs for applications whose scope includes cultivation?

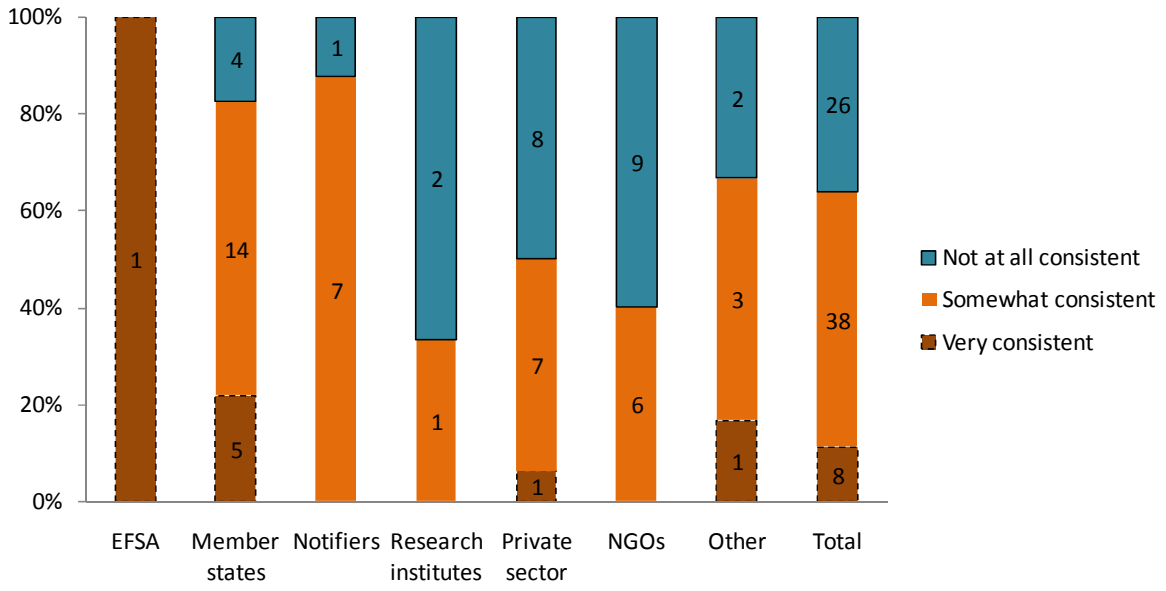


Figure 4.18 **To Notifiers only:** To what extent is the harmonisation of RA practices increasing?

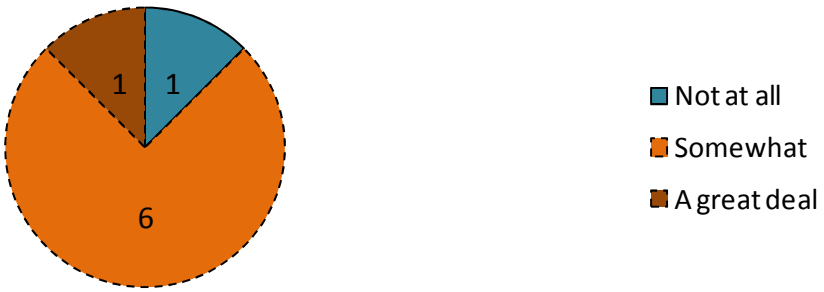


Figure 4.19 What level of harmonisation of risk assessment practices across Member States is appropriate?

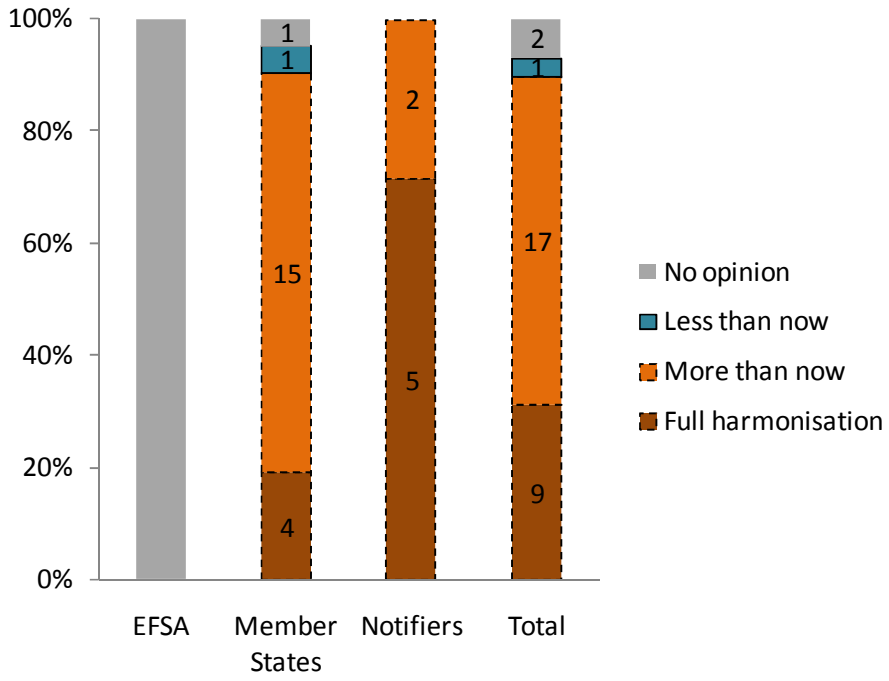


Figure 4.20C Should scientific opinions and conditions of consents take more account of regional variability?

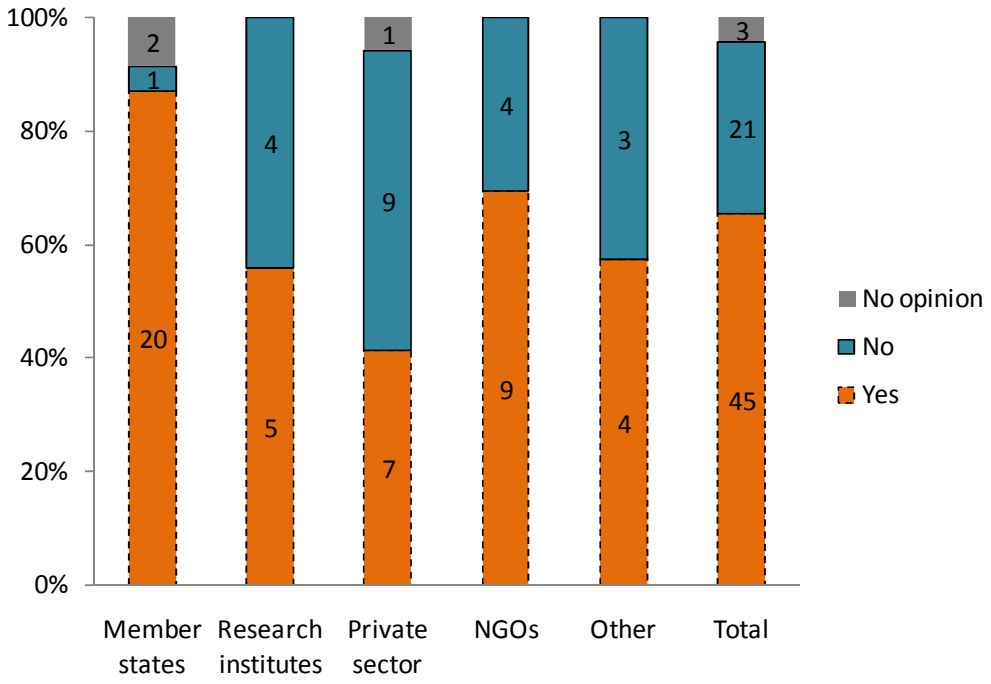


Figure 4.21C Unlike authorisation procedures for GMOs in other parts of the world, the EU requires that stacked events also require authorisation, even when single events have already been authorised. Do you think this should continue to be the case?

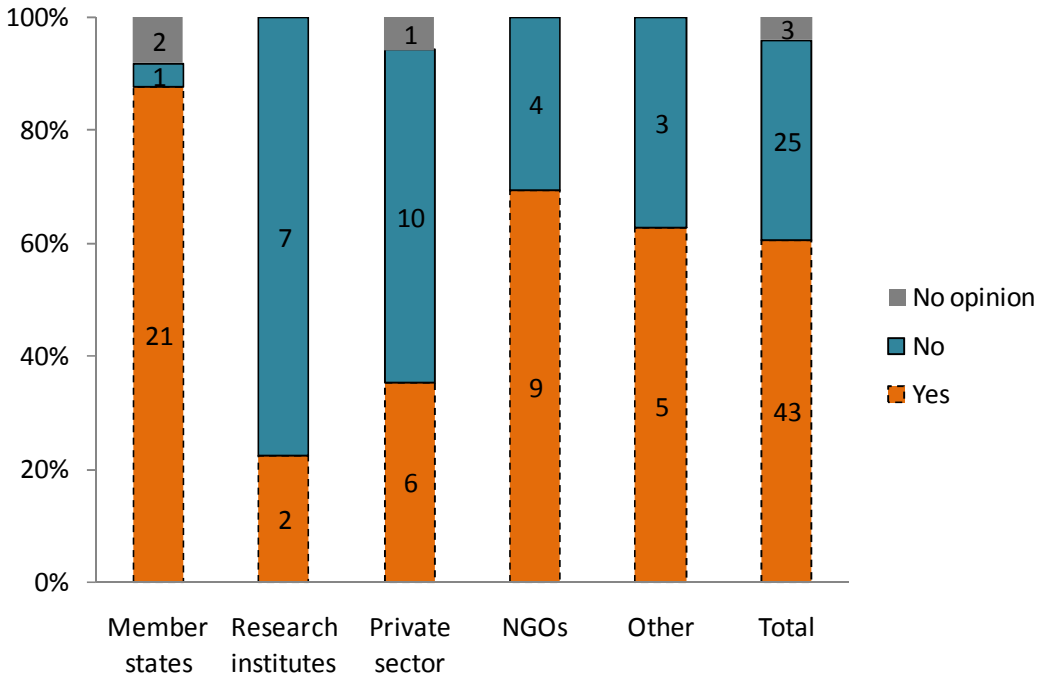
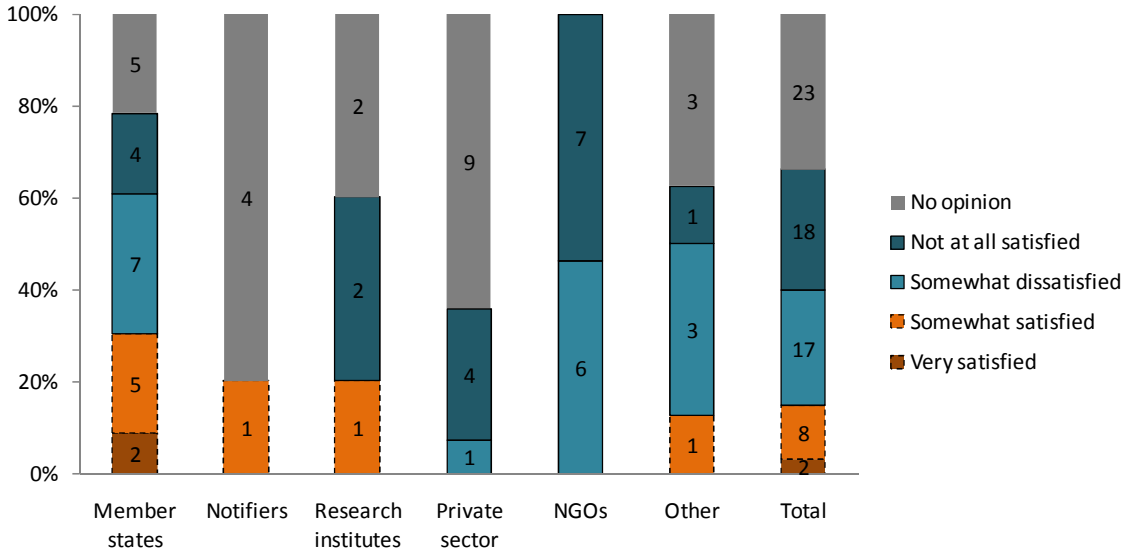


Figure 4.22 **To Notifiers only:** Unlike authorisation procedures for GMOs in other parts of the world, the EU requires that stacked events also require authorisation, even when single events have already been authorised. How significant is the impact on your organisation in terms of cost, resources and effort?

Figure 4.23C How satisfied are you with the way that herbicide tolerance, and its impact on the environment was treated in the ERA for the applications including cultivation, such as the application for NK603, Bt11 and 1507 maize, as well as soybean 40-3-2?



4.5 Figures corresponding to Section 4.5 of the Interim Report: On additional information requests

Figure 4.24 **To Notifiers only:** To what extent are requests for additional information / clarification from EFSA and NCAs generally reasonable and proportionate?

Figure 4.25 **To Notifiers only:** To what extent are requests for additional information / clarification from EFSA and NCAs consistent?

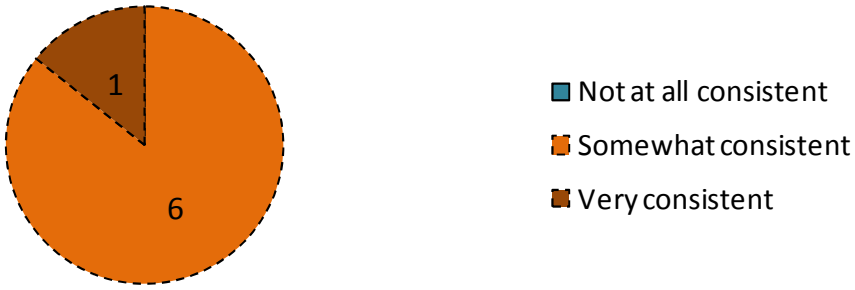


Figure 4.26 **To Notifiers only:** How often were requests for additional information difficult to understand?

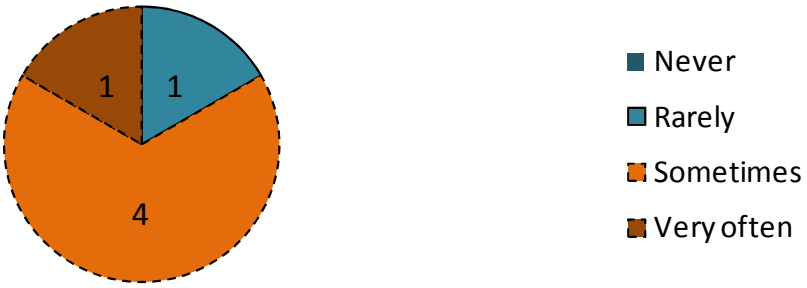
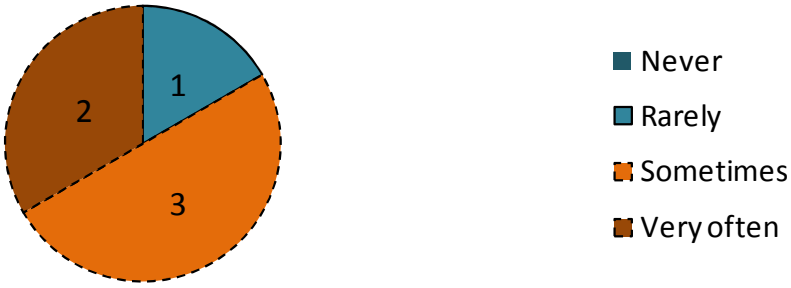


Figure 4.27 **To Notifiers only:** How often were requests for additional information unexpected?



4.6 Figures corresponding to Section 4.6 of the Interim Report: On the quality and quantity of dialogue among consultees

Figure 4.28 How satisfied are you with the process under which Member States are selected to assess the environmental risk assessment for cultivation, in applications made under the Regulation?

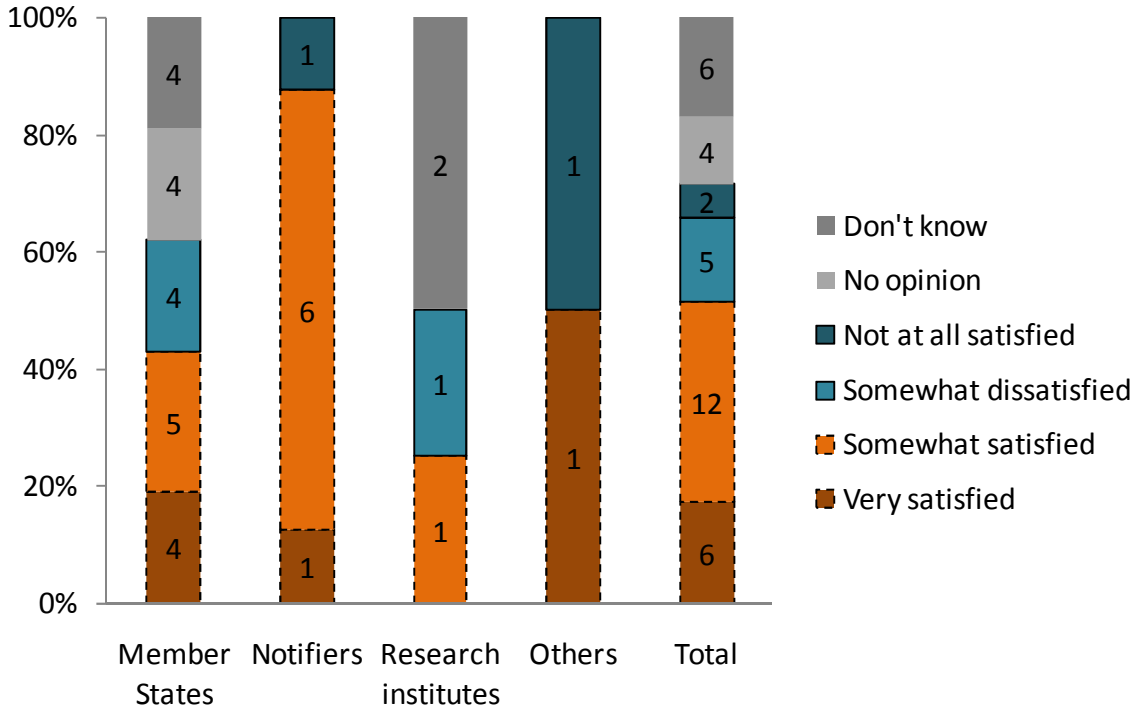


Figure 4.29 Member States are only consulted once by EFSA during the risk assessment procedure under Regulation 1829/2003, whereby national competent authorities have three months after the date of receiving the request within which to make their opinion known (Article 6(4), Article 18(4)).Does this arrangement provide sufficient opportunity to engage in and provide input to the assessment?

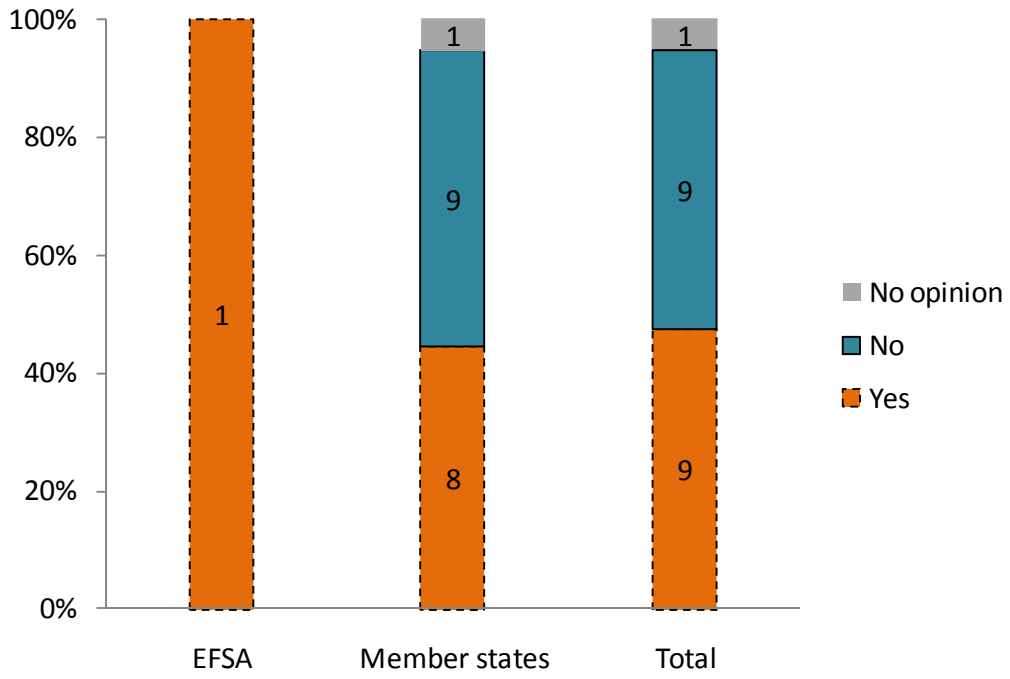


Figure 4.30 How satisfied are you with opportunities for to engage with and provide input on applications for placing GMOs on the market?

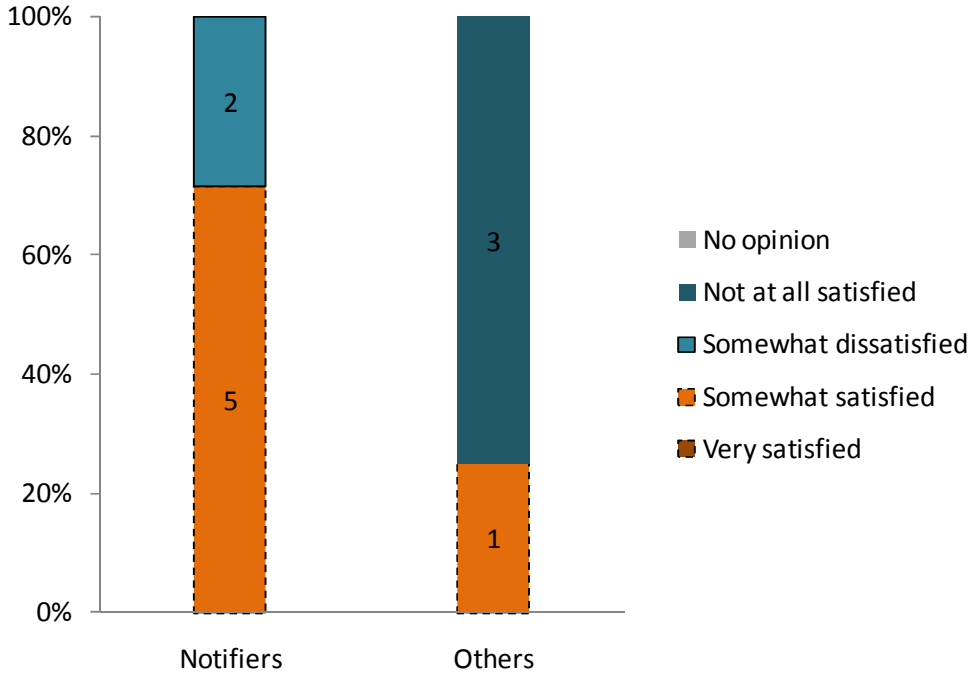


Figure 4.31 **To Notifiers only:** How satisfied are you with the possibilities to engage with EFSA before and during your application?

