

## Bt maize checklist ENV/08/07-2

Trait or process  (WHAT RISK)		Specific monitoring issue identified from an ERA <sup>1</sup>  (WHAT CHARACTER)	Monitoring methods (HOW) <sup>2</sup>		Environmental Surveillance system that might be used taking into account the exposure to crop/trait combinations (WHAT SYSTEM)	Environment e.g. field, natural habitats applicable to CSM/GS <sup>3</sup>  (WHERE)	Time for monitoring duration of period, timing applicable to CSM/GS  (WHEN)
			CSM <sup>4 5</sup> (if identified by an ERA)	General Surveillance			
Persistence and Invasiveness & selective advantage or disadvantage	Bt-maize volunteers (in fields)	Monitoring of Bt-maize volunteers <sup>6</sup>	<i>(Proposal to include the following CSM)</i> Floristic mapping /Volunteer mapping Gene detection methods	Volunteer mapping, if unexpected result identify whether GMO→CSM  Questionnaires <sup>7</sup> or other survey methods - <i>'other survey methods' deemed to be unclear</i>  Ecological surveys in wider areas, including: <ul style="list-style-type: none"> <li>Floristic mapping</li> <li>Population &amp; plant community monitoring</li> <li>VDI 4330 Part 9 (Assessment of the diversity of ferns and flowering plants – Vegetation surveys)</li> </ul> Gene detection method (PCR, Southern blotting, micro arrays) DNA-Chip-Technology VDI 4330 Part 5 + 7  <i>Some divergence of opinion among experts as to whether volunteer mapping and questionnaires were sufficient.</i>	Existing surveillance networks Agricultural monitoring (e.g. plant inspection service) Systems like: <ul style="list-style-type: none"> <li>French Biovigilance Surveillance</li> <li>Routine surveillance programmes suitable for combination of GMP<sup>8</sup> Surveillance, e.g. appropriate indicators &amp; parameters like: <ul style="list-style-type: none"> <li>Feral/ Volunteer GMP</li> </ul> </li> </ul> <i>The existence of feral maize in Europe was queried</i>	In fields In representative areas where Bt-maize kernels might survive during winter (mild winter, kernel fall down on soil at harvest and practices without tillage)	-5 years -During the authorisation period -During the authorisation period, and long term if necessary. -During the growing season -During the growing season and after harvest  <i>There was divergence of opinion among experts with regard to the duration of monitoring</i>
	Establishment of Bt-maize outside of fields	Monitoring of established Bt-maize outside fields <sup>9</sup>	Questionnaires <sup>7</sup> or other survey methods  Mapping abundance of maize outside fields. If unexpected spread, identify whether GMO (PCR). If positive, additional studies according to impact on NTOs below and flag for CSM – <i>Mapping abundance was suggested in place of the GS given below on the premise that if there is no increase in spread there will be no downstream effects. Further monitoring will be required where an increase in</i>	Existing surveillance networks Biodiversity monitoring Agricultural monitoring (e.g. plant inspection service) Systems like: <ul style="list-style-type: none"> <li>French Biovigilance Surveillance</li> <li>Routine surveillance programmes suitable for combination of GMP-Surveillance, e.g. appropriate indicators &amp; pa-</li> </ul>	Field margins and natural habitats in representative areas where Bt-maize kernels might survive during winter – <i>Certain experts deemed that this was sufficient</i>  Areas of processing facilities Loading and storage areas  Roadsides, Railroad tracks  Large scale surveys in areas	During the authorisation period, and long term if necessary.  During transport and processing - <i>it was suggested to delete this</i>  During the growing season and after harvest – <i>also suggested to delete after harvest</i>	

<sup>1</sup> ERA – Environmental Risk Assessment<sup>2</sup> Kjellson G. and Strandberg, M. (2001) Monitoring and surveillance of genetically modified higher plants. Guidelines for procedures and analysis of environmental effects. Birkhäuser Verlag Basel. 119 pp. VDI-Handbook Biotechnology, Part I: GMO-Monitoring, VDI 4330 (www.vdi.de)<sup>3</sup> GS – General Surveillance<sup>4</sup> CSM – Case Specific Monitoring<sup>5</sup> The CSM methodology would need to be adopted on a case-by-case basis<sup>6</sup> Some experts consider this risk to be low or negligible for Bt maize with cry1Ab or cry 1F proteins (*It was proposed to delete this footnote*)<sup>7</sup> Some experts were of the opinion that farmer questionnaires are not appropriate to detect such effects (*It was proposed to delete this footnote and replace it with the following* - Some experts were of the opinion that farmer questionnaires might be useful to provide information on agronomic issues. This solely visual method is not appropriate to detect effects on the environment within fields and in field margins - it does not provide scientifically sound environmental data.<sup>8</sup> GMP = Genetically Modified Plant<sup>9</sup> Methods listed under GS might also be useful if they could be adopted to test specific hypothesis in experiments with appropriate statistical power. (*It was proposed that this footnote be amended to read as follows* – Methods listed under GS might also be useful for CSM. The CSM methodology would need to be adopted on a case-by-case basis.)

