

**Statement to the draft paper on
General Surveillance of the Impact of GM plants
As a chapter of the EFSA guidance document for the risk assessment
of genetically modified plants and derived food and feed**

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Introduction

Monitoring of genetically modified plants consists of two components, Case Specific Monitoring and General Surveillance. General Surveillance complements the case-specific part of monitoring. It focuses on those issues, which remain to some extent uncertain in the environmental risk assessment (e.r.a) and which are not accessible in risk analysis e.g. due to the large spatio-temporal extent of the underlying interactions. The specification of a monitoring programme is an obligatory part of GM plants notification under current EU regulation. How these regulations have to be interpreted and operationalised, was not yet fully specified. Therefore, the EFSA considered it to be an important task to provide notifiers with appropriate guidance which information are expected to be included in the notification documents. The currently commented text deals with the requirements for General Surveillance which are considered as relevant by the European authorities.

The author of this comment has worked in various research contexts with a wide range of conceptual as well as technical issues of GMO monitoring². From this background the recommendations and comments below are given. The text consist of a general part, addressing structural and conceptual issues referring to various paragraphs of the EFSA draft document, and a specific part. The latter is organised in a synoptic form, where on the left column the EFSA draft text is copied and on the right column specific details are addressed.

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² see e.g.

Menzel G, Lünsmann I, Middelhoff U, Breckling B, Schmidt G, Tillmann J, Windhorst W, Schröder W, Filser J, Reuter H 2005: Gentechnisch veränderte Pflanzen und Schutzgebiete – Wirksamkeit von Abstandsregelungen. Bonn – Bad Godesberg (BfN, Reihe Naturschutz und Biologische Vielfalt Bd. 10)

and

Züghart W, Breckling B 2003: Konzeptionelle Entwicklung eines Monitoring von Umweltwirkungen transgener Kulturpflanzen (Vol 1 + 2). Berlin (Umweltbundesamt Texte 50/03)

General Statement

The monitoring of Genetically Modified Organisms, in particular agriculturally cultivated plants are under discussion here, is conducted to make sure that no safeguard subjects, values or protected goods are compromised by the GM cultivation implications. This requires, that potential effects and changes brought about by GMO are observed *on a scientific basis and in sufficient completeness*. Otherwise informed decisions concerning the relevance and adverseness of potential effects would not be possible. To assure a sufficient observational coverage of safeguard subjects with regard to relevant effects, the development of a systematic approach is mandatory. Guidance is required how to achieve such a systematic completeness. This needs to be the main intention of the Guidance Document.

The conceptual systematisation can be best achieved by using known effects as starting points to investigate further cause-effect chains, which can be weighted concerning their relevance according to the criterion to which extent they may affect safeguard subjects. Cause-effect chains as starting points are identified in the environmental risk assessment. To check them for completeness and relevance it is useful to assign them to organisation levels. Organisation levels represent organismic, physiological environmental and social interaction networks, which can be distinguished by properties which require specific concepts and methodologies to be handled³. The main organisation levels relevant to classify potential GMO effects are

- molecular effects,
- effects on the level of the individual
- population effects
- ecosystem effects
- landscape and regional effects.

This approach is very helpful to make sure that no relevant interactions are omitted and left out of consideration. In addition it is required to assign the relevant surveillance issues on these levels to the identified safeguard subjects.

A key issue which is not yet resolved in the current draft of the EFSA guidance document concerning general surveillance is a listing of safeguard subjects which have to be focused in the observation context. They largely follow from general legal rights.

Though the EFSA draft lists a number of important points, it leaves several relevant issues unclear. The questionnaire approach is the only part, which is described in some detail, however, in principle this approach can cover only a rather small fraction of what is relevant. In the other areas, a comparable specification would be required. Furthermore, there are some conceptual weaknesses, which require correction to assure operability and to avoid misunderstandings. In further detail these points are commented below.

Important are the following general points:

- The implementation of General Surveillance requires to follow the principle of *best scientific practice*. This should be explicitly stated. The draft states so far, that General

³ see e.g.