Figure 4.32 **To Notifiers only:** If EFSA offered the opportunity to engage in pre-application discussions for applications submitted under the Regulation, would you make use of it?

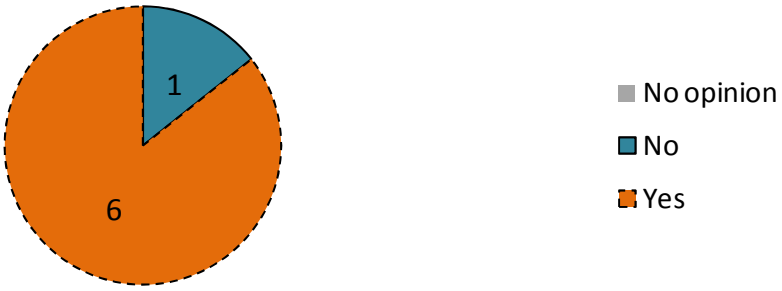


Figure 4.33 **To Notifiers only:** How beneficial do you think pre-application discussions for applications submitted under the Regulation would be?

Figure 4.34 **To Member State authorities only:** How often do you comment on GMO applications for cultivation being handled by EFSA?

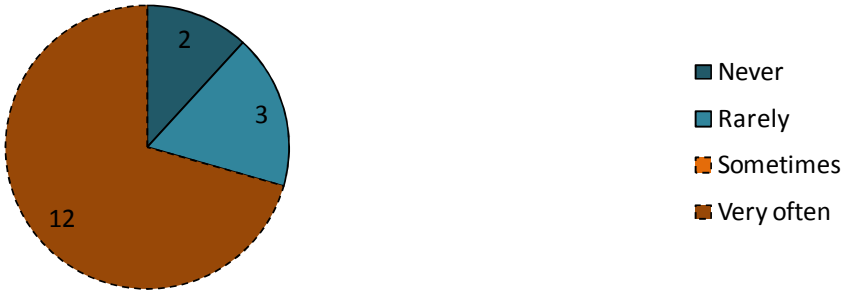


Figure 4.35 **To Member State authorities only:** How satisfied are you with the way your comments are dealt with by EFSA (the process by which they are received, examined, and responded to, as well as the responses)?

Figure 4.36 **To Member State authorities only:** An EFSA Scientific Cooperation (ESCO) Working Group has examined risk assessment approaches across Member States, and how they could be harmonised. It has recommended that:

- EFSA and Member States develop 'country profiles' for a better understanding of the role and competencies of national risk assessment institutions in the different countries;
- Risk assessment outputs of national organisations should be made publicly available;
- Quality management tools should be implemented in the risk assessment process;
- Risk assessment approaches need to be further harmonised within the specific scientific areas.

a. How important or useful are these moves?

b. How realistic is the aspiration?

c. Have any steps been taken to implement these recommendations?

4.7 Figures corresponding to Section 4.7 of the Interim Report: On the impacts of notifiers consistently choosing to use the Regulation instead of the Directive for applications whose scope includes cultivation

Figure 4.37C Does the "one door one key" option available under Regulation 1829/2003 improve on the process available under Directive 2001/18EC?

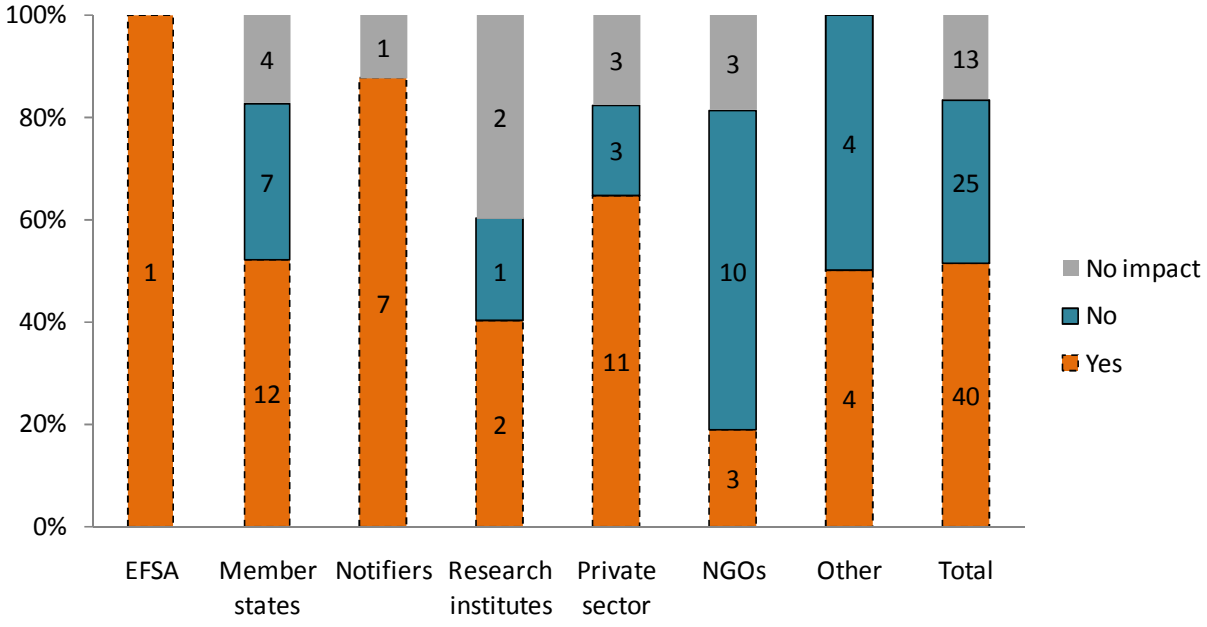
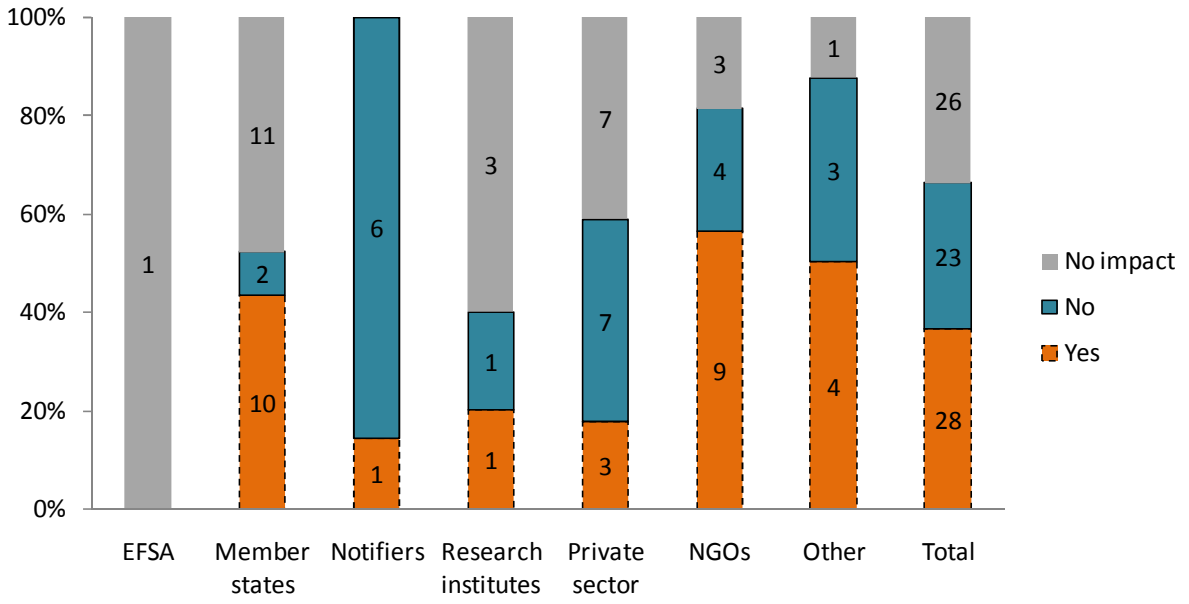


Figure 4.38C Does the "one door one key" option available under Regulation 1829/2003 impact on the quality or the outcome of the ERA assessment?



5 IMPLEMENTATION OF THE PART B OF DIRECTIVE 2001/18/EC GOVERNING FIELD TRIALS OF GMOS

The following figures supplement the text in Section 5 of the Interim Report.

5.1 Figures corresponding to Section 5.1 of the Interim Report: On trends in field trial numbers

Figure 5.1 How do you expect the number of GM field trial applications submitted in your country to change over the next 5 years?

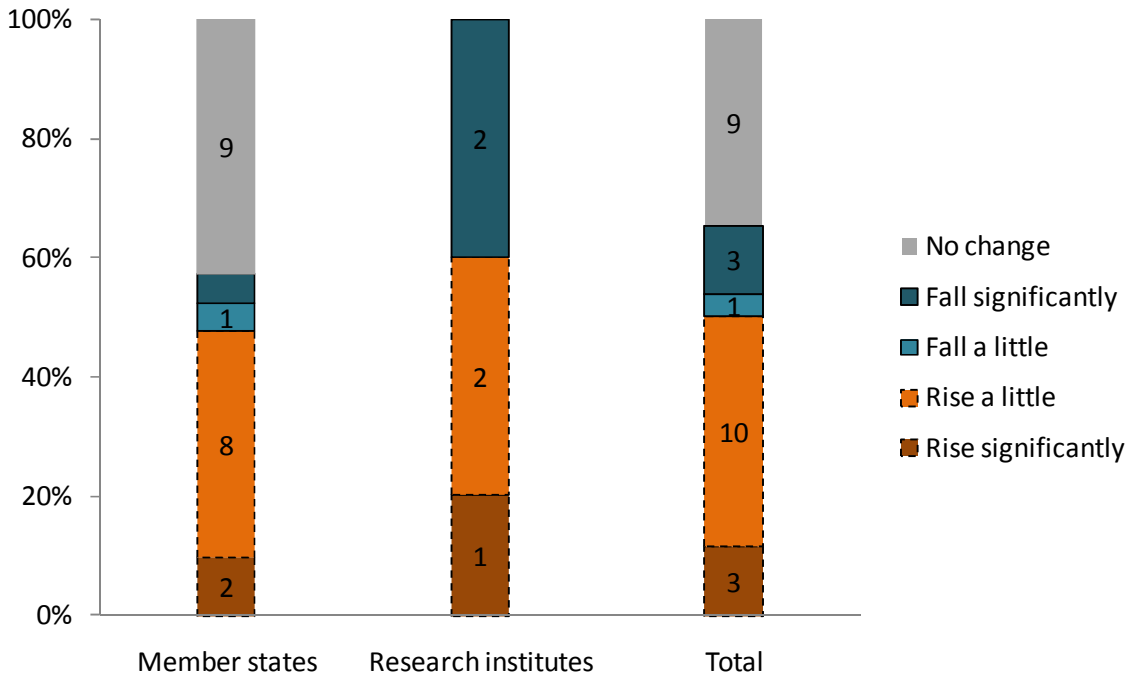
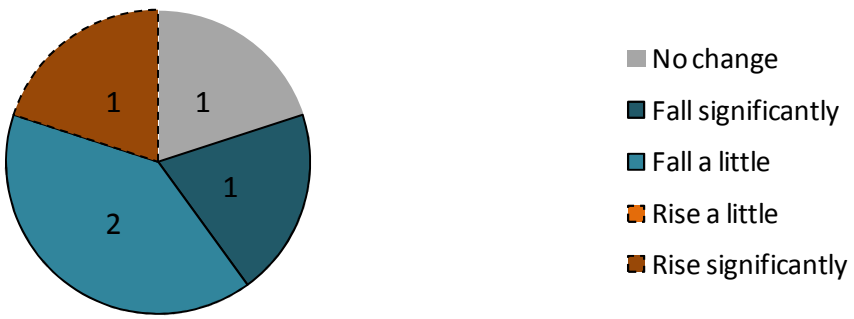


Figure 5.2 **To Notifiers only:** How do you think the number of applications submitted under Part B is likely to change over the next 5 years?



5.2 Figures corresponding to Section 5.2 of the Interim Report: On obtaining approvals for field trials

Figure 5.3 How clear is the guidance provided on what is required?

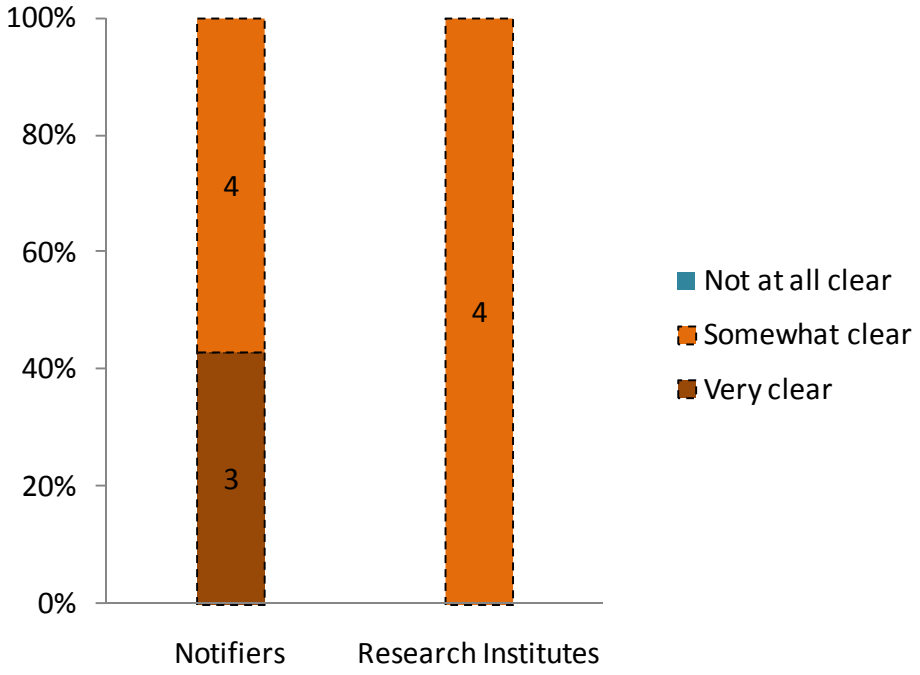


Figure 5.4 How satisfied are you with the clarity and rigour of EFSA's guidance on the statistical methods and design of field trials?

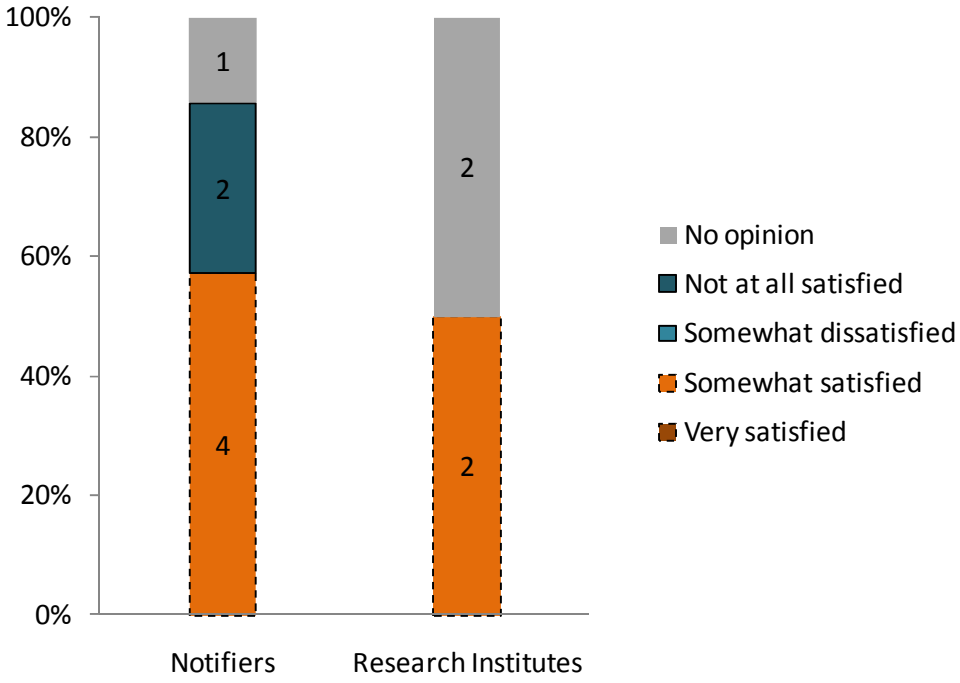


Figure 5.5 How consistent are Member States in the way they assess the ERA for a Part B field trial (including the information required to complete a dossier, and conditions for a consent to be issued)?

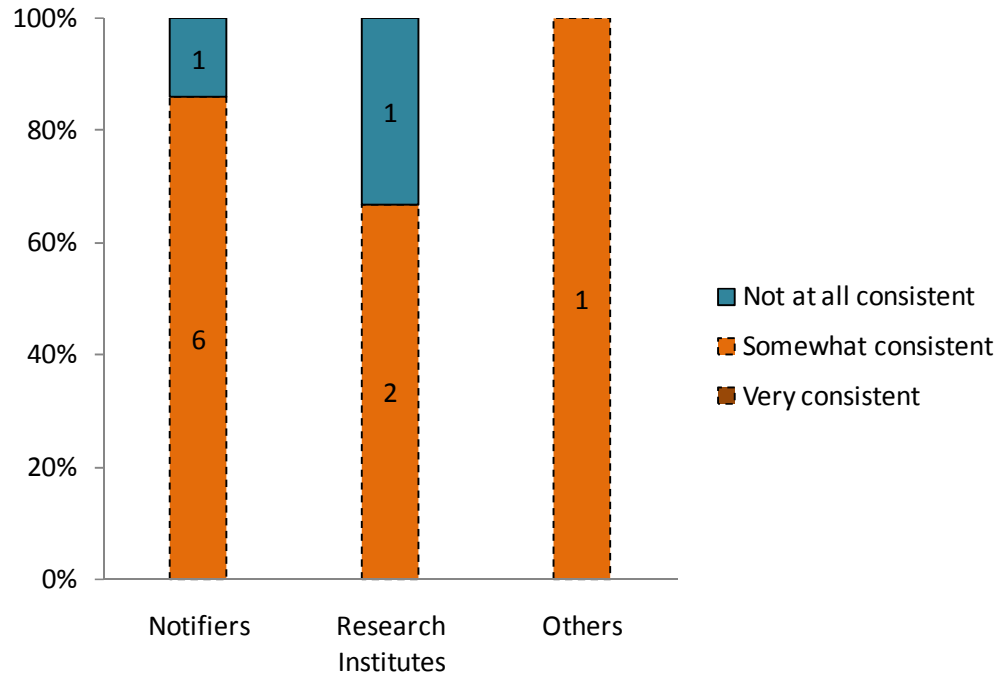


Figure 5.6 To what extent is the process for applying and conducting a field trial sufficiently transparent?

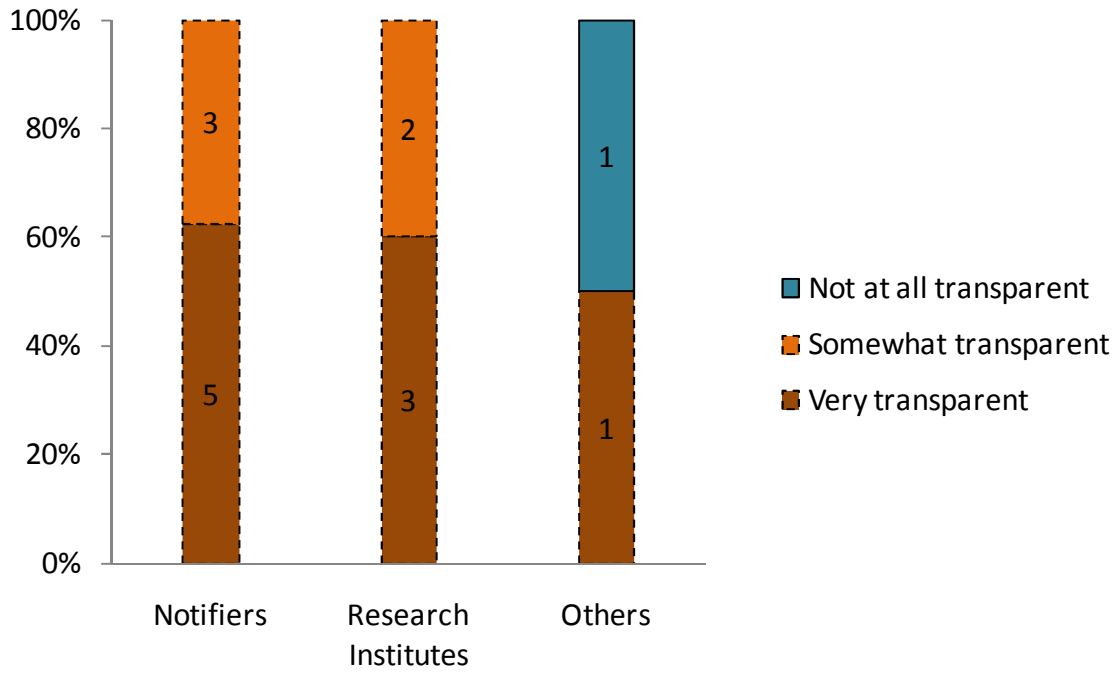
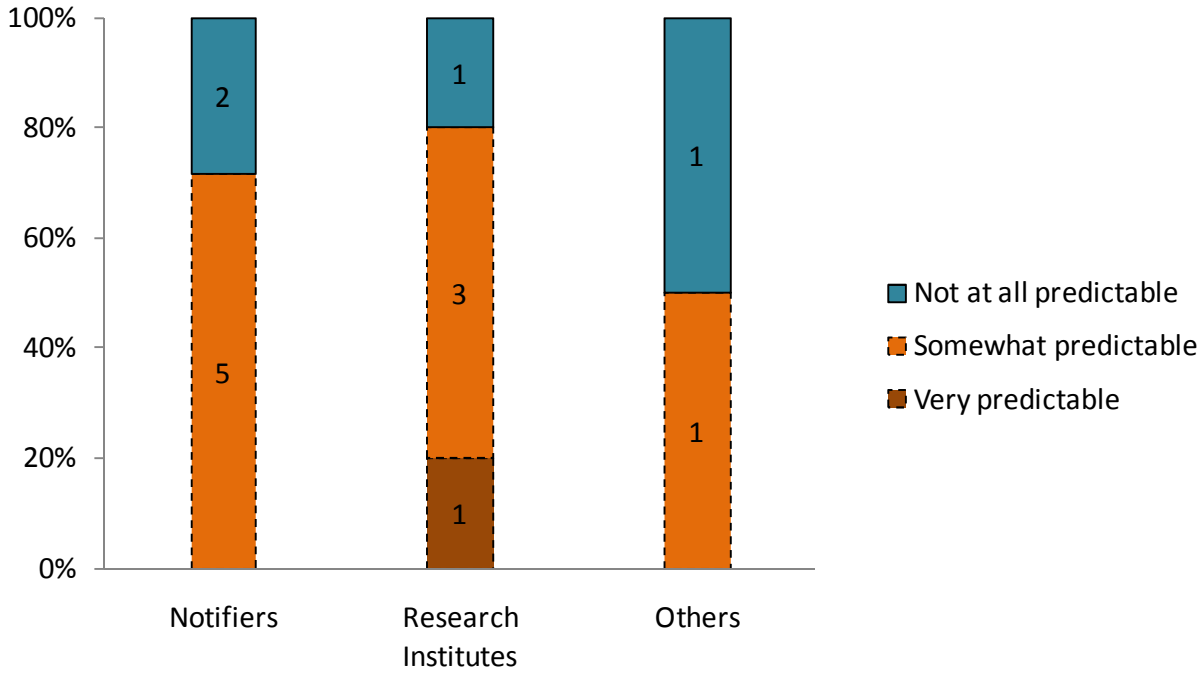


Figure 5.7 To what extent is the process for applying and conducting a field trial sufficiently predictable?



5.3 Figures corresponding to Section 5.3 of the Interim Report: On conducting and completing field trials

Figure 5.8 How often have there been incidents of unanticipated problems whilst conducting a field trial?

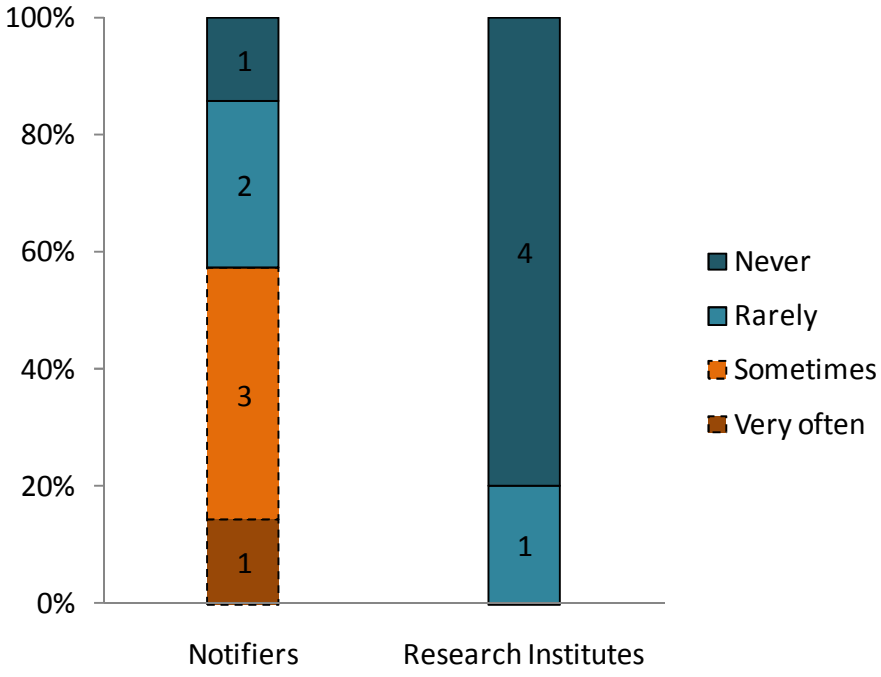


Figure 5.9 How often have your field trials been vandalised?

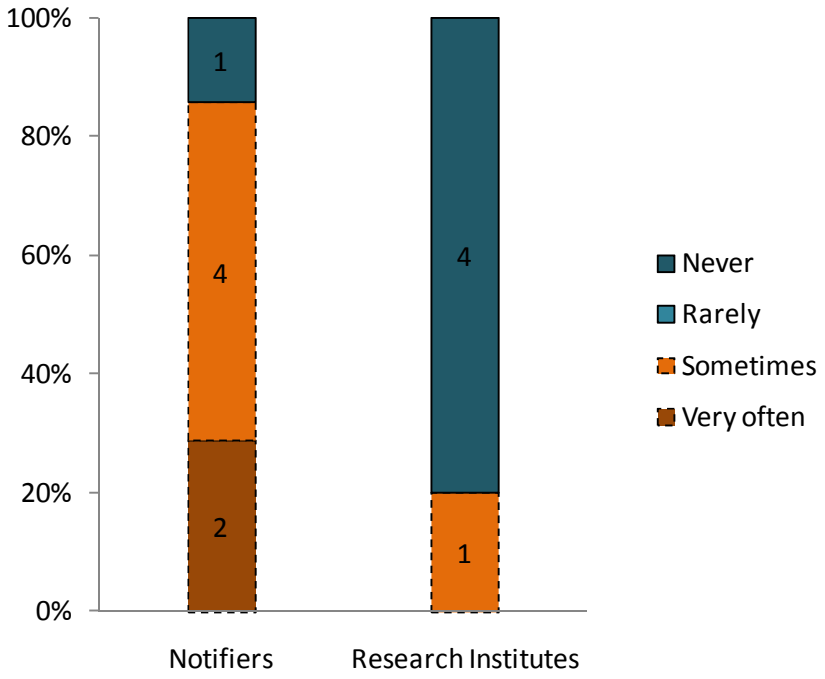


Figure 5.10 How often has vandalism led to the termination of field trials?

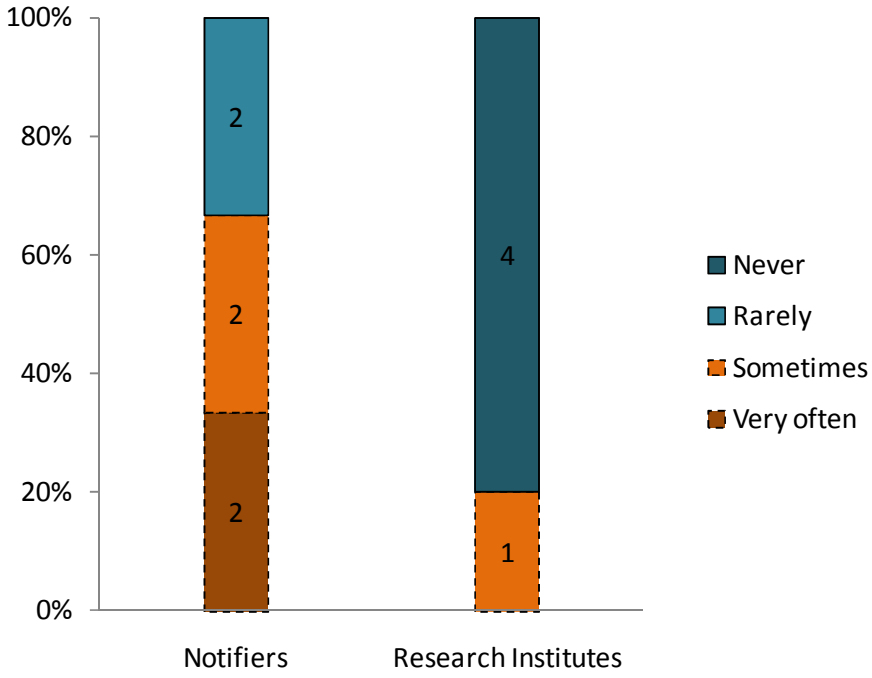


Figure 5.11 To what extent has the risk of vandalism discouraged you from conducting more field trials in the future?

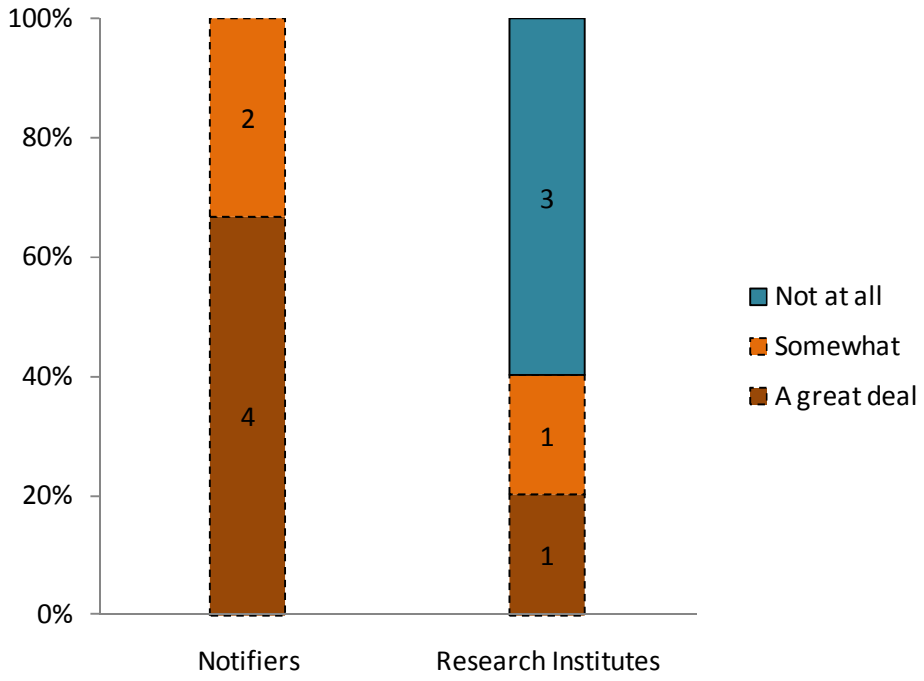


Figure 5.12 To what extent do you think this position will affect the use of Antibiotic Resistance Markers (ARMs) in field trials and in GMOs which are placed on the market?

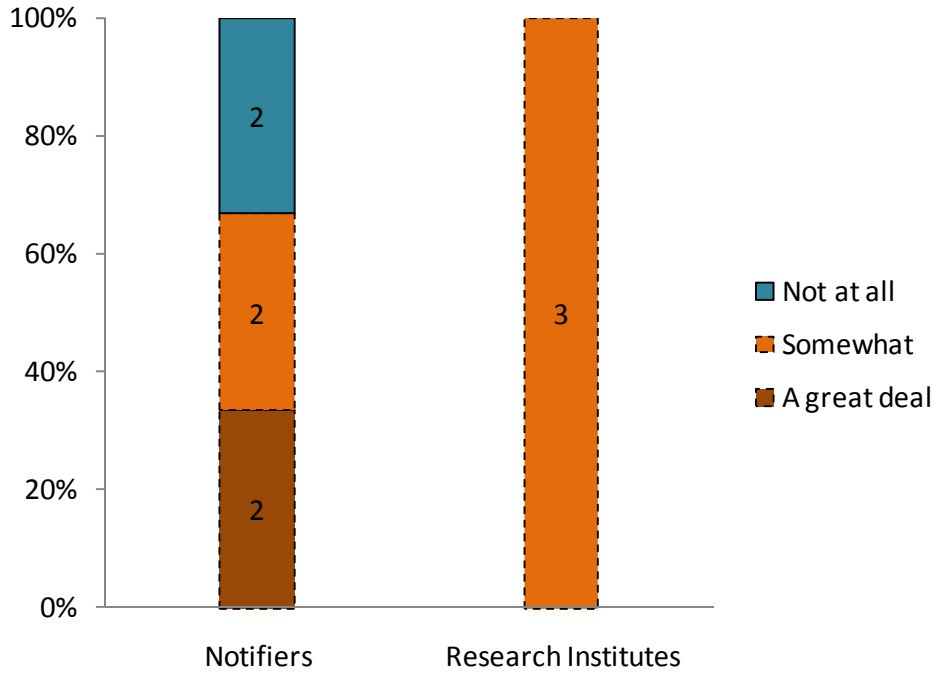


Figure 5.13 To what extent have the legislative requirements and EFSA's position on ARMs had an impact on your Research and Development?

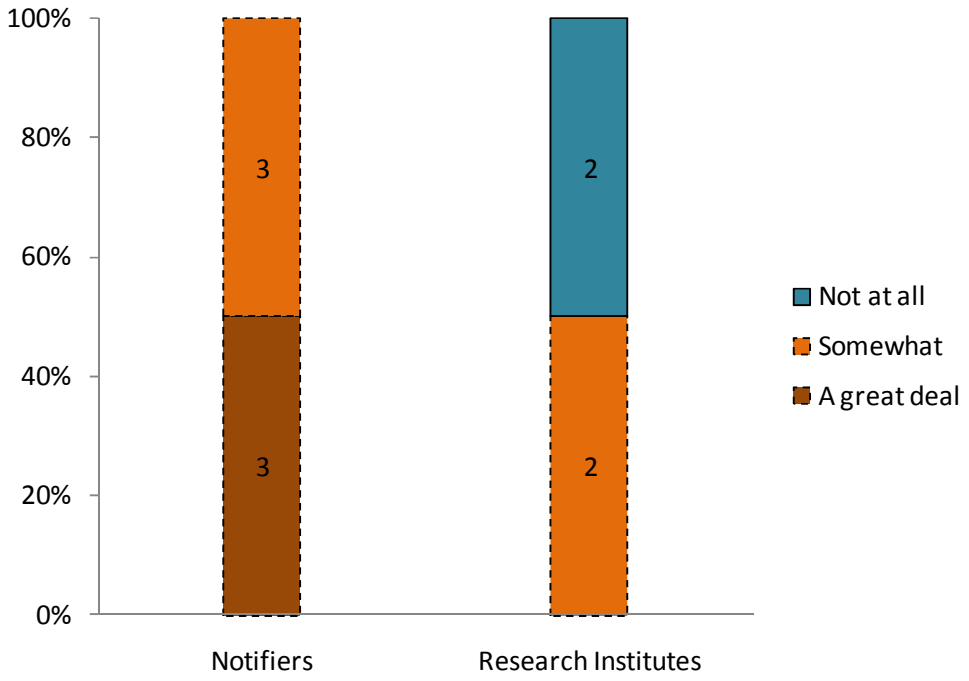


Figure 5.14 **To Notifiers only:** To what extent has the regulation of ARMs affected the pipeline of applications under Part C?

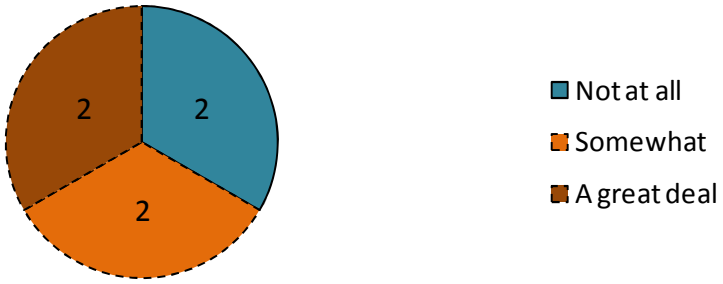


Figure 5.15C To what extent do you agree with EFSA's current position on ARMs?

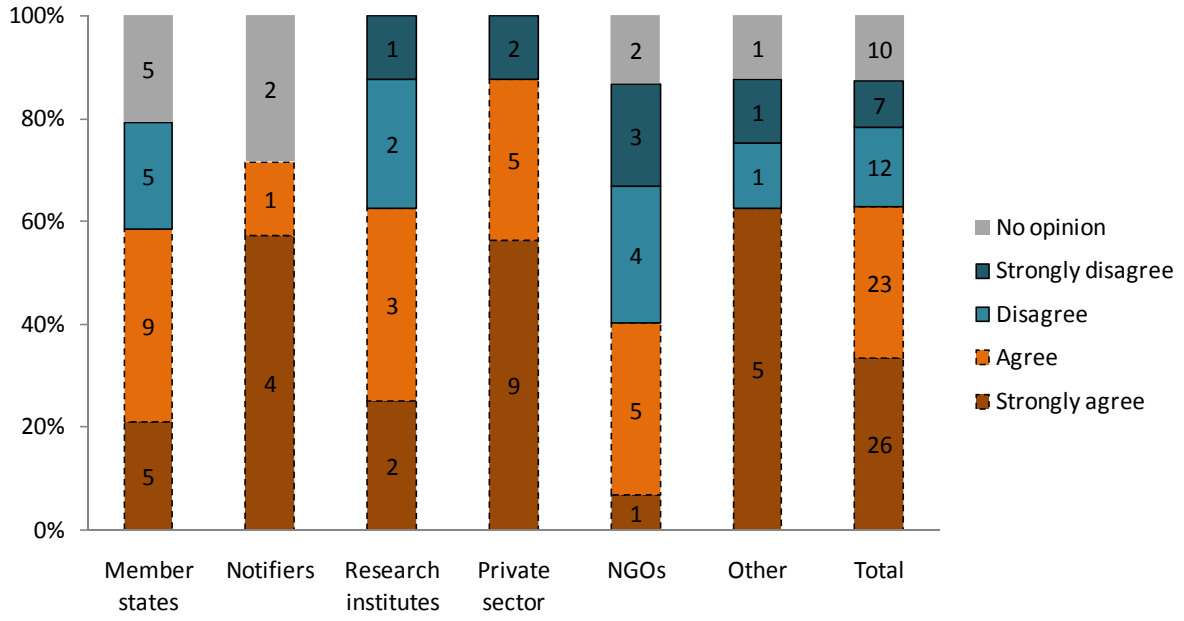
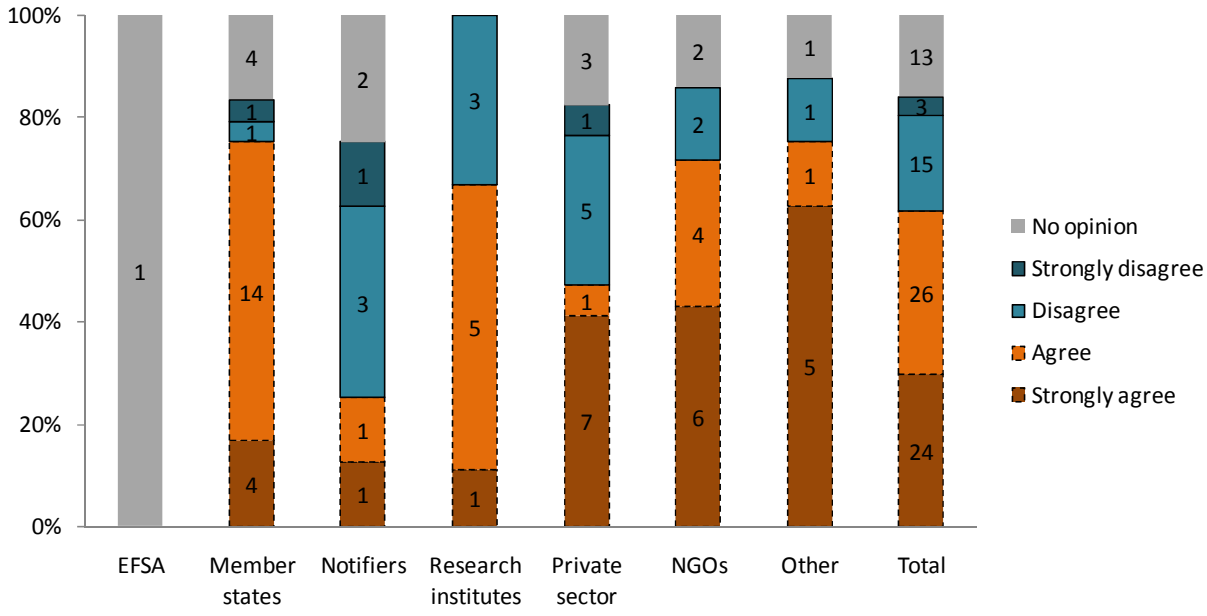


Figure 5.16C To what extent do you agree that there is a need to further harmonise the way in which field trials are designed, conducted and analysed across Member States?



5.4 Figures corresponding to Section 5.4 of the Interim Report: On the links between field trials and cultivation

Figure 5.17C To what extent do you agree that the current operation of Part B of Directive 2001/18 is affecting the number of applications submitted for placing a GMO on the market (given possible difficulties in obtaining approval, or obstacles to successfully completing a field trial)?

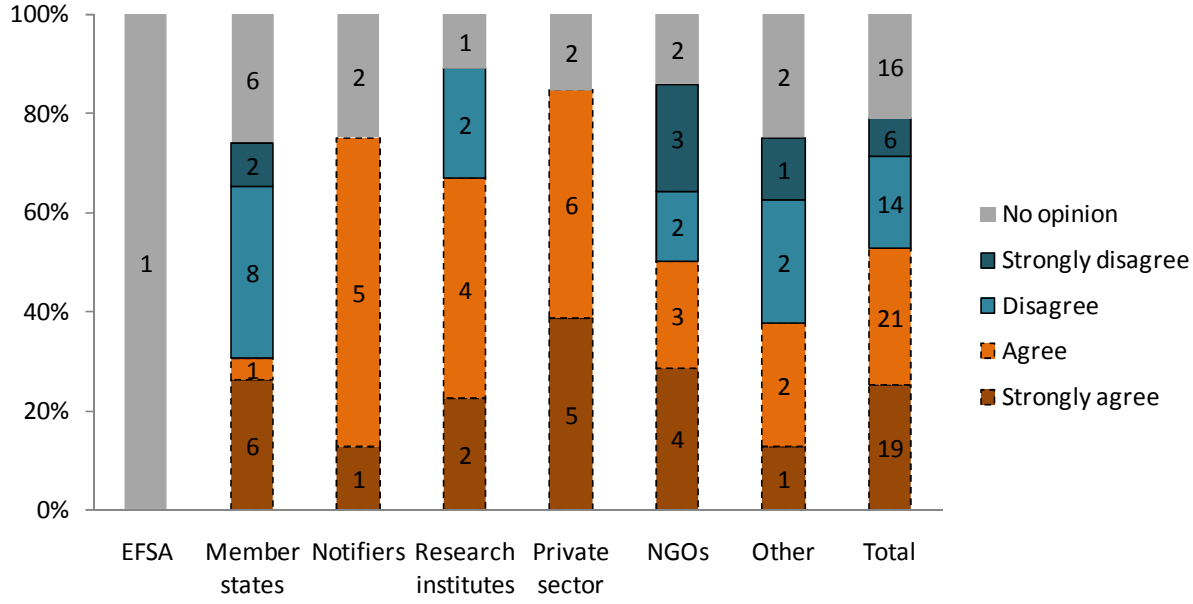
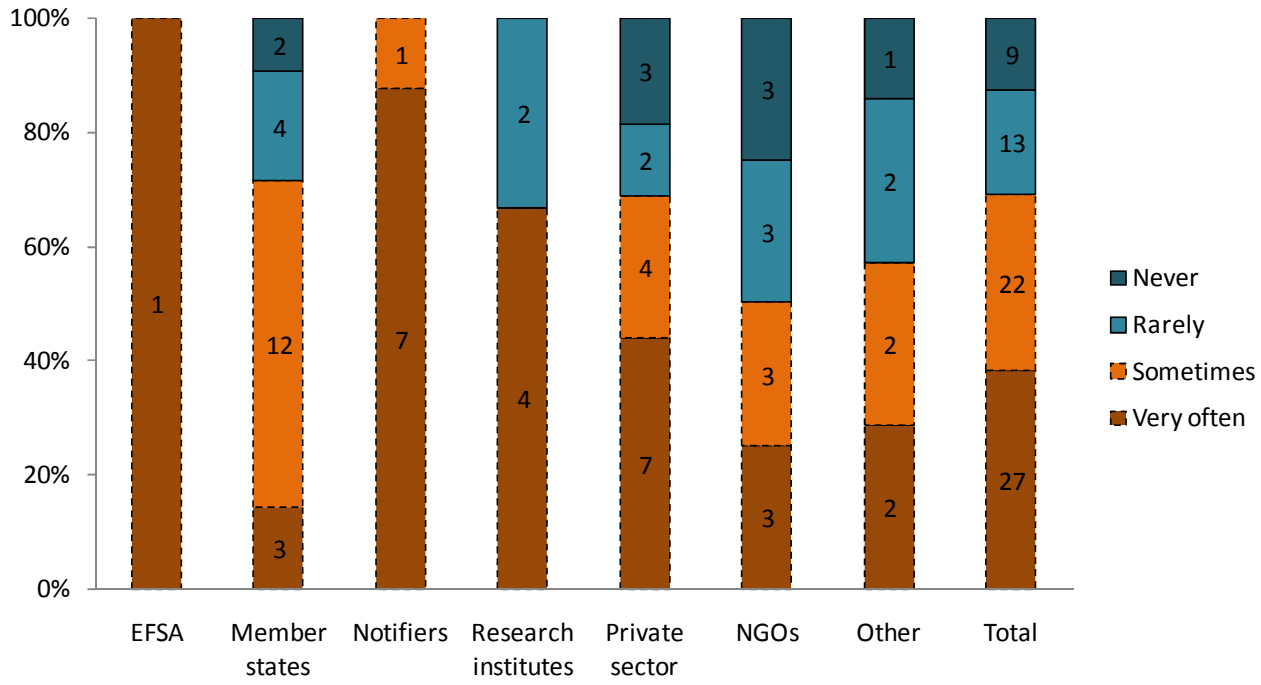


Figure 5.18C Does the design, conduct and analysis of Part B field trials provide adequate evidence (in terms of quality and quantity) for subsequent authorisation for cultivation?