Reuter H, Hölker, F, Middelhoff U, Jopp F, Eschenbach C, Breckling B 2005: The concepts of emergent and collective properties in individual-based models – summary and outlook of the Bornhöved case studies. Ecological Modelling 186: 489 - 501

Surveillance should not employ a hypotheses based approach. Best practice requires a clear decision base what to look at, for what reason, and what to leave out of consideration. Surveillance without knowing what to look for is simply methodologically impossible in a scientific context. Any “looking at whatever something” implies a hypothesis about appropriate methods and potential outcomes. This is constitutive for any scientific methodology. Any attempt to decide about presence or absence, Yes or No, or about intensities implies underlying hypotheses. The authors of the EFSA draft wish to exclude the execution of arbitrary experimental approaches which are not a useful and targeted contribution to General Surveillance. However, this should be achieved in a more consistent way. And it is achievable by specifying criteria to prioritise observation requirements and sampling protocols according to a coverage of the relevant safeguard subjects. Otherwise, if the interpretation holds that hypotheses oriented investigations should be excluded, the guidance document opens way to abandon *any* monitoring activity since it will always be possible to identify an underlying hypothesis.

- It is misleading to suggest a focus on “unusual” effects or events. By the time, certain effects *will* be observed and it is a task of result evaluation to allow decisions whether these effects turn to affect safeguard subjects to a relevant extent. Any effect will by the time turn into something usual. It will be a major issue of general surveillance to provide the data for the formation of an opinion whether these already known effects aggregate or expand to a level where they become relevant and adverse. To an important degree monitoring will have to deal with known effects and observe their development, potential interaction and overlay. If this would be excluded, then General Surveillance would necessarily turn into an empty set since due to a good e.r.a there will be little space left for something *entirely* unexpected or unusual. Despite, there is a lot to do to determine remaining uncertainties, to deal with aggregated, combinatory or delayed effects and to survey, whether these effects come to compromise safeguard subjects.

Finally, one of the most important structural objections to the current draft. The Directive 2001/18/EC and Annex VII to this directive generally consider “human health and the environment” as monitoring targets. Repeated times, monitoring of “human health” is mentioned in the first place. The current draft almost entirely fails to provide guidance how to monitor human health. The methodological differences in monitoring of GMO-effects concerning health issues and monitoring of environmental issues are quite obvious. Both complexes of safeguard subjects require separate and explicit guidance concerning a differentiation of relevant observation points and adequate methodologies. It would be very useful to treat these issues in two sub-chapters -

- (1) how to specify a monitoring in human health and
- (2) how to specify the environmental monitoring.

The draft of this guidance document primarily deals with environmental effects and does not appropriately guide the specification of monitoring the human health at all.

Specific Comments

<p><i>The numbers at the end of each line are the line numbers which appear on the left side of the original PDF document, from which content of the column below was copied – see http://www.efsa.eu.int/science/gmo/gmo_consultations/1034/gmo_consultation_pmem_en1.pdf Footnotes in the original document were not included in this copy.</i></p>	
<p>EFSA draft</p>	<p>Comments</p>
<p>European Food Safety Authority 1 DRAFT New chapter 11.4: General surveillance of the impact 3 of the GM Plant 4 EFSA Guidance document for the risk assessment of 5 genetically modified plants and derived food and feed 6 (EFSA, 2004)</p>	
<p>12 Table of contents 13 14 11.4 General surveillance of the impact of the GM plant 15 11.4.1 Approach and principles 16 General approach and principles 17 General surveillance for import and processing 18 11.4.2 Main elements of general surveillance 19 Use of existing monitoring systems 20 Use of GMO-focussed monitoring systems 21 11.4.3 Importance of baseline data 22 11.4.4 Data management and statistical analyses 23 11.4.5 Review and adaptation 24 25</p>	