6 RISK MANAGEMENT

The following figures supplement the text in Section 6 of the Interim Report.

6.2 Figures corresponding to Section 6.2 of the Interim Report: On the institutional decision-making for GMO cultivation

Figure 6.1C On the 25th of June, 2009, Austria submitted a paper to the Environmental Council concerning the right of Member States to opt-out of growing GMOs on their territory which have already been approved by the EU. The proposal was supported by Bulgaria, Ireland, Greece, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland and Slovenia. Previously, the Netherlands submitted a similar declaration to the Environmental Council on 2 March 2009 and to the Agricultural Council on 23 March 2009. To what extent do you think this is an appropriate solution to the problems represented by Member States' inability to achieve a qualified majority?

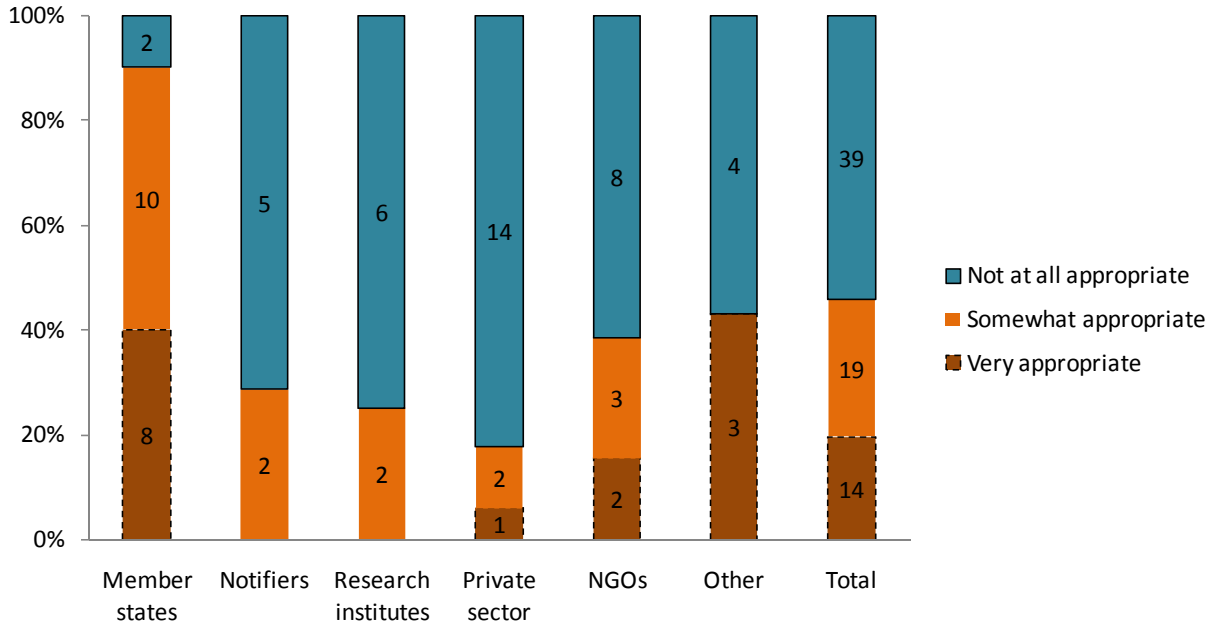


Figure 6.2C To what extent do you agree that socio-economic concerns should be taken into account when making decisions on the authorisation of GMOs for cultivation?

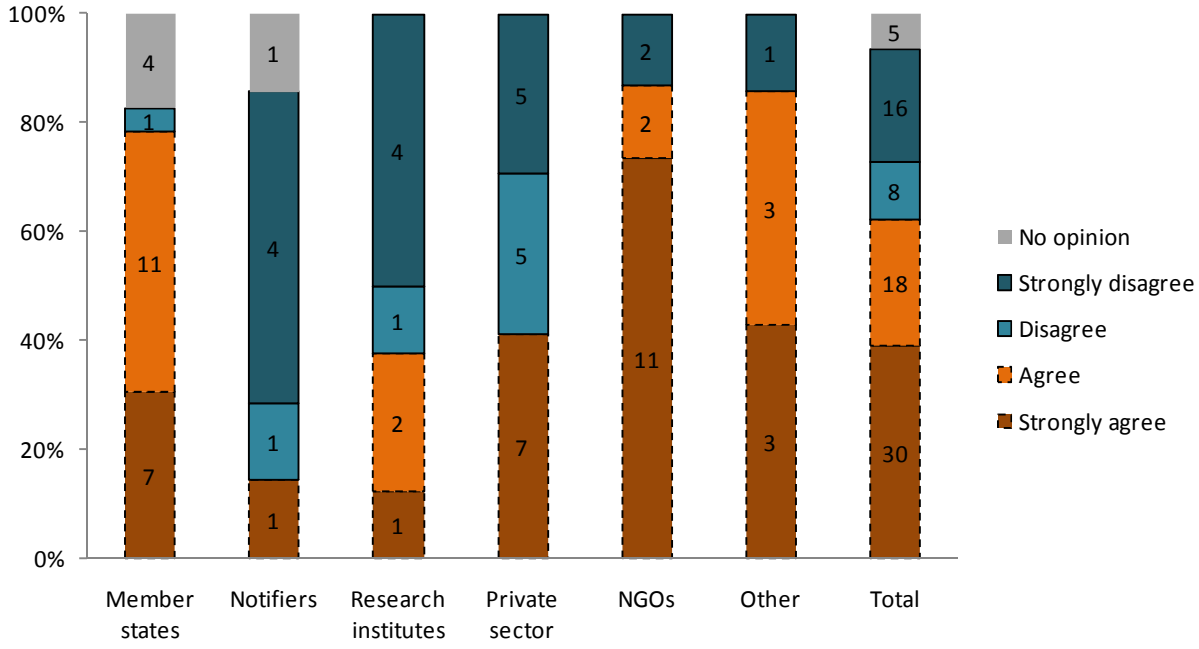
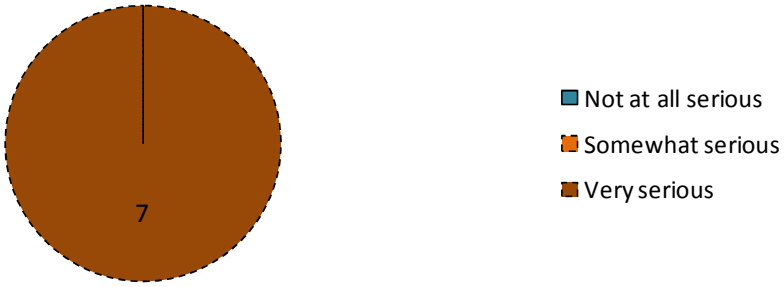


Figure 6.3 **To Member State authorities only:** In your view, does the implementation of the current system of national safeguard and emergency measures address the objectives of the legislation, in terms of efficiency?

Figure 6.4 **To Member State authorities only:** In your view, does the implementation of the current system of national safeguard and emergency measures address the objectives of the legislation, in terms of transparency?

Figure 6.5 **To Member State authorities only:** In your view, does the implementation of the current system of national safeguard and emergency measures address the objectives of the legislation, in terms of protection of eco-systems, environments and geographical areas?

Figure 6.6 **To Notifiers only:** How serious do you consider the impacts of a national ban to be?



6.4 Figures corresponding to Section 6.4 of the Interim Report: On practical risk management measures

Figure 6.7C To what extent do you agree that the provisions in Directive 2001/18/EC and Regulation 1829/2003 for inspections, controls, monitoring and special protection of eco-systems, environments and geographical areas, are fit for purpose?

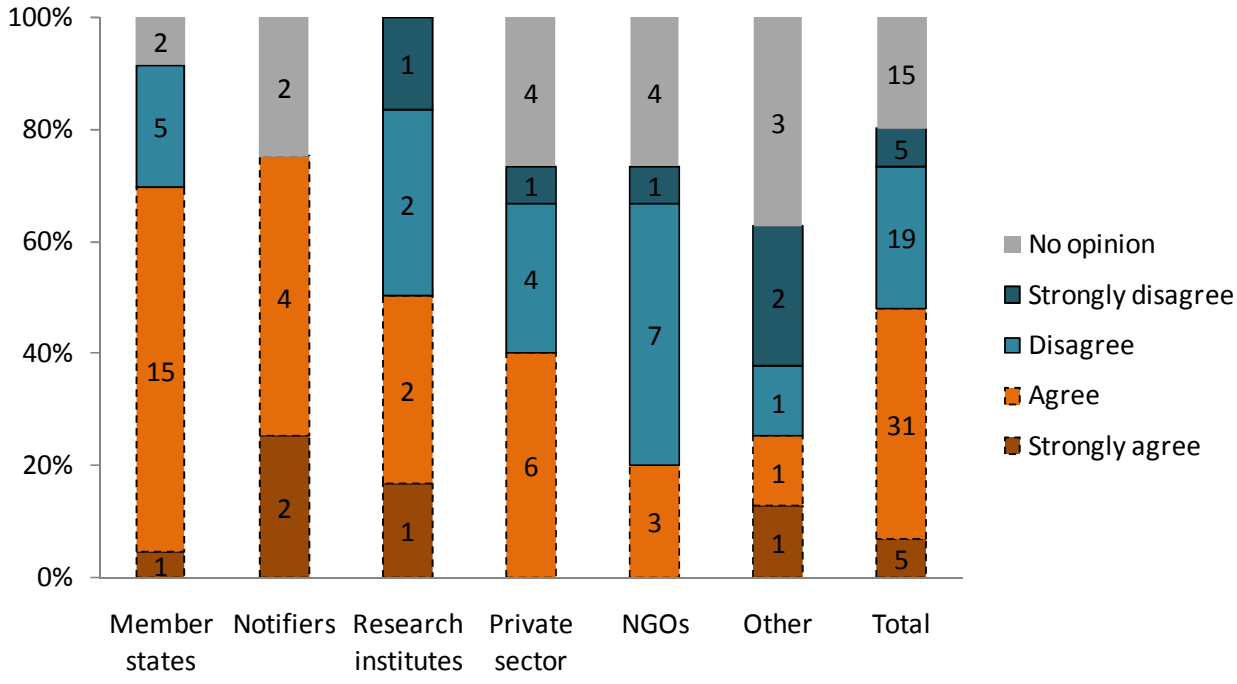


Figure 6.8C To what extent do you agree that the risk management requirements introduced in Directive 2001/18/EC and Regulation 1829/2003 provided a more transparent and predictable EU regime compared to that under the Directive 90/220/EEC and the Novel Foods Regulation (258/97/EC)?

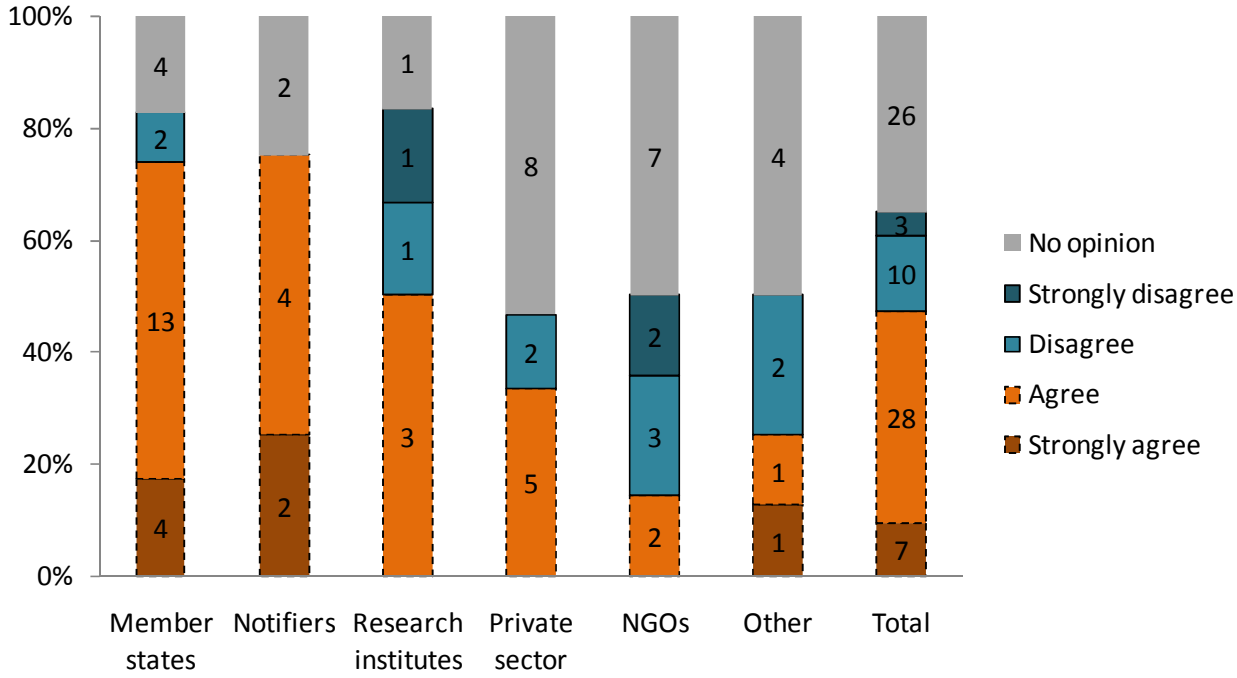


Figure 6.9 **To Notifiers only:** To what extent have the provisions in Directive 2001/18/EC and Regulation 1829/2003 for monitoring and special protection of eco-systems, environments and geographical areas, encouraged relevant authorities across Member State to establish links with notifiers in order to coordinate data collection and analysis from different monitoring programmes?

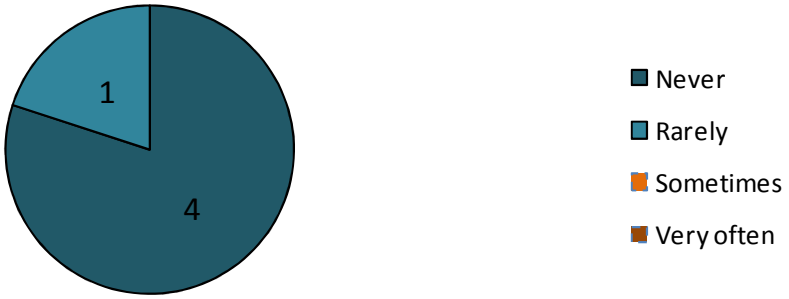


Figure 6.10 One of the key objectives of the Directive 2001/18/EC (EC, 2001) is to protect the environment including biodiversity, water and soil. To what extent does the general surveillance plan in the PMEM plan link monitoring to the environmental protection goals?

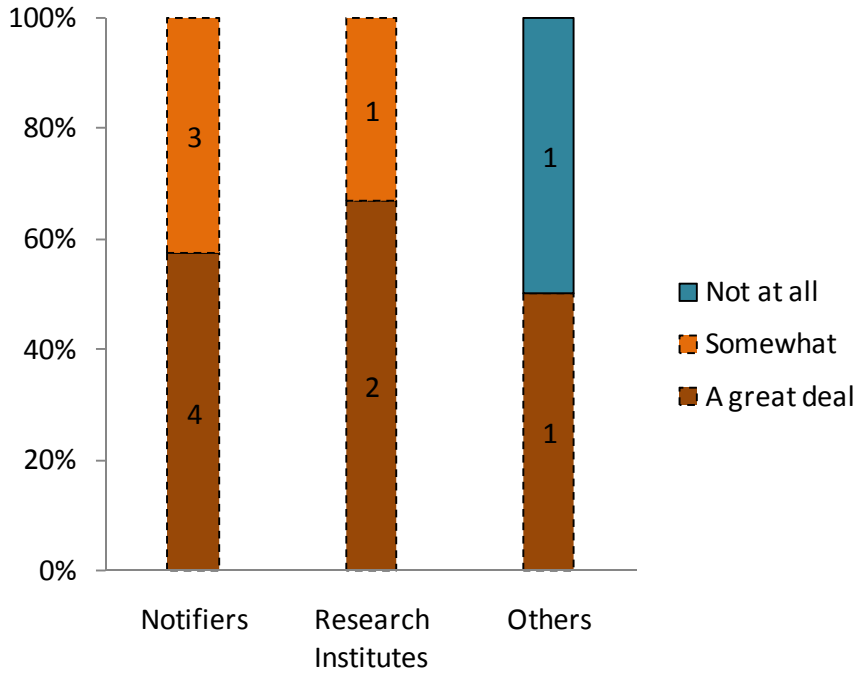


Figure 6.11C Has standard practice or best practice been clearly defined for management of cultivated GMOs in your Member State? (e.g. isolation distances or "buffer zones", or use of border rows of non-transgenic plants to catch pollen)

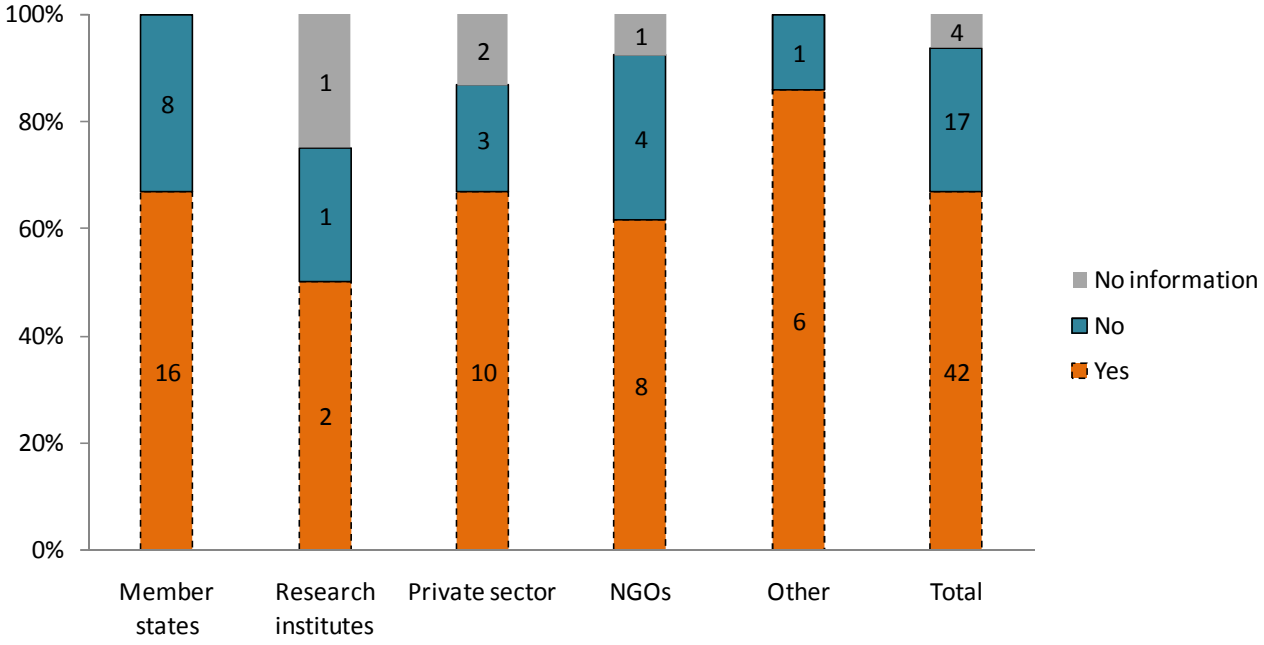


Figure 6.12 **To Notifiers only:** To what extent are consent holder reporting requirements for the PMEM plan similar across Member States?

Figure 6.13C To what extent do risk management measures as defined in your Member State take into consideration the variability in ecosystems/environments and/or geographic areas?.

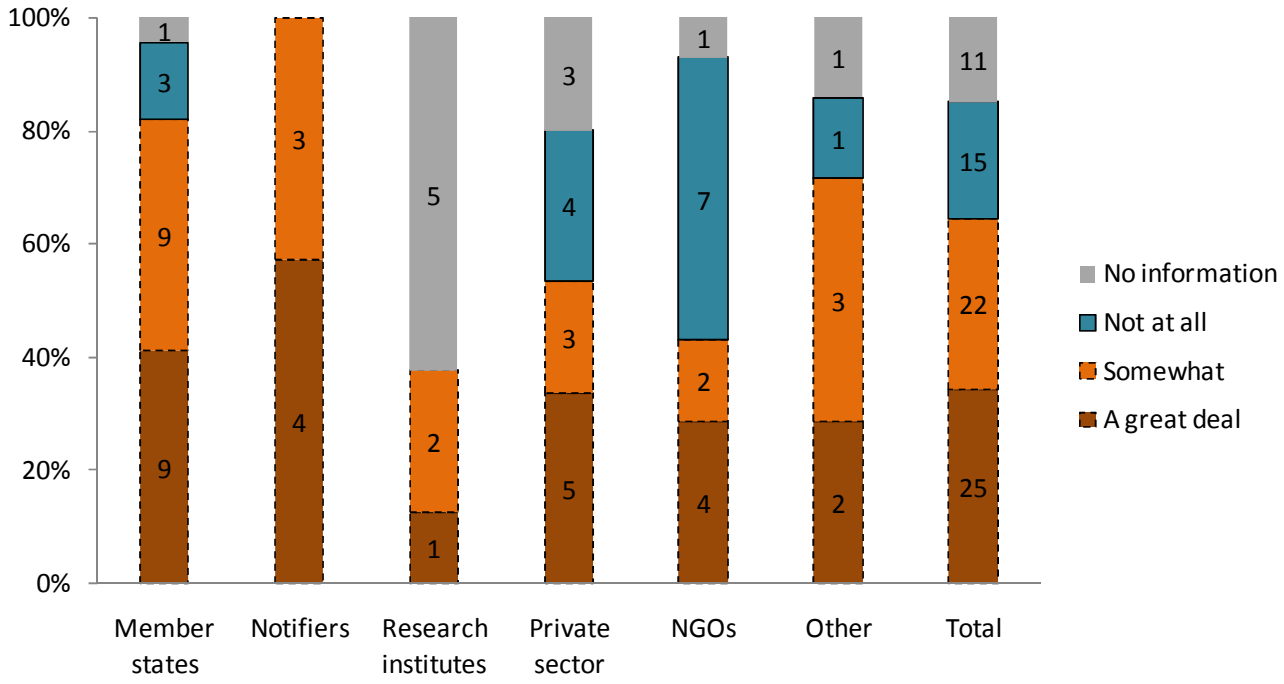


Figure 6.14 To what extent do you agree that the design of the PMEM plans that are submitted by applicants under Part C and Part B generally meet the legislation's objectives (Annex VII of the Directive 2001/18/EC)?

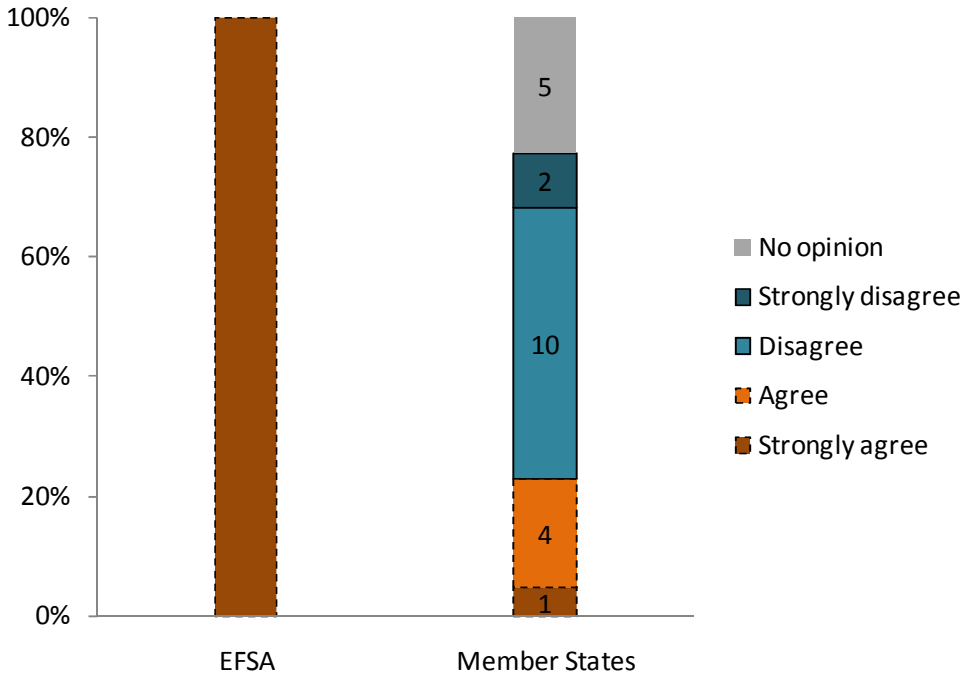


Figure 6.15C Given the guidance that has been developed by the Commission, to what extent do you believe that the types of post-market monitoring that will be required will be consistent in terms of design, scope and application across all Member States?

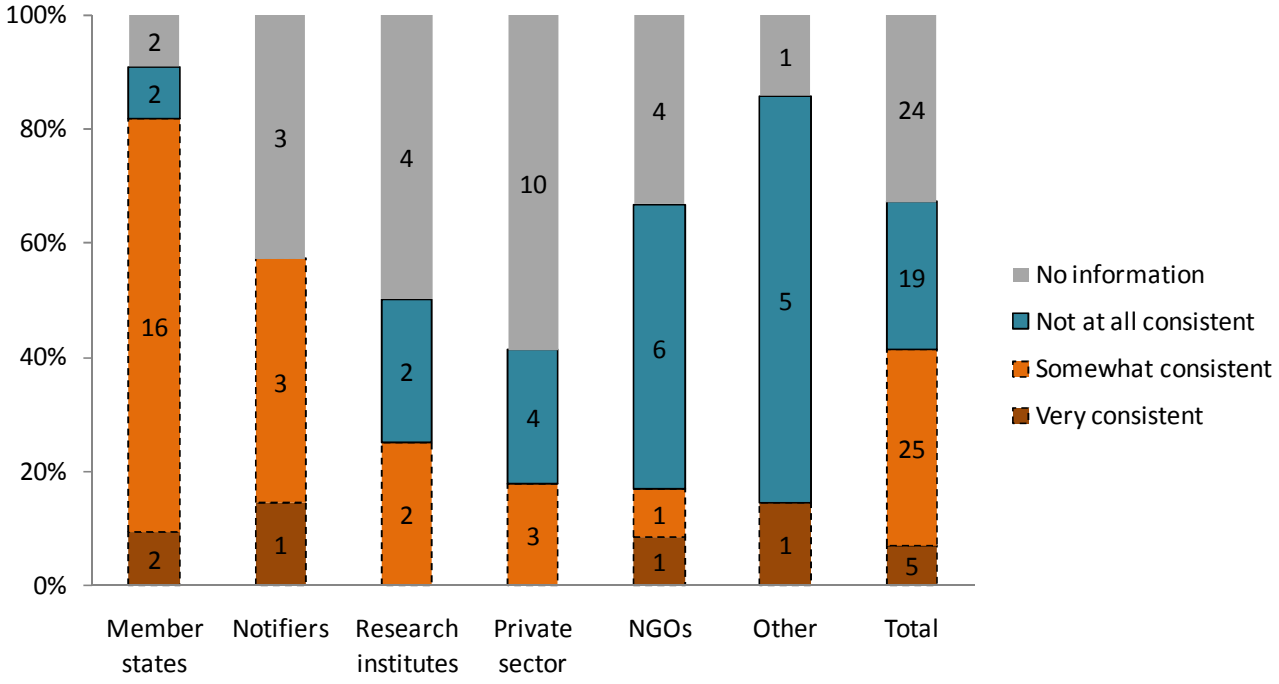


Figure 6.16 **To Research Institutes only:** Have procedures for monitoring of your releases been explained to you?

Figure 6.17 **To Research Institutes only:** Are procedures for monitoring of your releases easy to comply with?

Figure 6.18 Do the provisions in Directive 2001/18/EC and Regulation 1829/2003 for monitoring and special protection of eco-systems, environments and geographical areas, encourage relevant authorities in your Member State to establish links with applicants in order to coordinate data collection and analysis from different monitoring programmes?

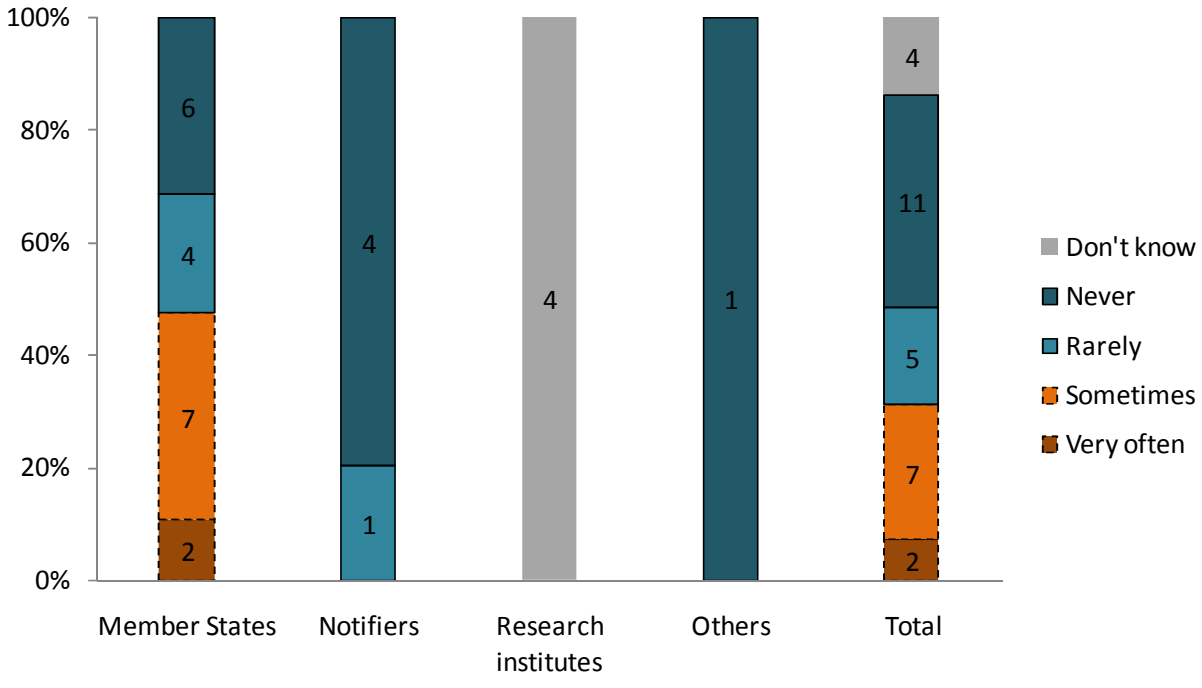


Figure 6.19C Are there any issues concerning the boundary between case-specific monitoring and general surveillance monitoring which you would like to see addressed?

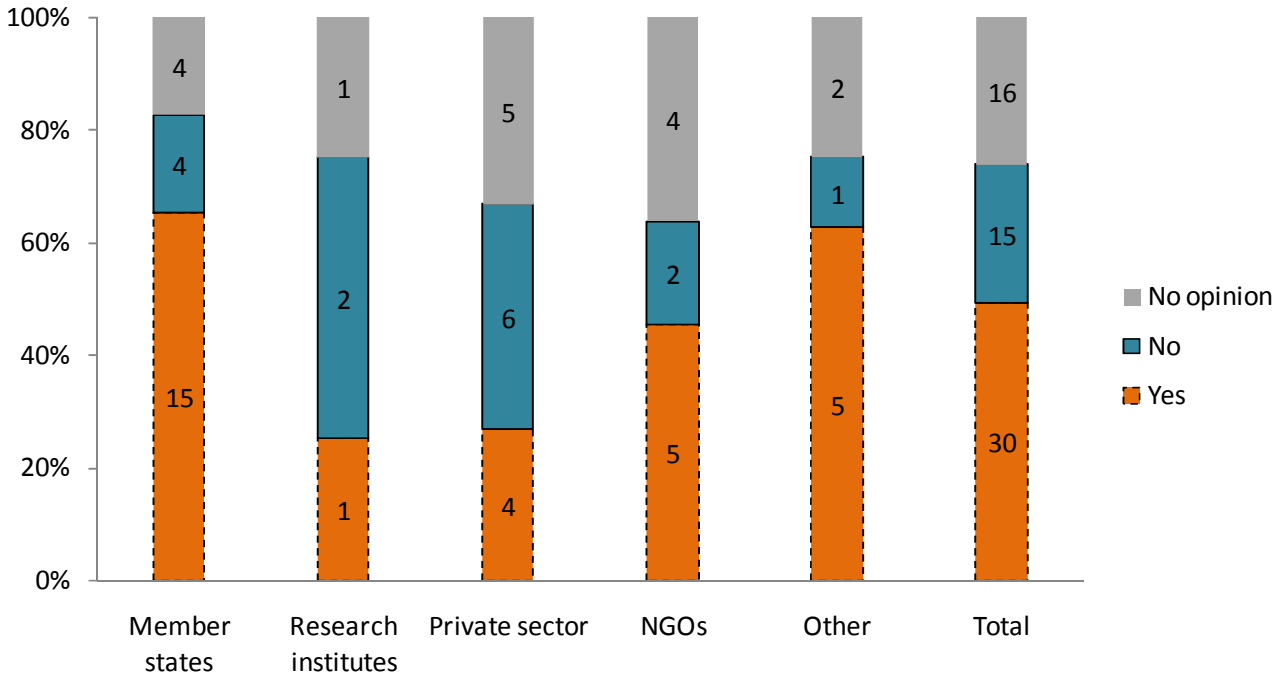


Figure 6.20C Is there a need for further action on case-specific post-release monitoring?

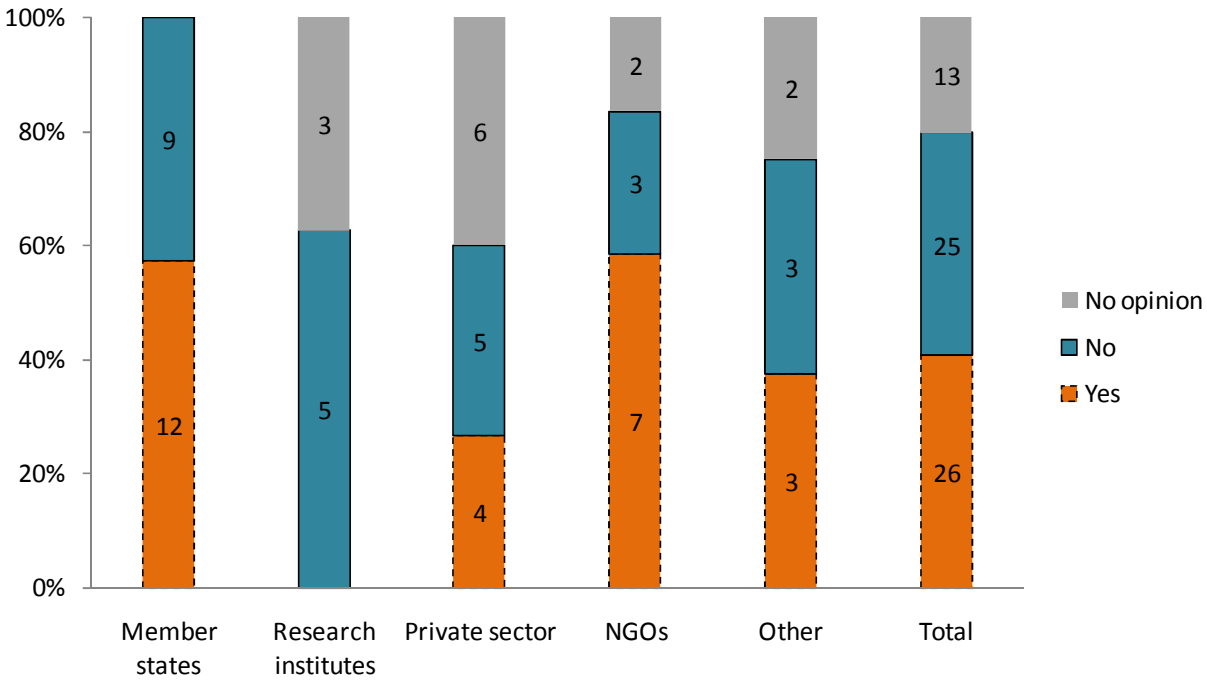


Figure 6.21C Is there a need for further action on general surveillance?

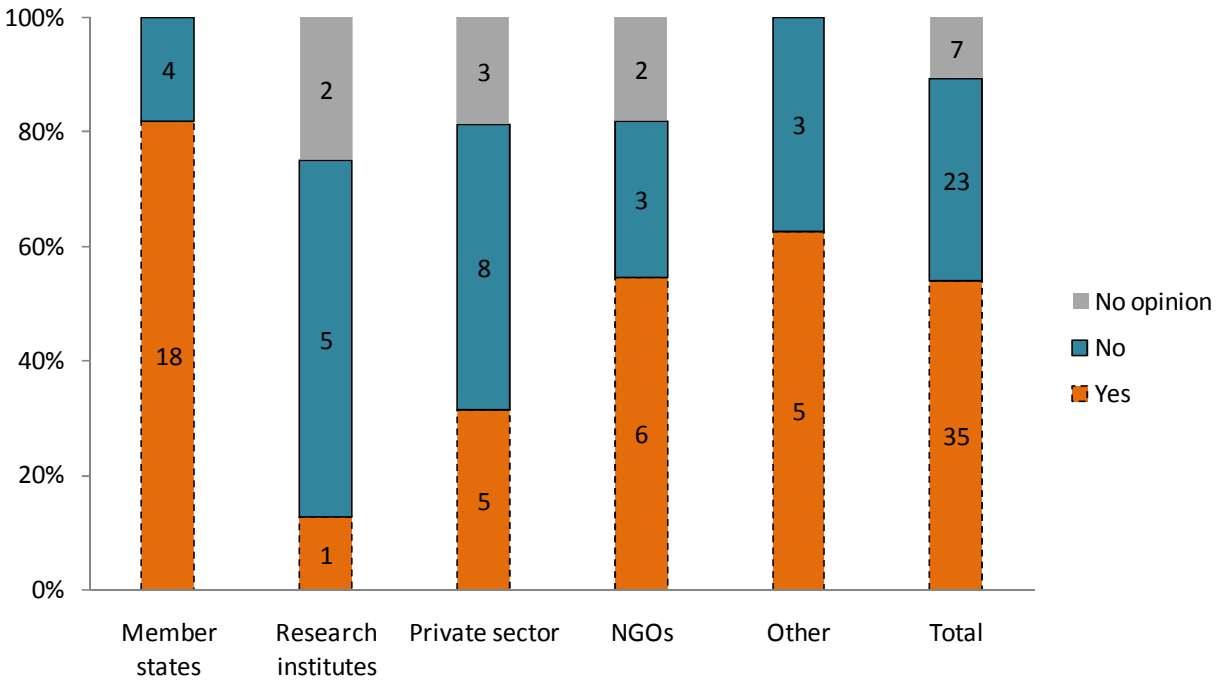


Figure 6.22C To what extent do you agree that the EFSA GMO Panel's recommendations for the management and conduct of PMEM by both applicants and risk managers are clear and practical?

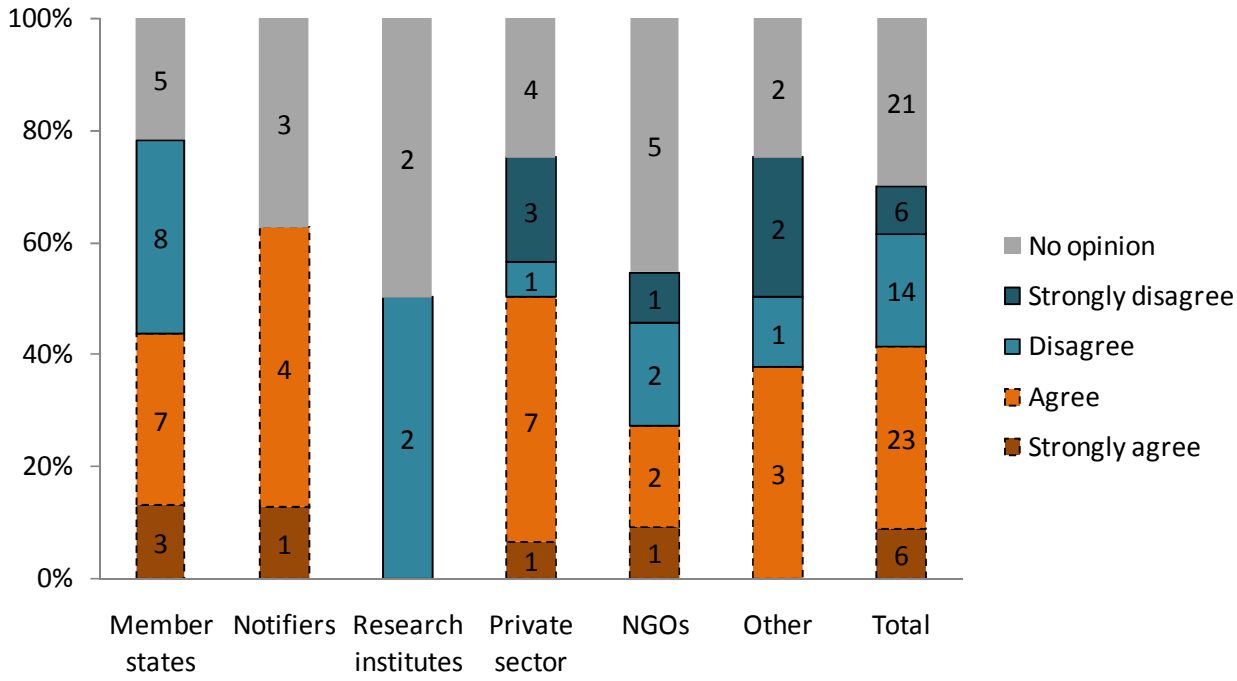


Figure 6.23C To what extent do you agree that the EFSA GMO Panel's recommendations for the management and conduct of PMEM by both applicants and risk managers are cost-effective and comprehensive?