<p>11.4 GENERAL SURVEILLANCE of the impact of the GM plant 26 General surveillance applies where no adverse effect has been identified in the risk 27 assessment, but is required in order to detect unforeseen or unanticipated adverse 28 effects. Monitoring of potential adverse cumulative long-term effects and areas of 29 uncertainty identified in the environmental risk assessment are important objectives of 30 monitoring (Guidance note supplementing Annex VII, 2002/811/EC₂) which should be 31 considered initially within case-specific monitoring. However, if there is negligible degree 32 of uncertainty in the environmental risk assessment then no case-specific monitoring is 33 indicated but unanticipated long term effects remain an important component of 34 general surveillance. 35</p>	<p>What is specified in 11.4 as a the topic for general surveillance is only a part of what has to be covered.</p> <p>In addition, monitoring is required for those effects identified during environmental risk assessment (e.r.a), which may have an unclear potential to become adverse or which may turn into adverse effects in a certain context under certain conditions, in particular in combination with other GM impact or as a result of regional environmental or cultural variation.</p> <p>It has to be monitored, whether the assumptions on adverse effects made during e.r.a. actually hold, including, that certain effects that were assumed to be not adverse actually do not change their importance, relevance or impact under changing conditions of commercial use. As one of various points, this concerns on the molecular level, e.g. the identity of the admitted construct with respect to genetic re-arrangements.</p> <p>Furthermore, it is not always possible to decide in anticipation, whether an effect will become adverse, even if the effect as such is expected: Take the example of oilseed rape. It is known, that hybrids with weedy species are possible and likely to occur. In environmental risk assessment (e.r.a.) it may have been hypothesised, that hybrids will not cause damage. The ecological properties of hybrids, however, can be anticipated only partly. Hybrids with previously unknown characteristics may</p>
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	<p>emerge. Thus it remains a task for monitoring to confirm, whether the underlying assumptions or expectations from risk assessment actually hold. This is also a clear task for monitoring as stated in Annex VII to Directive 2001/18</p>
<p>One of the objectives of the Directive 2001/18/EC (EC, 2001) is to protect the 36 environment e.g. including biodiversity, water, and soil. Sustainable agriculture 37 contributes to achieving pre-defined protection goals and minimising environmental 38 damage. Thus, one of the most important tasks within general surveillance is to link any 39 activity to the environmental protection goals and sustainable agriculture. Recently, EU 40 Directive 2004/35/EC on environmental liability with regard to the prevention and 41 remedying of environmental damage (EC, 2004b₃) defined environmental damage as a 42 measurable adverse change in a natural resource or measurable impairment of a 43 natural resource service which may occur directly or indirectly. 44</p>	<p>It is a highly important issue to determine clearly what the safeguard subjects are. Notifiers will expect from a guidance document to obtain a clear orientation, which specific safeguard subjects are of concern. Therefore, it seems necessary, not only to give few very coarse examples (“e.g....”) but to outline the relevant safeguard subjects precisely – including the legal basis where the protection is defined. This is not a task for a scientist but a legal key issue. However, the scientific part of the investigations must be adjusted in order to be able to provide statements whether the safeguard subjects remain unaffected.</p>
<p>Within a broader concept of environmental issues, unanticipated adverse effects on 45 human health also have to be addressed in the monitoring plan presented by the 46 applicant (according to Directive 2001/18/EC). The EFSA GMO Panel is currently 47 considering how these particular aspects might be integrated into the monitoring plan 48 presented by applicants. 49 Agriculture, the rural environment and the associated biota in Europe are in constant 50 change and flux. Farmers adopt new or different crops and practices in response to 51 economic and other requirements. A major challenge of general surveillance is 52 determining whether: 53</p>	<p>As stated above, the Directive 2001/18/EC generally uses the term “human health and the environment”. This makes it obvious that a monitoring of human health is regarded as an issue of primary order. It is not appropriate to sub-summarise human health monitoring “within a broader concept of environmental issues”</p>
<p>an observed effect is unusual 54 an unusual effect is adverse and 55 the adverse effect is associated with the GM crop or its cultivation. 56 57 The use of a range of monitoring systems to supply data and the ability to compare data 58</p>	<p>It is logically inconsistent and scientifically not operational to require observed effects to be unusual to qualify for further investigation. There may be adverse effects, which are <i>usual</i>, but may be increased or accelerated by GM associated</p>

<p>from these different sources will help to indicate whether an effect is unusual and 59 adverse. The identification of a novel adverse effect would trigger the need for a specific 60 study to evaluate harm and determine cause.</p>	<p>measures. Biodiversity decline is an example. To require an effect to be “unusual” cannot be used as an entry point for investigation. Steps need to be taken, if a safeguard subject (which may be compromised by other processes already) would suffer an additional impact by GMO (combinatory or aggregated effects). The wording used in the draft could support the aberrant interpretation, that <i>anything</i> we are used to is not relevant for monitoring. In an ultimate consequence, this might exclude <i>any</i> previously known negative effect from being monitored. Instead, it is more consistent to systematically observe the safeguard subjects and check whether detrimental changes may be connected with GMO effects.</p>
<p>11.4.1 Approach and principles 63 The objective of general surveillance is to identify the occurrence of unforeseen adverse 64 effects of the GMOs or its use on human health and the environment that were not 65 predicted in the risk assessment.</p>	<p>The objective of general surveillance is also to confirm (or falsify) the assumptions of risk assessment. The assumptions made, may turn out not to hold – in either way, bringing out the irrelevance of previous assumptions about potential harm as well as substantiating that effects considered as irrelevant increase and gain importance.</p>
<p>An effect is defined as a difference that is outside the 66 normal variation expected in agronomic or non-agronomic environments. 67</p>	<p>This statement is clearly not scientifically valid and not a reasonable definition of the term “effect”. It is generally accepted that an effect is any change of an observable variable which occurs as a result of an underlying cause (see e.g. http://en.wikipedia.org/wiki/Causality). The given definition has not only the problem, that it deviates from the general consensus in science what an</p>

	<p>effect is. In addition, it suffers from a lack of consistent criteria what is regarded as “normal”. Normality is a <i>value statement</i> and depends on perspective, experience, scale, etc.</p> <p>Take the 26th December Tsunami as an example. At first glance, you may consider it as a tremendous deviation from the normal water level. However, on a geological scale, Tsunamis of that order of magnitude are a completely “normal” phenomenon. Normality in addition does not help at all to discuss, whether the impact on a safeguard subject is tolerable or requires measures. Biodiversity losses are meanwhile usual and in that respect “normal”, however, this does not say that adding to this loss would be acceptable. A single storm in Mexico may destroy more than one third of the Monarch butterfly population during one winter as a “normal” natural process, however, this would not justify that the cultivation of an insect toxic GM variety might do the same.</p>
<p>By definition, general surveillance is a general overseeing of the geographical regions 68 where GM plants are grown</p>	<p>... full support</p>
<p>without having any hypothesis on adverse effects on human 69 health and the environment.</p>	<p>Absolutely not. To exclude “any hypothesis” in principle means to exclude anything measurable and to exclude science as an underlying methodology of monitoring. As soon as a measurement is executed, you necessarily have a hypothesis in mind what you are looking for and which method would be appropriate to help to answer the hypothesis. This is a precondition for scientific investigation. Scientific activity implies dealing with underlying hypotheses.</p>
<p>Existing surveillance systems should be used where 70 practical (e.g. routine farm recording systems),</p>	<p>... full support, so far...</p>

<p>and any 'unusual' observations, not 71 occurring in similar situations within conventional cropping, should be recorded. 72 73</p>	<p>...however, this is a difficult task. If "observations" should mean only observations by farmers, it captures only those changes, which can be accessed with the "naked eye" – not requiring a scientific approach or instrument. And this is not really much with regard to the complex nature of the safeguard subjects. It is o.k. if it means the recording of existing surveillance systems, which may cover a part of the GM general surveillance tasks.</p>
<p>General approach and principles 74 The establishment of a GM plant is not an environmental hazard in itself,</p>	<p>Presumably the EFSA draft means a self-organised establishment of GM plant populations outside cultivation (as a feral or volunteer plants). It is not possible to claim in absolute generality that this is no harm. From our present perspective we cannot know whether there may be a case where the establishment itself represents a hazard. A <i>context free</i> establishment of a plant is physically not possible. Whether an establishment <i>is</i> or <i>turns into</i> a hazard depends on the context. It makes no sense to come up with context free statements. In a guidance document, this would only trigger the misunderstanding, that the authors mean that establishment of a GM plant is <i>never</i> considered as a hazard – and that would be clearly misleading.</p>
<p>but an 75 unforeseen adverse effect is more likely to occur where the level of environmental 76 exposure is highest. Similarly, dispersal and gene flow per se are not hazards and the 77 focus of general surveillance should be on recording any unanticipated consequences of 78 the cultivation of the GM plant, such as enhanced weediness, invasiveness or changes in 79 plant population dynamics or populations of biota associated with the GM plants. Thus, 80 an evaluation of how and where the GM plant will be deployed and the associated 81 environmental exposure is considered a good starting point in any general surveillance 82 plan. 83</p>	<p>As a basic information you need to know where the transgenes are, in which environmental media they occur and how frequent. The starting point should be the transgene level (and where it occurs) rather than the plant level. This would omit gene transfer and transgene dispersal in the environment.</p>