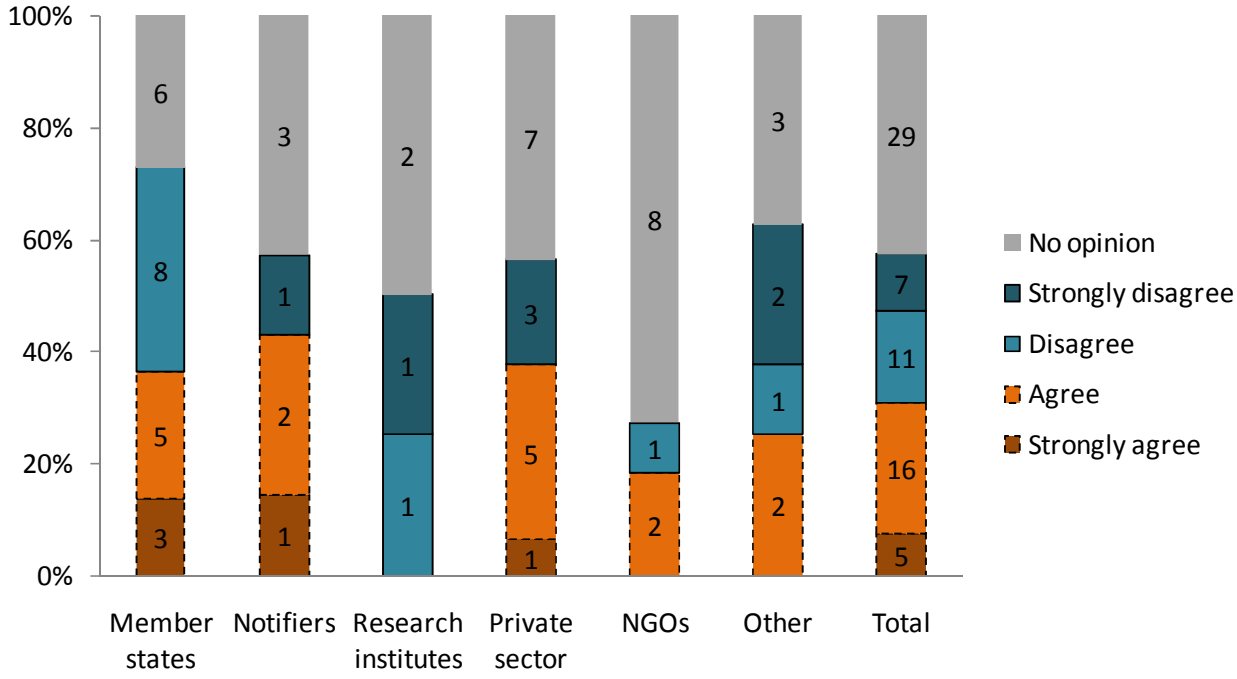


Figure 6.24 **To Member State authorities only:** To what extent do you agree that risk management measures (e.g. monitoring and reporting) are providing good quality data for scientific analysis at Member State and EU level?

Figure 6.25 **To Member State authorities only:** Are adequate arrangements in place (at EU and Member State level) for learning from monitoring and reporting data?

Figure 6.26 **To Member State authorities only:** Do notifiers have to demonstrate that they have acted in accordance with their duty of care in your Member State?

Figure 6.27 To what extent do you agree that further action or further regulation is needed at EU level to deal with the risk of adventitious presence of GMOs (e.g. guidance, harmonised evaluation criteria, validated detection methods, authorised reference material)?

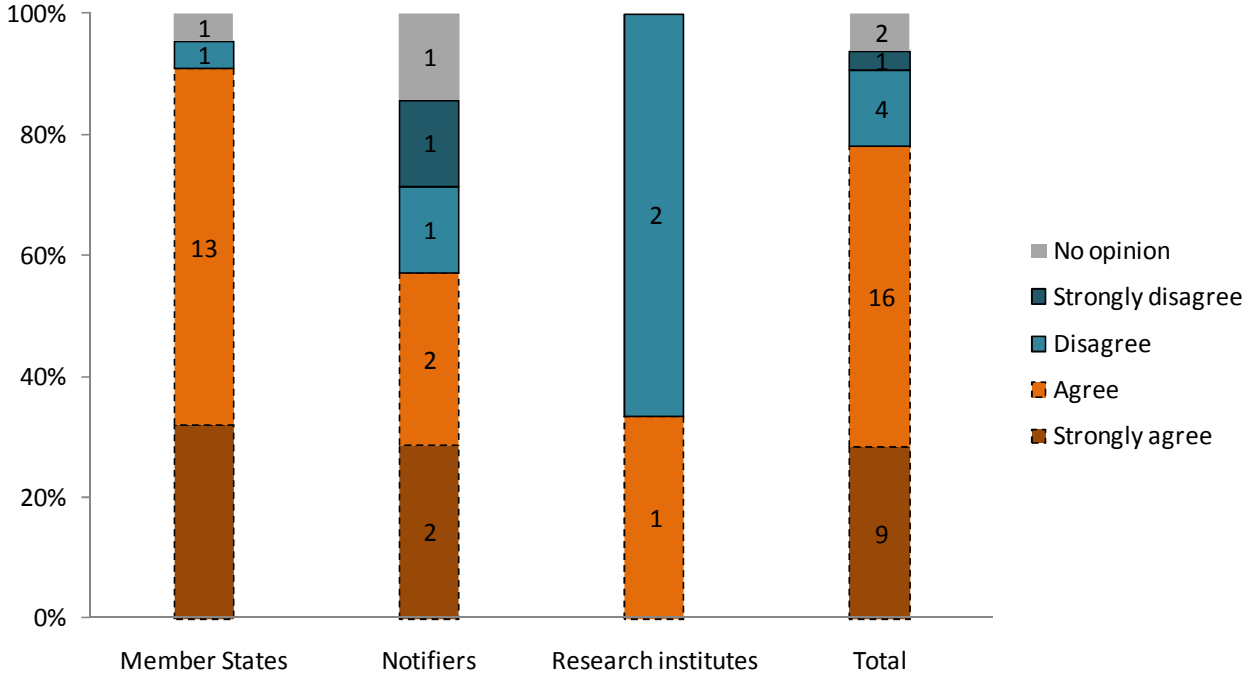


Figure 6.28 **To Research Institutes only:** In your view, is there still a gap in knowledge of how to detect the adventitious presence of unauthorised GMOs in the EU?

Figure 6.29 **To Research Institutes only:** Were procedures for inspection of your releases for regulatory purposes explained to you?

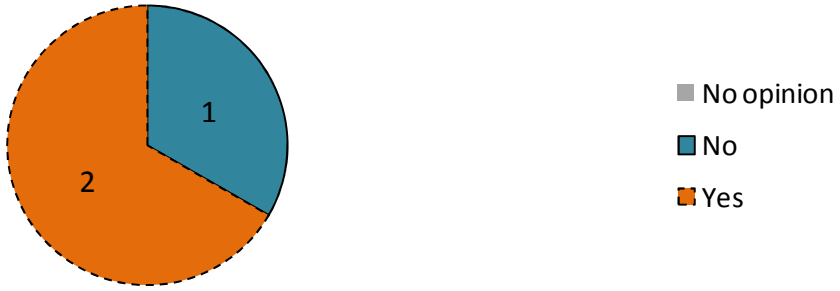


Figure 6.30 **To Research Institutes only:** Are procedures for inspection easy to comply with?

Figure 6.31 **To Research Institutes only:** Were any unanticipated effects of the GMO release noted during or after the release?

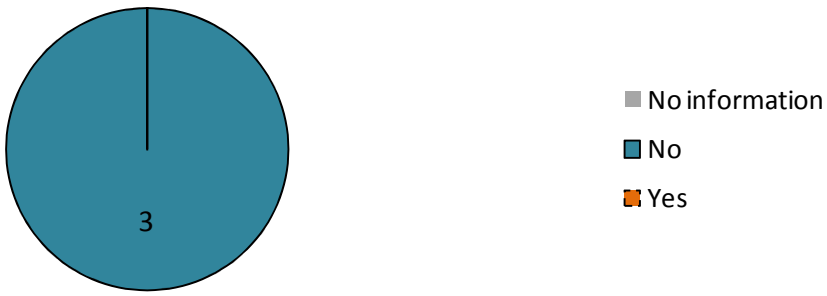


Figure 6.32 **To Member State authorities only:** Has your Member State nominated an inspectorate specifically for GMO deliberate releases?

Figure 6.33 **To Member State authorities only:** Does your Member State have documented procedures for dealing with noncompliances, including criteria for initiating a formal investigation?

Figure 6.34 **To Member State authorities only:** Is the guidance given in Recommendation 2004/787/EC for sampling and detection being taken into account in your Member State?

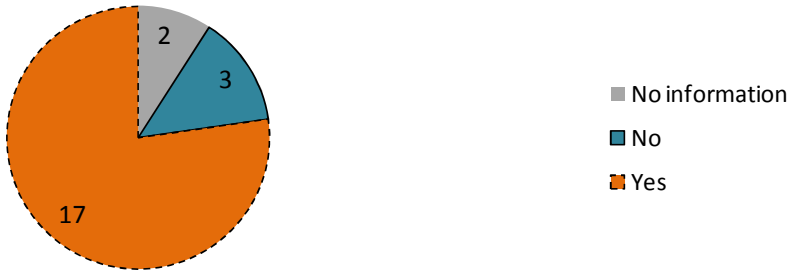


Figure 6.35 **To Member State authorities only:** Have your national procedures for sampling been changed or updated accordingly?

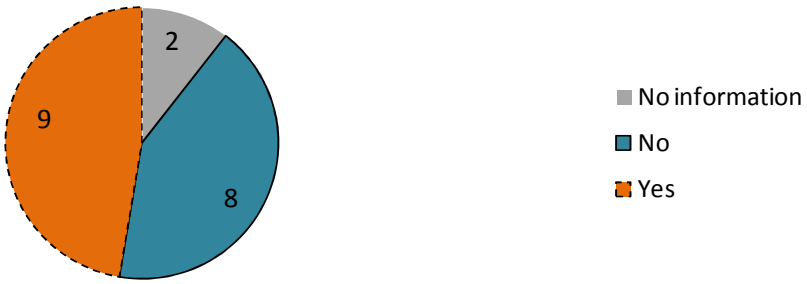
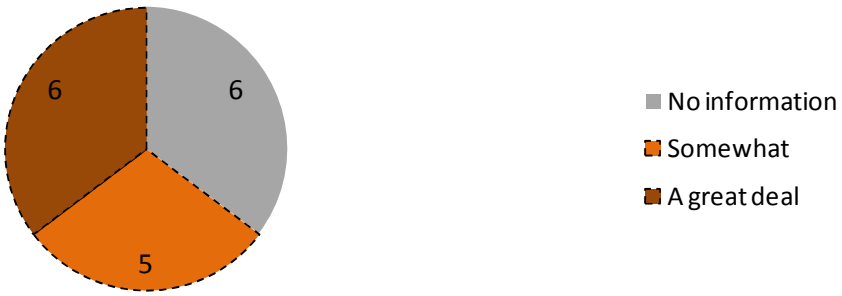


Figure 6.36 **To Member State authorities only:** The European Commission's Three-year Member State report for 2002-2005 reported that Member States found the protocols of Recommendation 2004/787/EC to be time-consuming and expensive, and that comprehensive coverage was almost impossible to achieve. To what extent do you still find the recommendations to be time-consuming and expensive?



7 RISK COMMUNICATION WITH THE PUBLIC

The following figures supplement the text in Section 7 of the Interim Report.

7.2 Figures corresponding to Section 7.2 of the Interim Report: On the provisions of for risk communication in the legislation

Figure 7.1C How satisfied are you with the current arrangements for public consultation and engagement regarding authorised GMO releases under the Directive (Parts B and C) and the Regulation?

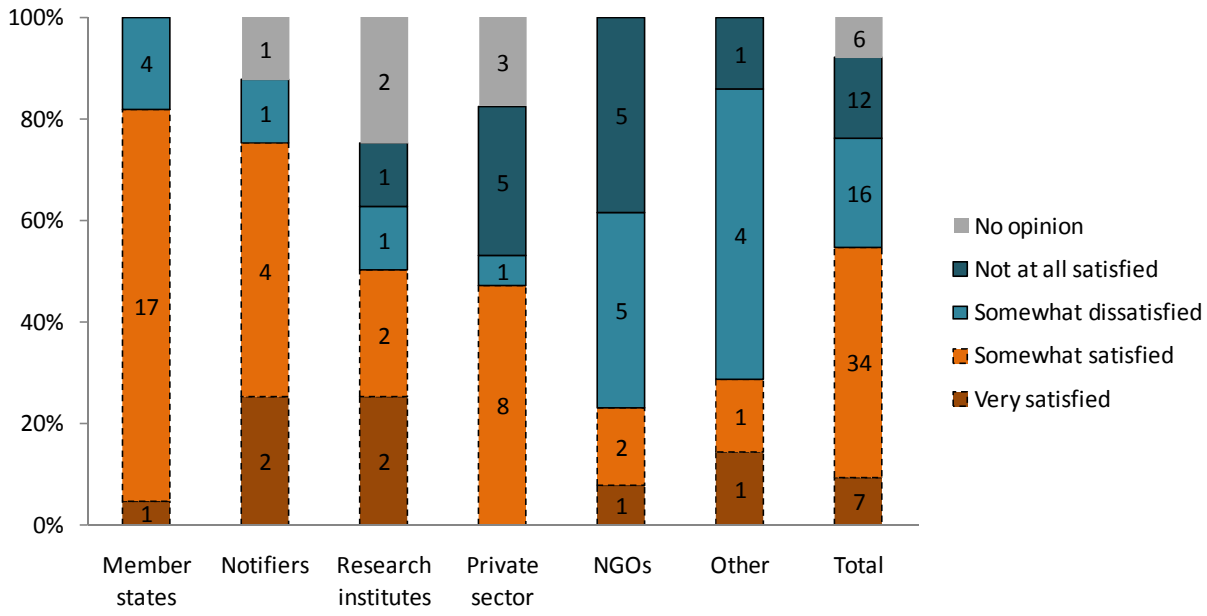
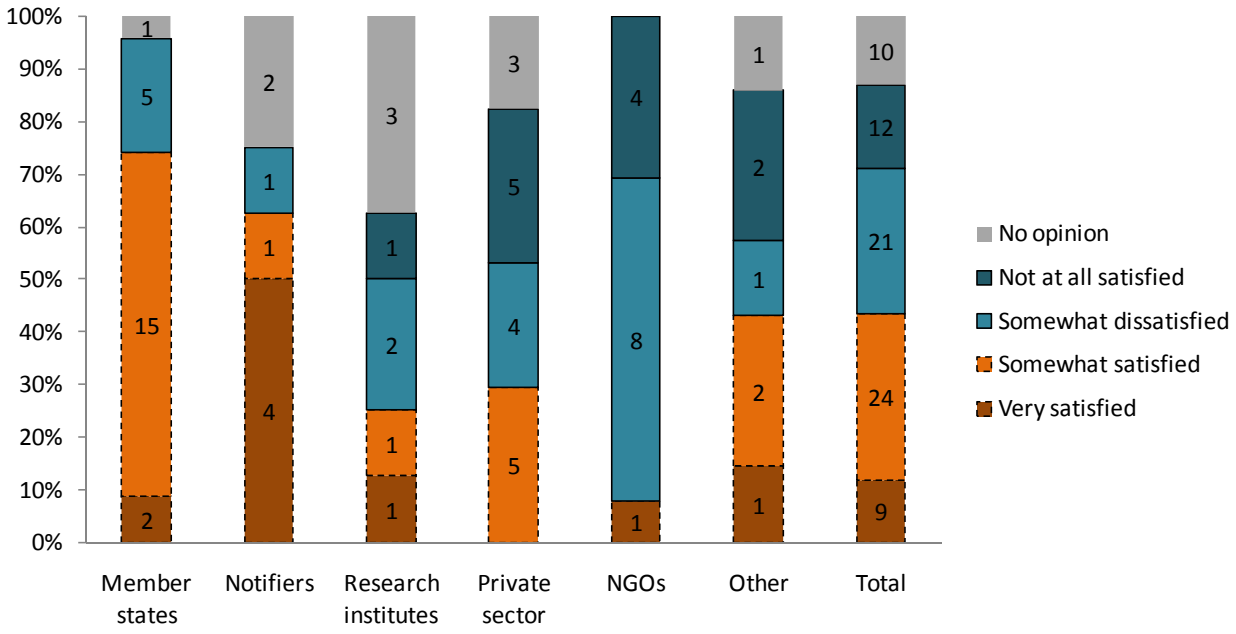


Figure 7.2C How satisfied are you with the substance and clarity of the information provided to the public in the context of consultation under the Directive and the Regulation?



7.3 Figures correspond to Section 7.3 of the Interim Report: On the implementation of risk communication provisions

Figure 7.3 **To Member State authorities only:** At what levels do you consult?

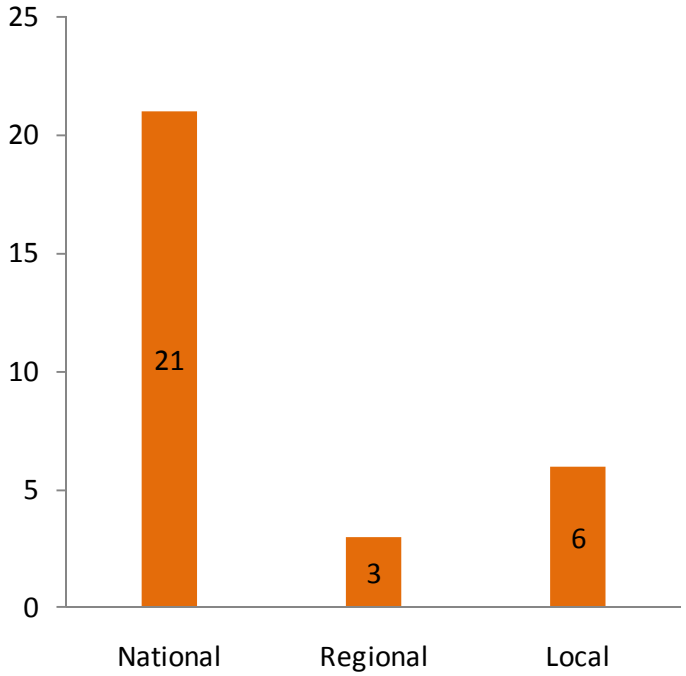


Figure 7.4C How significant are the differences across Member States in the provision of information to the public?

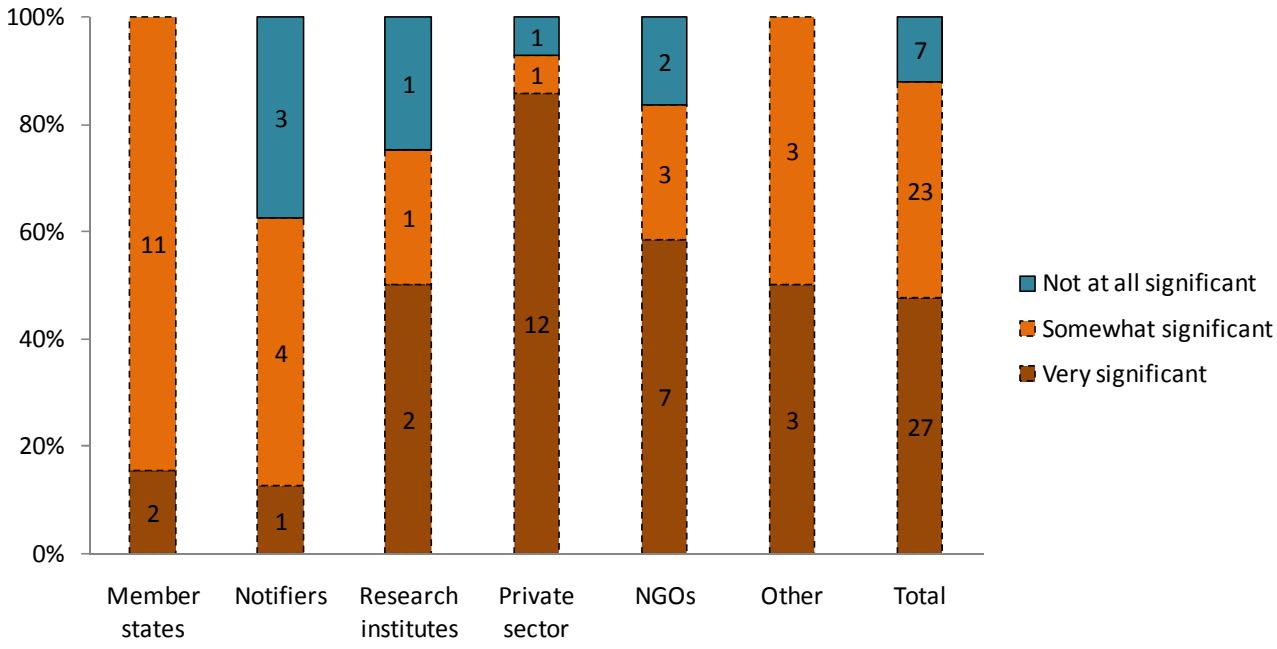


Figure 7.5 **To Notifiers only:** How, and to what extent, are you involved in deciding what information is released to the public (once you have identified information which you think should be confidential)?

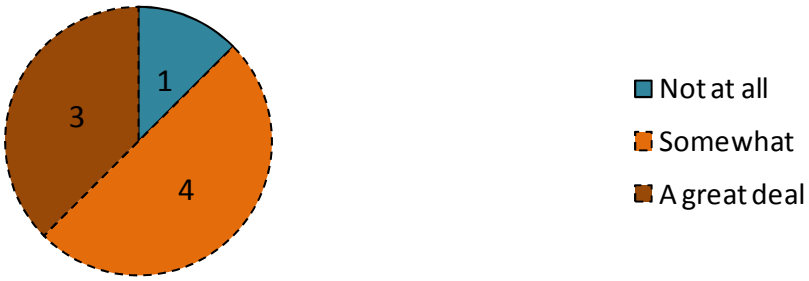


Figure 7.6 **To 'Others' only:** On a scale of 1 to 5 (where one is poor and five is excellent), how well do you think risk is communicated through the website of DG Environment?

Figure 7.7 **To 'Others' only:** On a scale of 1 to 5 (where one is poor and five is excellent), how well do you think risk is communicated through the website of GMO Compass?

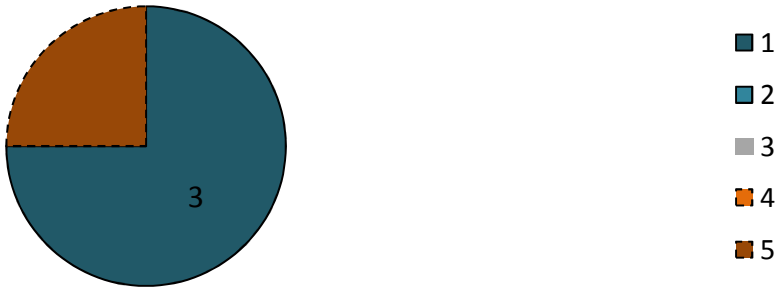


Figure 7.8 **To 'Others' only:** On a scale of 1 to 5 (where one is poor and five is excellent), how well do you think risk is communicated through the websites of EFSA?