<p>General surveillance is not hypothesis driven and so it is not conducted using directed 84 experimental approaches. However, robust scientific methodology should be applied. 85 This especially refers to defining sample sizes, sampling and recording methods, in 86 order to produce statistically valid data for relating causes and effects. 87 General surveillance of the impact of GM plant should 88</p>	<p>The re-iteration that General Surveillance is not hypothesis driven is misleading. The authors of the draft should realise, that <i>any</i>, in particular robust scientific methodologies imply a hypothesis about what you do, what you observe and why it is relevant. Hypothesis free science is simply not possible. What you mean is something different: Monitoring is usually not dealing with setting up small scale experiments, however, monitoring necessarily deals with an observation of processes which occur in an order of magnitude unsuitable for experimentation. General surveillance follows and tracks known causal relationships and observes, whether they interfere or aggregate to bring up effects harming safeguard subjects, and furthermore, observes representative contexts to find early indications of previously unknown causal relations negatively affecting safeguard subjects. A “hypotheses free” monitoring is equivalent to a “science free” monitoring. And that would turn the whole exercise into something useless and irrelevant with respect to the tasks defined in the binding legal regulations.</p>
<p>be adequate for monitoring the GM plant in all environments in which it occurs. 89 If unusual observations on human health and the environment are reported, 90 more focussed in-depth studies could be carried out in order to determine cause 91 and relationship with GM plants. Such additional case-specific (monitoring) 92 studies would require an experimental approach to confirm the specific 93 hypothesis that an observed effect is associated with the GM plant. 94</p>	<p>The starting point of the observation should not be the plant but the transgene. In bees honey, for example you do not find GM plants, but GM pollen, which however, may have a relevant effect there. There is no reason to exclude e.g. pollen monitoring and comparable approaches from general surveillance. On the contrary, pollen monitoring can be used as a very important indicator of potential</p>

	combinatory effects.
complement general environmental monitoring conducted by Member States. 95 The higher the ecological integration and scale (from the individual to a 96 population, from single farms to regions) the more difficult it is to distinguish 97	
potential effects of the GM plants from other factors. Initially, general 98 surveillance should focus on each event individually. Ultimately, when several 99 GM plants have been commercialised, the interactions between these GM 100 plants and their management regimes should also be examined where 101 appropriate. 102	
Applicants should primarily consider general surveillance at the field and farm level. 103	General surveillance needs to aim at a reasonable completeness. There is no scientific reason why the organisation level of the field and farm should be primarily considered. A surveillance concept needs to come up with systematic considerations which processes on which level are of potential interest relating to safeguard subjects. Effects can be detected on the molecular, organismic, population, ecosystem and landscape level. On all levels there are specific safeguard subjects and context specific methodologies. The general surveillance plan requires to take this into account.
However, a mechanism will need to be found to ensure surveillance of interactions of 104 different GMOs from different applicants at regional or national levels as this is beyond 105 the applicant's direct capability. 106	If it is beyond the direct capability, the applicant can suggest an approach to deal with these issues, in co-operation with competent authorities, other monitoring networks, and together with other applicants.
The methods and approaches for the monitoring of unforeseen adverse effects of the 107 GMO and its use for human health and the environment should be appropriate, 108 proportional and cost-effective. 109 110	In first place, it should be stated, that general surveillance requires to be reasonably <i>complete</i> with regard to the safeguard subjects and use best scientific practice. Then, secondly, attributes like proportional and cost effective are in place.

	Certainly not the other way round. It would turn upside down if a relevant observation of a safeguard subject would be abandoned with the hint that it might be not cost efficient. If it would be too expensive to provide (and observe the provision) of environmental safety, a notification is in principle inadmissible.
<p>General surveillance for import and processing 111</p> <p>The extent of the general surveillance plan for import and processing only notifications 112 will depend on the level of environmental exposure and the persistence/establishment 113 of the GM plant. For example, if GM import products contain viable propagating material 114 which is likely to be released and establish, general surveillance plans should take 115 account of this. On the other hand, if GM import products contain only non-viable 116 material then the general surveillance of the environment impact could be very limited. 117</p> <p>Examples of acceptable general surveillance plans for import and processing only are 118 indicated by the EFSA GMO Panel for notifications on Maize NK603 (EFSA, 2003₄) and 119 oilseed rape GT73 (EFSA, 2004₅). 120</p>	<p>General surveillance covers also the issue, that impurities of non-notified varieties are imported (e.g. with imported harvests, with imported seeds or as self-dispersing populations across national borders). This task goes beyond of what a single notifier can cover. It is an issue that the competent authorities need to deal with. It is debateable to what extent the biotech industry as a whole should participate in the financial implications of this issue.</p>
<p>11.4.2 Main elements of general surveillance 126</p> <p>The applicant should 127</p> <p style="padding-left: 40px;">define the methods and approaches that will be used to conduct general 128</p> <p>surveillance of regions where the GM plant occurs, 129</p>	<p>The general surveillance should not only cover the regions where the GM plants occur (i.e. where they are cultivated). In case of plants that may expand as ferals to other regions, these regions should also be covered – in the case of oilseed rape (OSR) for example all those regions are potentially relevant, where ferals or hybrids may be able to establish regardless whether the region has OSR cultivation to a large extent.</p>
<p style="padding-left: 40px;">refer to introduction, stewardship and exploitation plans for the GM plant, and 130</p> <p style="padding-left: 40px;">make proposals for the time period, area covered, and the frequency of 131</p> <p>monitoring. 132</p>	<p>A reasonable minimum time period for general surveillance is as long as the transgene persists in cultivation and/ or in the natural environment. In case of substantiated additional effects, it might be extended to the persistence time of these effects.</p>
133	As far as regionalisation is concerned, not only the

<p>Use of existing monitoring systems 134 Applicants will have developed plans for the introduction and marketing of the GM plant 135 and will be establishing management or stewardship programs for their GM plant 136 varieties. These should be described as they relate to where and how the GM plant will 137 be cultivated and will provide data on which to base monitoring plans . 138</p>	<p>area where the plant is marketed should be covered but also those areas where the plant may get through impurities, and contaminations.</p>
<p>General surveillance could, when compatible, make use of established routine 139 surveillance practices such as monitoring of agricultural plants, variety/seed 140 registration, plant protection, plant health as well as ecological monitoring and 141 environmental observations (EC, 2002b). Use of an existing monitoring system might 142 not always be appropriate. Therefore it is also important in the Monitoring Plan to 143 describe the types of surveys that could be used to supply data related to effects 144 associated with GMOs or their cultivation. 145 The applicant should 146 decide which parameters could be monitored through existing monitoring 147 schemes and then seek appropriate networks to do this (e.g. monitoring of 148 agricultural cultivars and plant protection surveys), 149 identify existing environmental networks that monitor areas where GM plants 150 are grown, 151 describe how these existing monitoring networks will be evaluated and 152 selected, 153 describe how arrangements for collecting, collating and analysing data will be 154 made, 155 identify which category of additional surveys will be asked to contribute to the 156 general surveillance (for example, public institutions, farm associations) in 157 selected Member States, 158 describe how formal agreements and procedures will be established with the 159 Commission and Member States or other third parties before commercial 160 market introduction, although detailed arrangements may not have been 161 agreed at the time of the application. 162 163</p>	<p>Full support.</p>
<p>164 monitoring plan should be clearly assigned in the notification. Where third parties are 165 employed or contracted to conduct monitoring studies, the structure of their 166</p>	