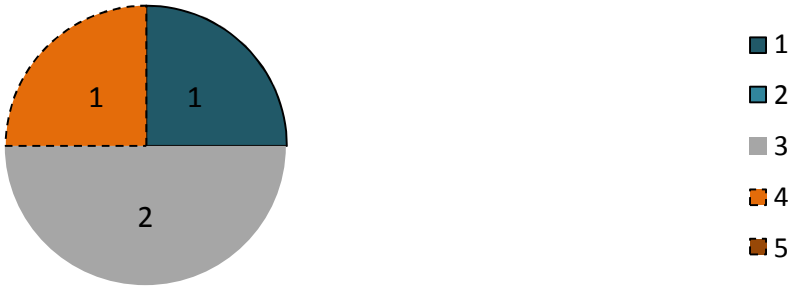


Figure 7.9 **To 'Others' only:** On a scale of 1 to 5 (where one is poor and five is excellent), how well do you think risk is communicated through the websites of DG SANCO?

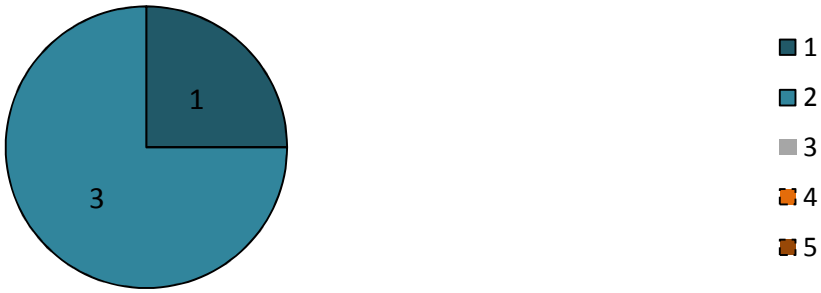


Figure 7.10 **To 'Others' only:** On a scale of 1 to 5 (where one is poor and five is excellent), how well do you think risk is communicated through the website of the main biotechnology companies?

Figure 7.11 **To 'Others' only:** How satisfied are you with the quality of the information on risk communication provided through these stakeholders' websites in terms of availability?

Figure 7.12 **To 'Others' only:** How satisfied are you with the quality of the information on risk communication provided through these stakeholders' websites in terms of coverage?

Figure 7.13 **To 'Others' only:** How satisfied are you with the quality of the information on risk communication provided through these stakeholders' websites in terms of accuracy / reliability?

Figure 7.14 **To 'Others' only:** How satisfied are you with the quality of the information on risk communication provided through these stakeholders' websites in terms of timeliness?

7.5 Figures corresponding to Section 7.5 of the Interim Report: On the impact of consultation with the public

Figure 7.15C Are there any examples of public consultation resulting in direct impacts on outputs or outcomes (e.g. risk assessment opinions and authorisation decisions)?

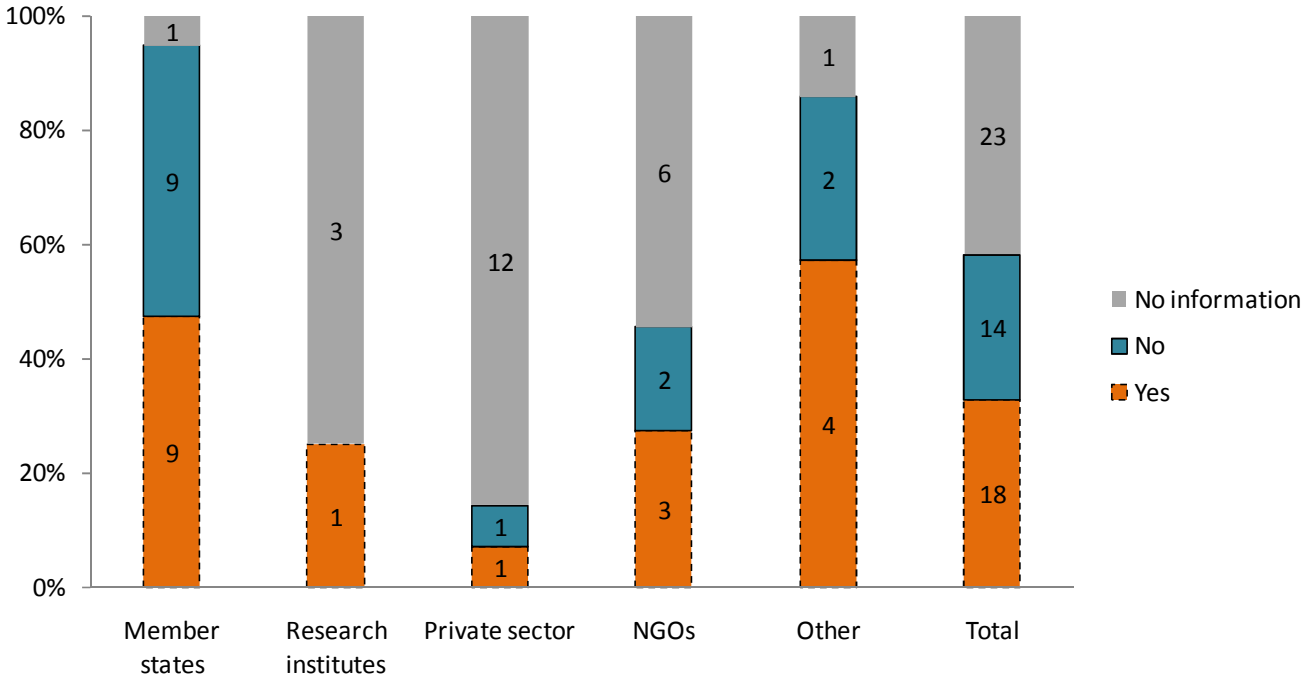


Figure 7.16C To what extent do the results of public consultation feed into risk assessment opinions and authorisation decisions on GMO releases?

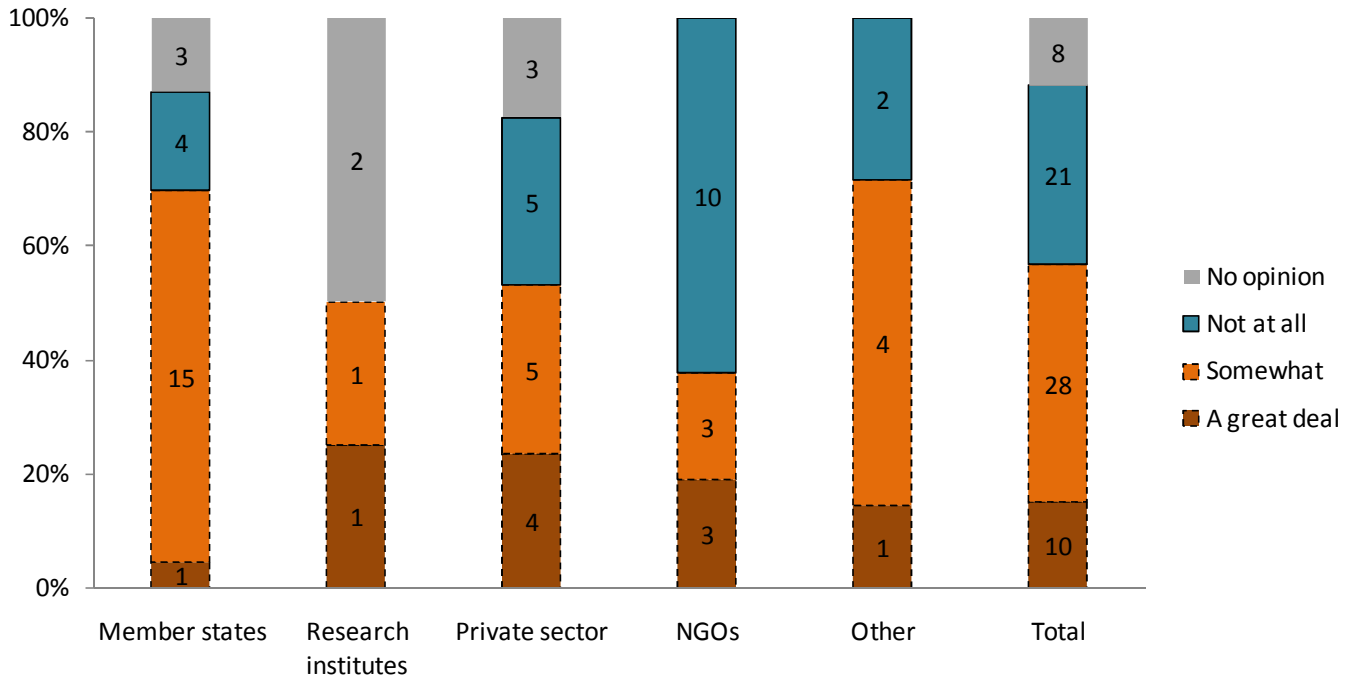


Figure 7.17C To what extent, are public views, expressed in the context of consultation, on socio-economic considerations taken into account?

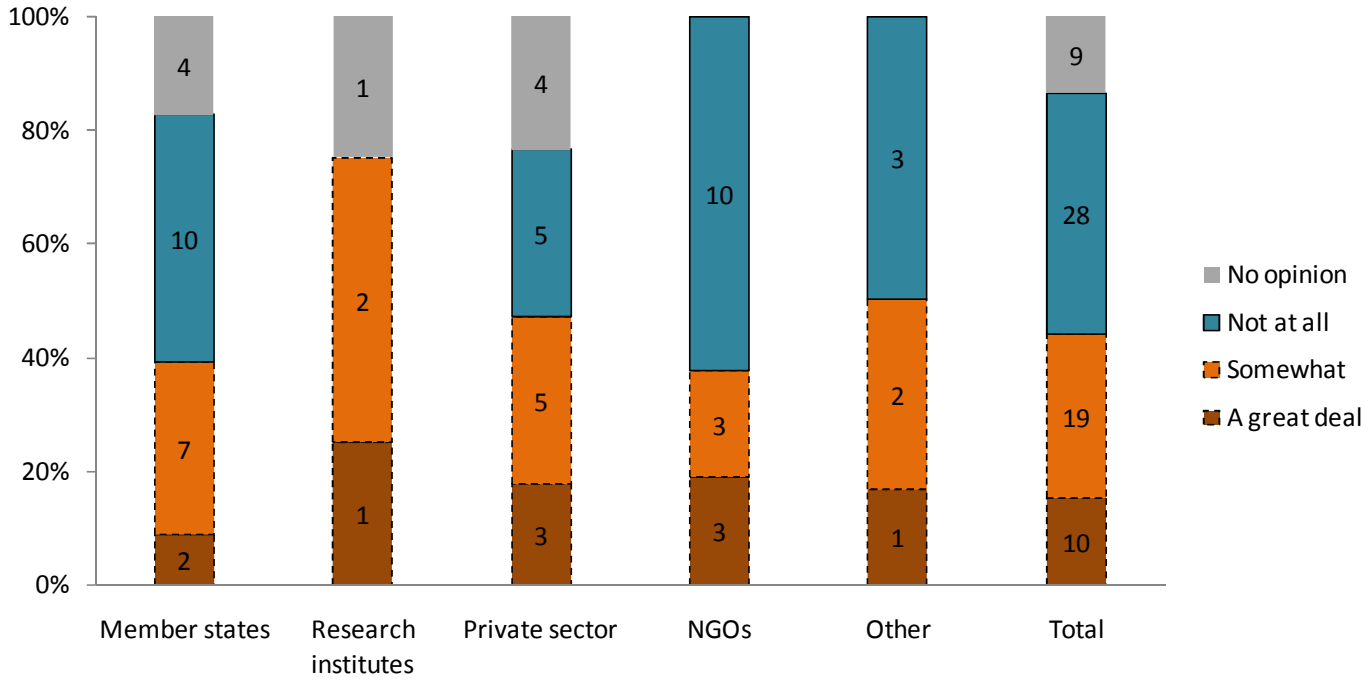


Figure 7.18C To what extent, are public views, expressed in the context of consultation, on concerns about uncertainty, knowledge gaps and ambiguity taken into account?

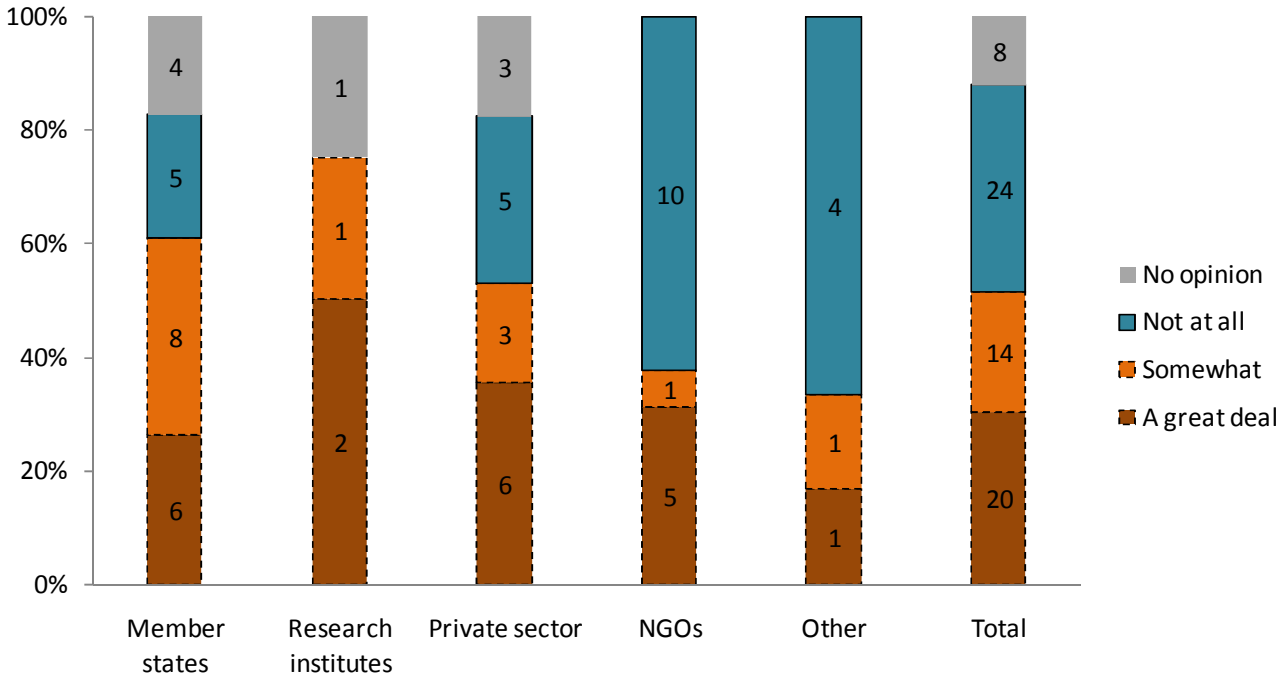
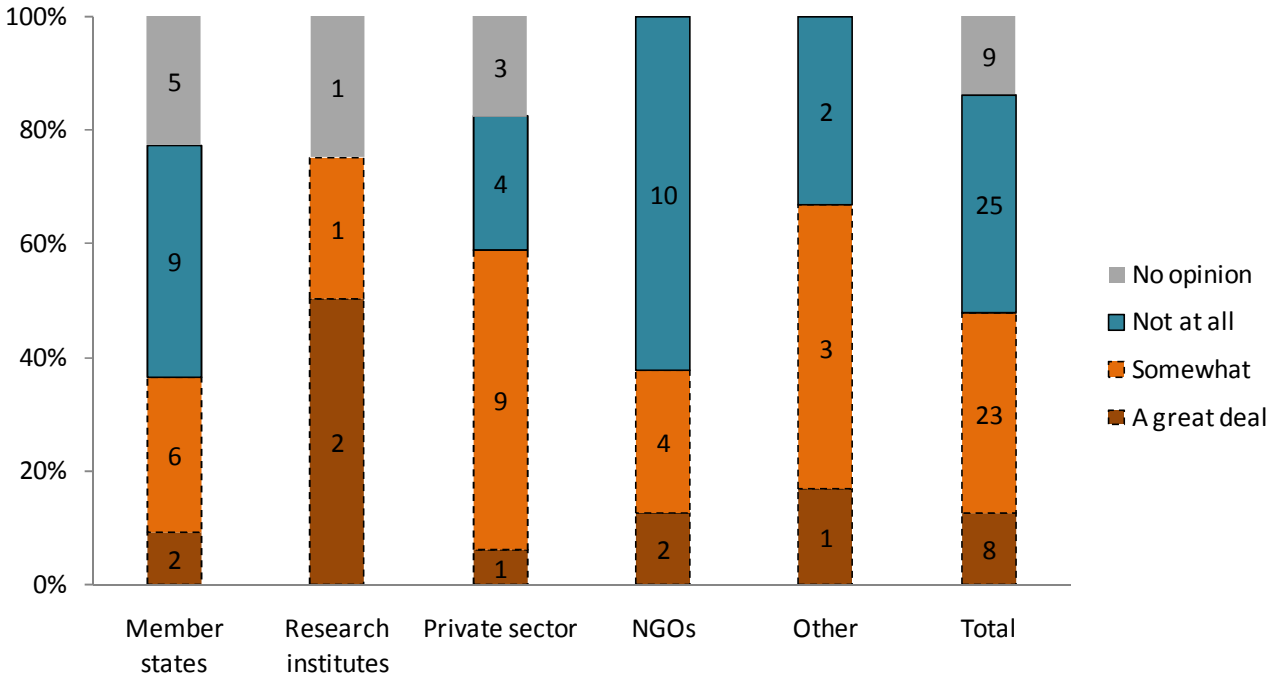


Figure 7.19C To what extent, are public views, expressed in the context of consultation, on ethical issues taken into account?



8 OTHER ISSUES

The following figures supplement the text in Section 8 of the Interim Report.

8.1 Figures corresponding to Section 8.1. of the Interim Report: On confidentiality

Figure 8.1C How satisfied are you with the provisions for confidentiality within the EU's GMO legislative framework (the Directive and the Regulation)?

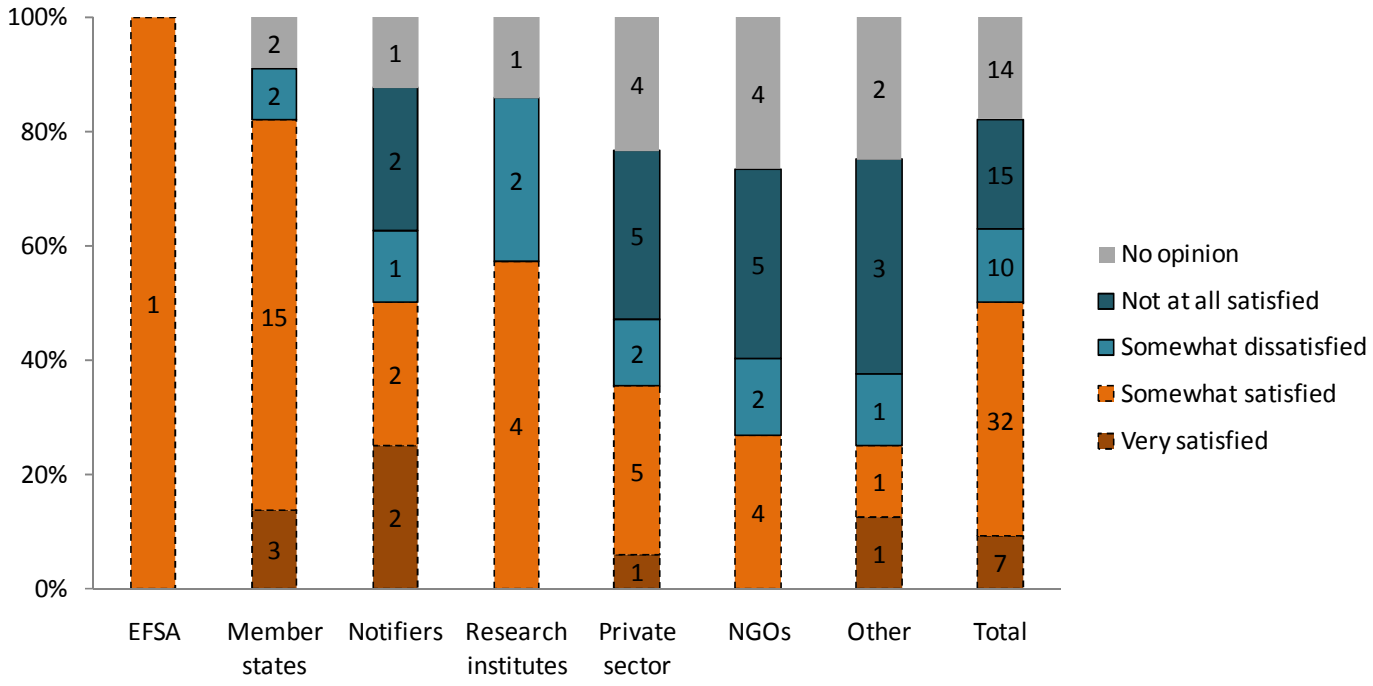


Figure 8.2C Are the confidentiality provisions of the Directive and the Regulation consistent?

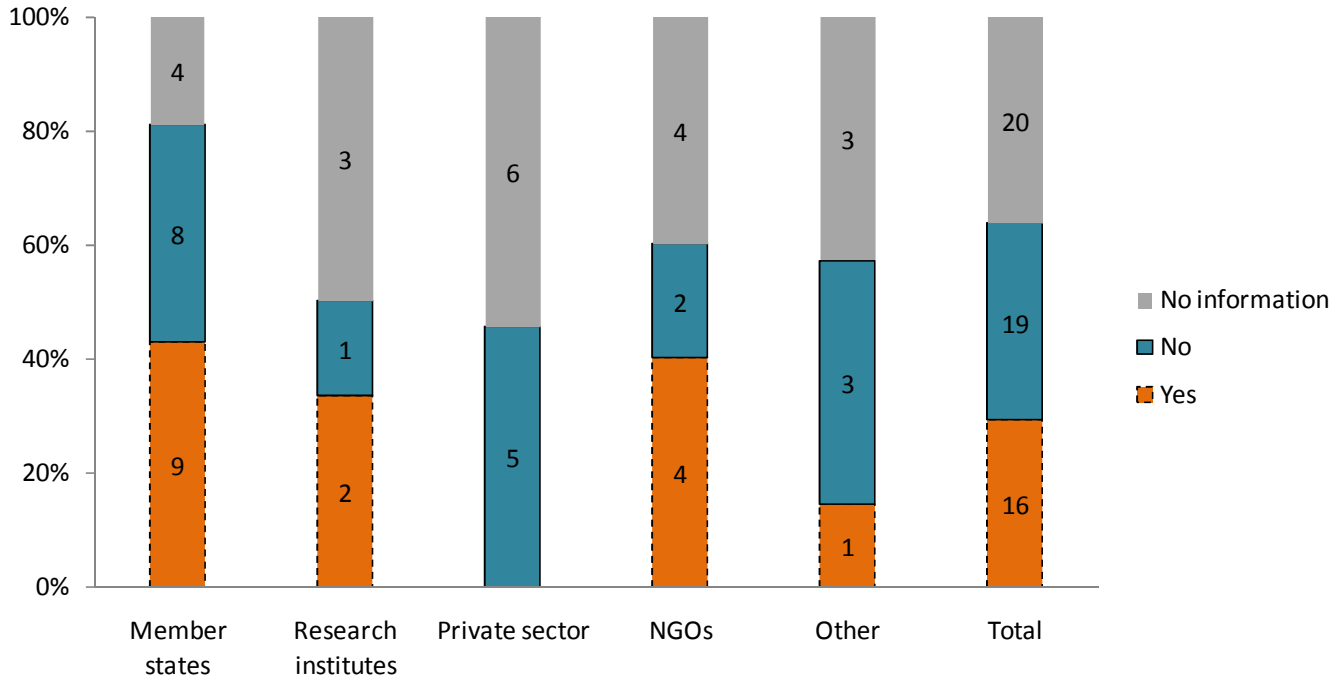


Figure 8.3C Is one more clear and rigorous than the other?