<p>involvement should be detailed. 167</p>	
<p>168 Limitations of existing monitoring systems 169 Many of the existing surveys and networks collecting environmental data are unlikely to 170 produce data of relevance or use in monitoring impacts of GM plants in their present 171 form. Applicants may not consider some existing networks to be sufficiently useful 172 sources of information for monitoring due to various reasons such as the design of the 173 survey, the time, frequency and scale of data collection. There may be a need for 174 additional environmental surveys and to amend the monitoring objectives of existing 175 monitoring schemes. Existing European biodiversity monitoring programs are mainly 176 focused on protected habitats or species (eg birds), have little common language 177 (scope, location, methodology), systems are site-specific, there is little environmental 178 monitoring of unprotected parts of landscapes (referring to Directive 2004/35/EC), and 179 very few long-term (>10 years) monitoring programmes. In Europe, highest proportion of 180 biodiversity is in the unprotected parts of the landscape and therefore it is often the 181 responsibility of Member States to establish environmental surveillance in these areas. 182 General surveillance plans would benefit if applicants could make use of relevant 183 environmental monitoring networks conducted by Member States in unprotected parts 184 of the landscape. 185 Because existing national monitoring networks can be of variable quality and 186 consistency, it is important that the consistency and reliability of surveys utilised in 187 general surveillance is evaluated in order to ensure long-term coherence and reliability 188 of data collection, and data quality. In addition, environmental surveys will differ 189 between Member States and methods for integrating data from different countries 190 should be evaluated. 191</p>	<p>Full support. In Germany, the (not yet implemented) Ecological Area Sampling (Ökologische Flächenstichprobe) might cover a part of the addressed tasks.</p> <p>The draft is in particular right with the observation, that major parts of the safeguard subjects (in particular biodiversity) occur in the normal landscape and not only in protected areas.</p>
<p>192 Use of GMO-focussed monitoring systems 193 In addition to existing monitoring systems, applicants are encouraged to develop new 194 and more focused monitoring systems especially at the plant production and farm level. 195</p>	<p>There is no reason why plant production and farm level are emphasised here. General surveillance requires to aim at a complete coverage of the relevant safeguard subjects.</p>
<p>Questionnaires, directed at farms where GMOs are grown, are considered a useful 196 approach to collecting first hand data on the performance and impact of a GM plant and 197 for comparing it with conventional plants. There should be emphasis on the statistical 198</p>	<p>Yes, it is nice to have questionnaires distributed to growers and other stakeholders, however, this covers only a minor part of the surveillance task.</p>

<p>design and representiveness of questionnaires. Experience in designing questionnaires 199 and their statistical analysis is available from other established surveillance and 200 monitoring systems (e.g. those used for consumer and pharmaceutical surveillance 201 systems). 202</p>	<p>One weakness of the approach is, that the data gathering process itself does not base on science (farmers describe their opinions and impressions) regardless whether there is a posterior application of statistics. It is observed only what you can see without instrumental support and interpretation is on the level of personal opinion. Another weakness might be that it does not even cover the farm level sufficiently, if only GM growers would be requested to fill it. Also non-adaptors from the neighbourhood, stakeholders from transportation, and the processing chain, etc. need to be included because effects are quite unlikely to be limited to GM farms or fields. However, as an additional tool complementing other investigations it may be o.k.</p>
<p>203 Applicants should 205 involve growers, seed suppliers or other stakeholders in supplying data on seed 206 sales, areas sown, plant management etc... 207 be pro-active in developing reporting systems so that farmers (or their agents 208 and advisors) intending to purchase genetically modified seeds will be involved 209 in reporting adverse occurrences during and after the cultivation of the GM 210 plant, 211 describe the number of farmers/growers involved, the area covered, the 212 reporting methods and the suitability of the data collected for statistical 213 analysis, 214 establish independent audits to ensure the independence and integrity of all 215 monitoring data, 216 indicate the likely frequency of inspections. 217</p>	<p>We all love statistics. Even though it should not be overlooked, that many relevant effects require to answer a question of <i>existence</i> rather than requiring quantitative statistics. If gene transfer, hybridisation, formation of resistance occurs, it is relevant to report the first occurrence of the phenomenon. A quantification of the locations where it did not occur is then a second step. It would be reasonable to state, for which types of effects a statistical survey is useful and which type of events just requires an observation and statement of existence.</p>
<p>218 Farm questionnaires should 219 be designed to ensure the statistical validity and representativeness of the 220 collected data, including the proportion of fields growing the GM plant in a 221</p>	<p>It is apparent, that the farm questionnaire is the only monitoring approach which is described in further detail.</p>

<p>region and the number of questionnaires required to achieve statistical power in 222 the data collected, 223 be designed to generate data on the agronomic management of GM plants as 224 well as data on impacts on farming systems and the farm environment, 225 use a field or group of fields growing the GM plant as the basic unit for 226 monitoring. 227 observe the field/fields in subsequent years for any unusual residual effects 228 be user friendly and also information rich, 229 be constructed to encourage reliable responses from farmers and should not be 230 associated with other statutory or regulatory requirements for GMOs. 231 232 Questionnaires adapted to agronomists or other stakeholders working on the farms 233 growing the GM plants may also be useful sources of information. Focussed 234 questionnaires and interviews are generally accepted by respondents. Professional 235 interviewers may be an additional help. 236</p>	<p><i>The same level of detailed description should be done with other issues – e.g. impurity issues, gene transfer, cross pollination, etc.</i></p>
<p>237 Reporting adverse effects 238 Farm questionnaires and reports should be distributed, completed and collated annually 239 via an arranged reporting system (e.g. farm questionnaire forms or online systems). 240 These should be analysed by the applicant and reports submitted annually to 241 appropriate competent authorities. These reports will also allow the applicant to check if 242</p>	
<p>farmers are complying with recommended management and stewardship of the GM 243 plant (e.g. insect resistance management). 244 If unusual occurrences are observed by farmers, agronomists or others, they should be 245 reported immediately to the applicant. The applicant should then decide whether the 246 effects are unusual and report to the Competent Authorities as described in chapter 247 11.5 of the EFSA Guidance Document (EFSA, 2004a₆). More focused in-depth studies 248 can then be carried out to determine cause and effect. Final decisions on the 249 significance of an identified effect can only be made if causality is clear and a 250 comparison made with the non-GM plant situation (see 11.4.3. below). 251 252</p>	<p>Again, it is not the main criterion whether an effect is unusual. It is important, whether there is the possibility that an effect is on the way to become relevant in compromising safeguard subjects.</p>
<p>11.4.3 Importance of baseline data 253</p>	<p>What about baseline data concerning human health?</p>

<p>There is a need for general surveillance systems using both existing and novel systems 254 to be able to compare impacts of GM plants and their cultivation with those of 255 conventional plants. The baseline could be current conventional cropping or established 256 historical data. Direct comparison with non-GM plant reference areas may not be 257 required. Reference can be made to the historical knowledge and experiences of the 258 "observer" (e.g. farmers, inspectors, wildlife surveyors) in relation to the situation prior to 259 the introduction of the GM plant. 260</p> <p>There is also a need to take into account the fact that the GM event will occur in a 261 changing genetic background of new varieties which may have an impact independent 262 of the GM trait and thus it is the trait that needs to be monitored in any variety. 263 264</p>	<p>The draft should provide guidance also concerning this topic.</p>
<p>11.4.4 Data management and statistical analyses 265</p> <p>The statistical design of monitoring programs for GM plants should take account of 266 stages of commercialisation and the levels of other GM plant production in different 267 areas to be monitored. Points to consider are the geographical areas to be studied and 268 which existing environmental monitoring programmes could be useful for inclusion. 269 National cultivation registers of GM plants (including co-existence measures) can 270 provide useful data. The applicant should describe how all information from different 271 monitoring networks is collated and analysed for any unusual effects. Applicants should 272 make proposals for the time period, area covered, and frequency of seeking 273 information. 274</p> <p>The general surveillance plan should describe the generic approach used for data 275 management and data exploitation within general surveillance (e.g. data from existing 276 networks and questionnaires)</p>	
<p>as well as the concept for identification of unusual 277 adverse effects related to GM plants including a detailed statistical concept. In 278 particular, the operational handling of data coming from different sources into a 279 'general surveillance database' should be described in detail. The applicant should 280</p>	<p>Again, adverse effect alone (without the attribute unusual) is sufficient. The adverse effect does not need to be unusual in addition to its adverseness.</p>
<p>describe the approach to categorise the data (e.g. influencing factor, monitoring 281 character), and should describe the way of data pooling/matching with GM cultivation in 282 time and space. This database should also contain any data from case-specific 283 monitoring. 284 285</p>	

<p>11.4.5 Review and adaptation 286</p> <p>Monitoring plans should not be viewed as static. It is fundamental that the monitoring 287 plan and associated methodology is reviewed at appropriate intervals and updated or 288 adapted as necessary. Competent authorities may adapt the monitoring plan after the 289 first monitoring period. The implementation of the revised monitoring plan remains 290 under the responsibility of the notifier. 291 292</p>	<p>In general, a close co-operation with the competent authorities is mandatory. Though the notifier has a main responsibility, certain issues (like a surveillance on not notified constructs) remains under the responsibility of the competent authorities. The mode of this co-ordination needs to be described.</p> <p>As a perspective, the guidance document could also contain a suggestion how to collate data. This requires a trans-regional organisation. Would the EFSA be an adequate body to cover this task or does it require specific forms to include national competent authorities?</p>
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