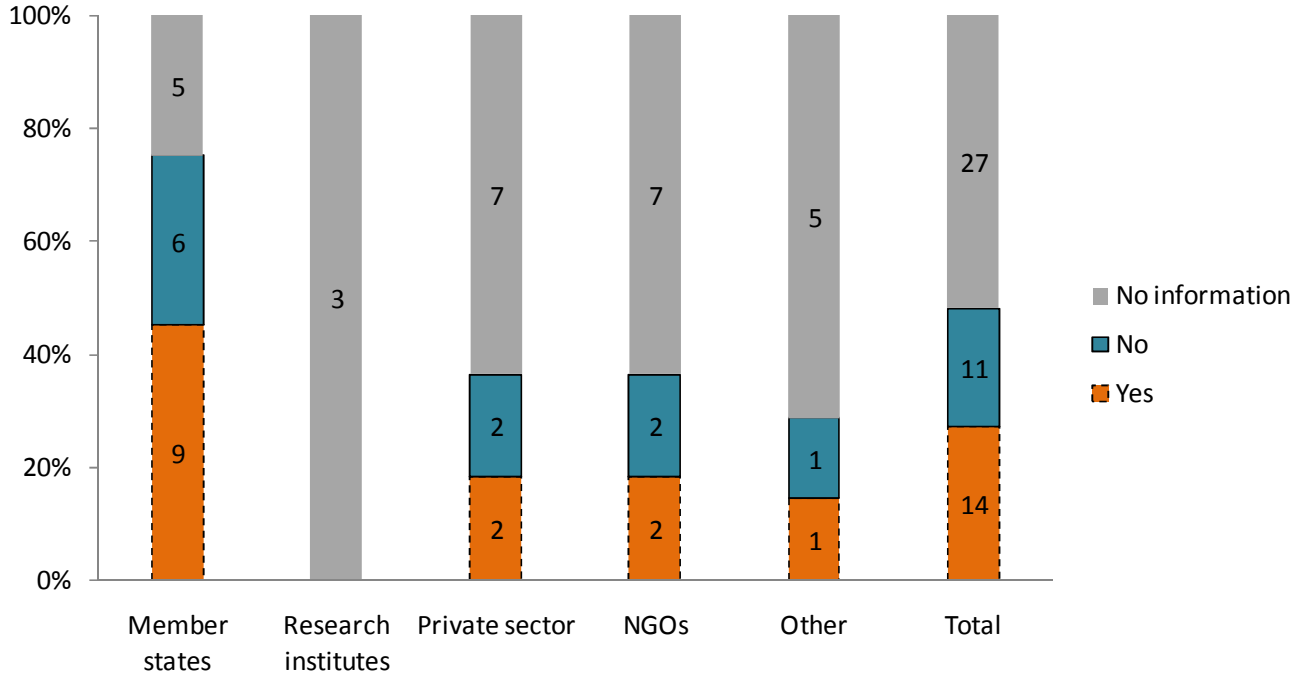


Figure 8.4C Are there any tensions between the requirements of the EU's GMO legislative framework (the Directive and the Regulation) and the requirements of Regulation 1049/2001 regarding confidentiality/disclosure of information?

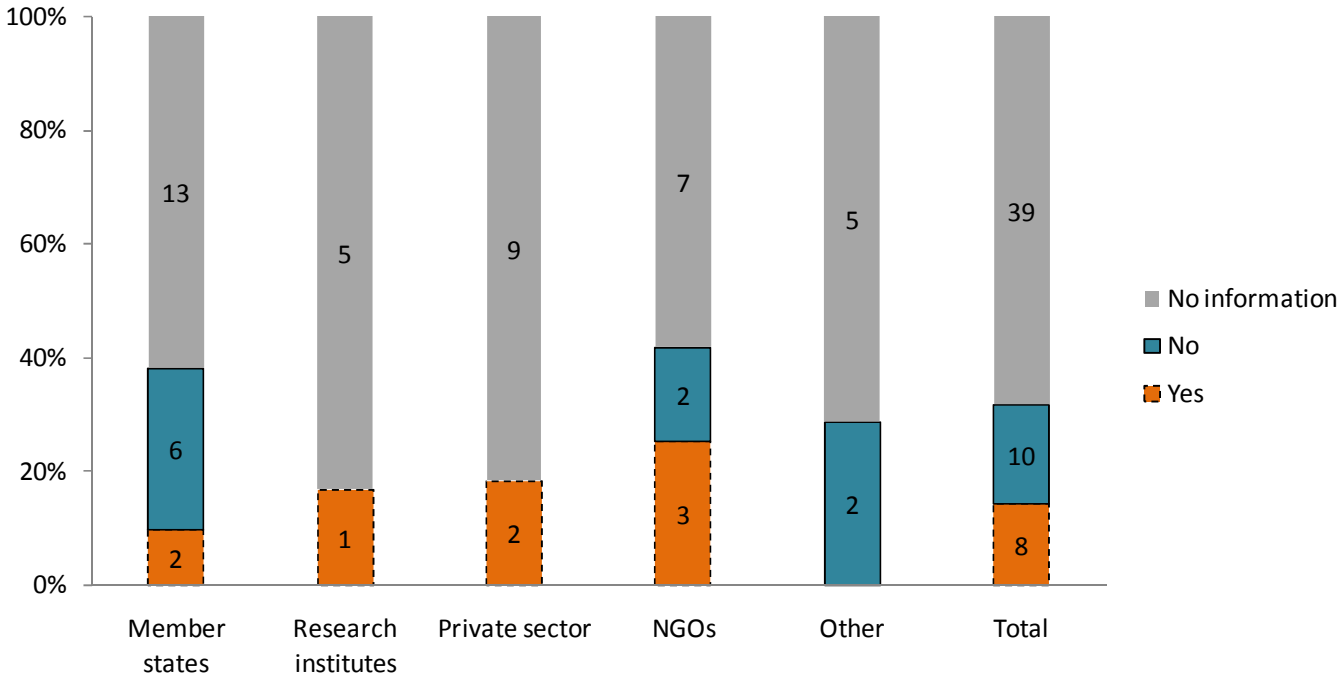


Figure 8.5 To what extent have the requirements of Regulation 1049/2001 and of Directive 2003/4/EC (on public access to environmental information) shaped, or challenged, decisions on confidentiality taken under the GMO legislative framework?

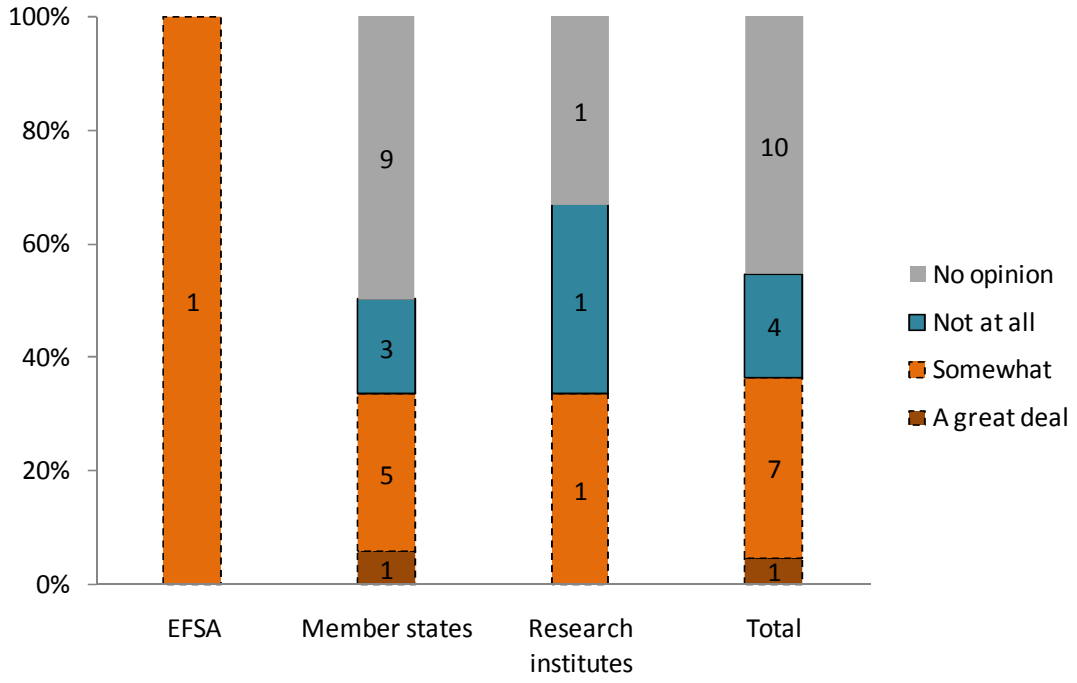


Figure 8.6 Member States vary in the way they have implemented the provisions of confidentiality under the Directive. To what extent does this impact on the activities of your organisation?

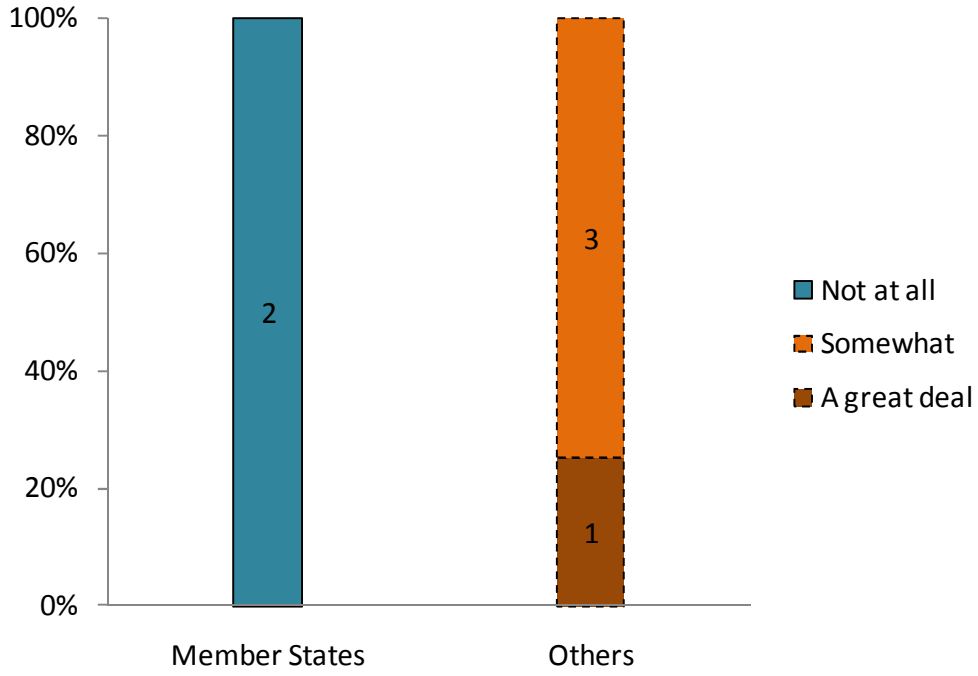


Figure 8.7 **To Notifiers only:** To what extent does the way verifiable justification is determined differ between Member States?

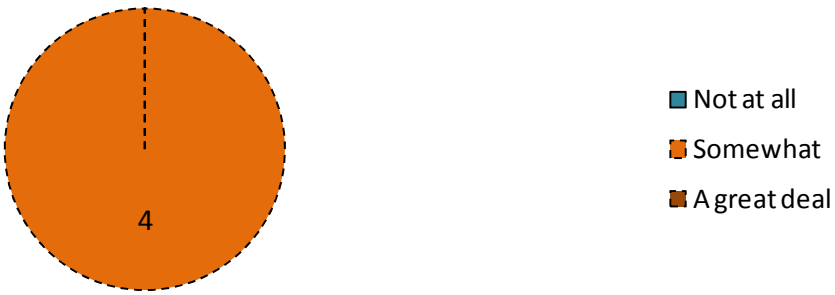
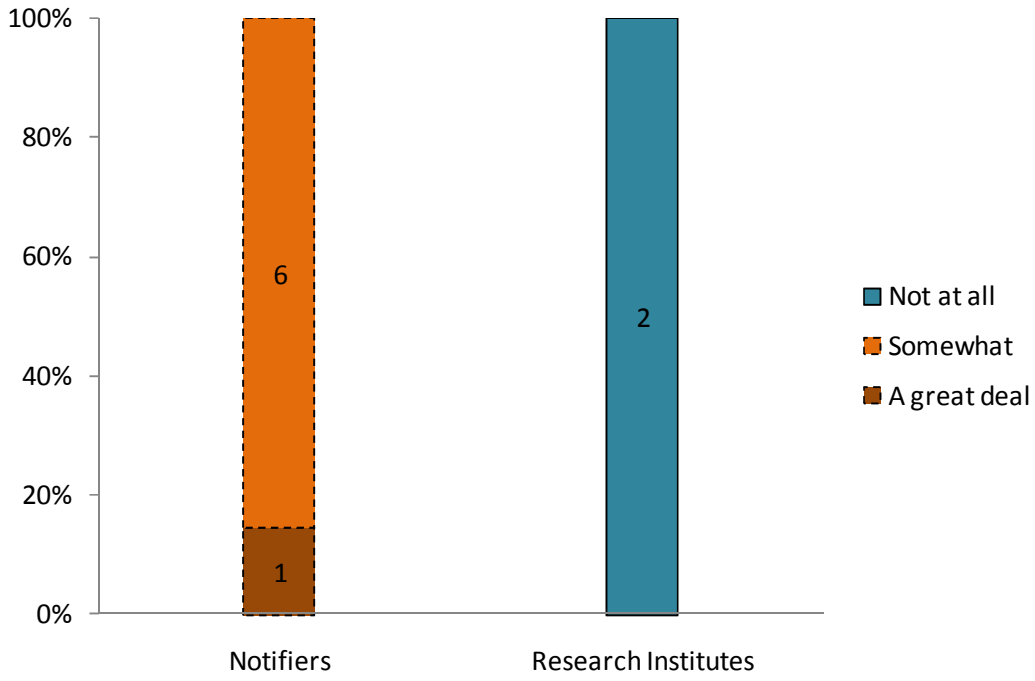


Figure 8.8 Member States vary in the way they have implemented the provisions of confidentiality under the Directive. To what extent does this impact on your organisation?



8.2 Figures corresponding to Section 8.2. in the Interim Report: On the zero-tolerance policy to unauthorised GMOs in seeds

Figure 8.9C To what extent do you agree that the 'zero-tolerance' policy for unauthorised GM materials in seeds is having a negative impact on trade (e.g. on imports of seeds and related seed prices)?

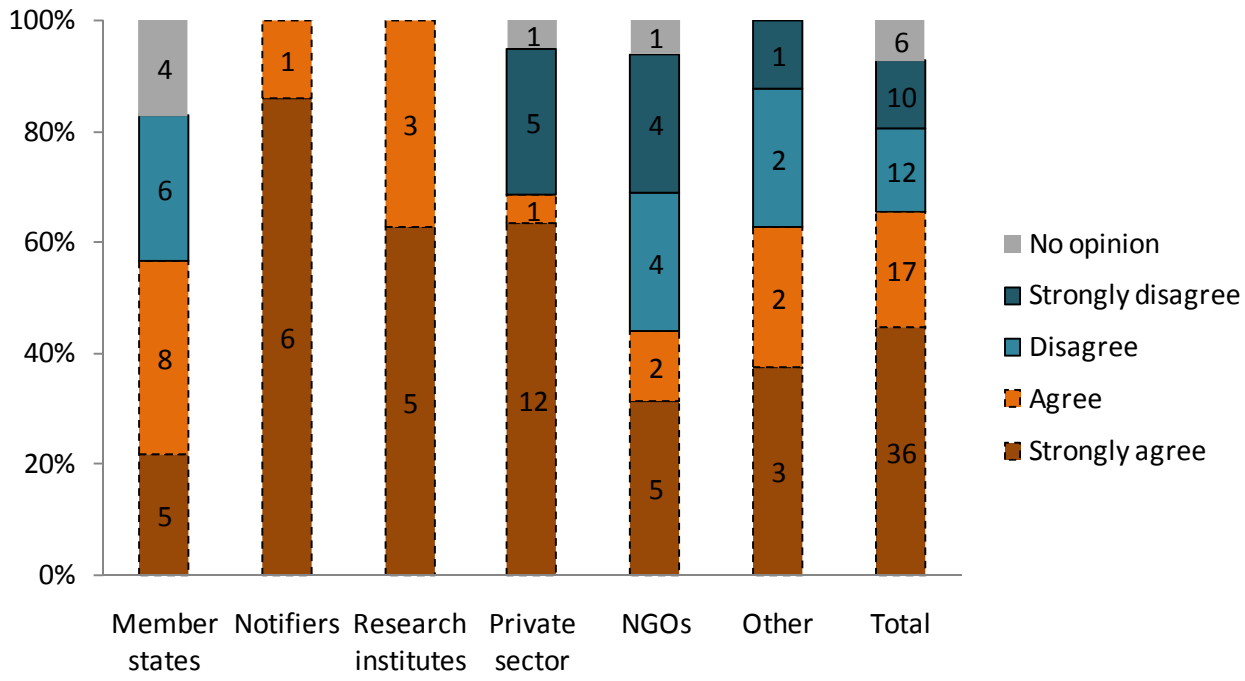


Figure 8.10C To what extent is the 'zero tolerance policy', having any environmental and social impacts in your Member State?

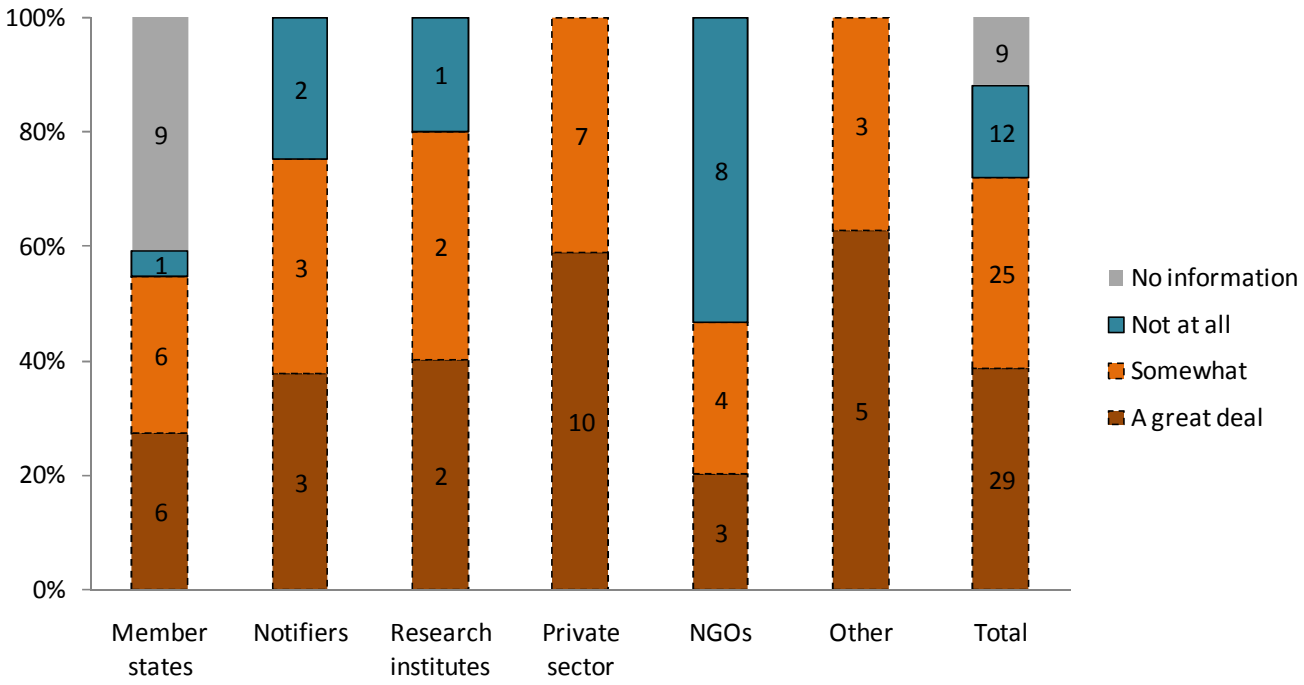


Figure 8.11 **To Research Institutes only:** Is the zero-tolerance policy for unauthorised GM material in seeds having any cost implications?

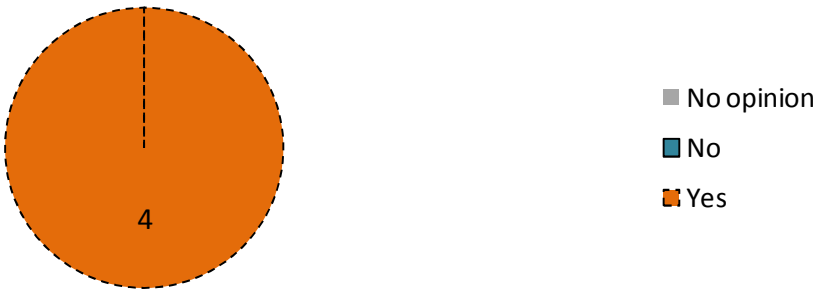


Figure 8.12 **To Research Institutes only:** Has the absence of thresholds for the adventitious presence of non-EU authorised GM seeds in lots of GM and non-GM seeds impacted your operations?

8.3 Figures corresponding to Section 8.3 of the Interim Report: On other national legislation impacting on the cultivation of GMOs

Figure 8.13 **To Member State authorities only:** Is there any other national or sub-national legislation in your country that must be observed when a GMO is placed on the market (excluding rules governing co-existence)?

Figure 8.14 **To Research Institutes only:** In addition to the bans introduced by a number of countries are there any other national restrictions that impact on the release of GMOs?