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		CSM <sup>4 5</sup> (if identified by an ERA)	General Surveillance			
			<p><i>spread has occurred.</i></p> <p>Ecological surveys in wider areas, including:</p> <ul style="list-style-type: none"> <li>▪ Floristic mapping</li> <li>▪ Population &amp; plant community monitoring</li> <li>▪ VDI 4330 Part 9 (Assessment of the diversity of ferns and flowering plants – Vegetation surveys)</li> </ul> <p>Gene detection method (PCR, Southern blotting, micro arrays) DNA-Chip-Technology VDI 4330 Part 5 + 7</p> <p>Pollen monitoring<sup>10</sup>: Technical pollen sampler VDI 4334 Part 3 Biological pollen sampler VDI 4334 Part 4</p> <p>ELISA VDI 4330 Part 11 (Detection of Cry-proteins in soil and plant residues, in prep.)</p> <p>Dot-tests with herbicides</p>	<p>rameters like:</p> <ul style="list-style-type: none"> <li>• Feral GMP</li> </ul>	outside of GMO-growing regions	

<sup>10</sup> Some experts believe that pollen monitoring should be excluded, one reason being that pollen samplers do not work correctly.

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Spread, persistence and accumulation of GMP in the environment	<p>Screening of GMP/transgenes<sup>11</sup> in appropriate environmental media and organisms (e.g. plants, soil, compost)<sup>6</sup> – <i>proposed by certain to exclude this character (in its entirety, character, GS, what system, where, when) since spread of GMPs is already accounted for above under “Establishment of Bt maize outside fields” above. It was also suggested that this is only relevant where volunteers or feral plants are present. As indicated above the existence of feral maize in Europe was queried.</i></p> <p><i>Other experts suggested that it be retained</i></p>	9	<p>Questionnaires<sup>7</sup> and other survey methods Ecological surveys in wider areas, including:</p> <ul style="list-style-type: none"> <li>▪ Floristic mapping</li> <li>▪ Population &amp; plant community monitoring</li> <li>▪ VDI 4330 Part 9 (Assessment of the diversity of ferns and flowering plants – Vegetation surveys)</li> </ul> <p>Gene detection methods (PCR, Southern blotting, micro-arrays) DNA-Chip-Technology VDI 4330 Part 5, 7</p> <p>Pollen monitoring<sup>12</sup>: Technical pollen sampler VDI 4334 Part 3 Biological pollen sampler VDI 4334 Part 4</p> <p>ELISA VDI 4330 Part 11 (Detection of Cry-proteins in soil and plant residues, in prep.)</p> <p>Dot-tests with herbicides</p>	<p>Existing surveillance networks Biodiversity monitoring Agricultural monitoring (e.g. plant inspection service) Systems like:</p> <ul style="list-style-type: none"> <li>• French Biovigilance Surveillance</li> <li>• Routine surveillance programmes suitable for combination of GMP-Surveillance, e.g. appropriate indicators &amp; parameters like: <ul style="list-style-type: none"> <li>• Feral GMP</li> </ul> </li> </ul>	<p>In representative fields, field margins and natural habitats where Bt-maize is grown Roadsides, areas of processing facilities</p> <p>Representative biogeographical regions</p> <p>In soil, plants, pollen/air, compost, silage, dung</p>	<p>During the authorisation period, and long term if necessary.</p> <p>During the growing season and after harvest.</p> <p>Long term observations</p>
	<p>Long term and large scale screening of persistence and dispersal of ferals and / or cultivars. <i>As above</i></p>				<p>In representative Bt-maize - growing regions as well as large scale surveys in areas outside of GMO growing regions</p> <p>Areas of processing facilities Loading and storage areas Roadsides railroad tracks representative biogeographical regions</p>	

<sup>11</sup> Some experts are of the opinion that monitoring the exposure and fate of transgenes in the environment is not necessary. It has been suggested the term GMP be used instead in order to clarify that the monitoring of naked DNA is not being suggested.

<sup>12</sup> Some experts believe that pollen monitoring should be excluded, one reason being that pollen samplers do not work correctly.

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		CSM <sup>4 5</sup> (if identified by an ERA)	General Surveillance			
Presence of GMP products in the environment – <i>It was proposed by certain experts to move this section to effects on NTO</i>	Quantification of GM Bt product e.g. in field soils, and water and sediment of nearby water bodies <sup>6</sup>	Detection of Bt toxin in fields / ELISA	<p><i>There was divergence of opinion among the experts as to the extent of GS required –</i></p> <p>Questionnaires<sup>7</sup> and other survey methods Ecological surveys in wider areas, including:</p> <ul style="list-style-type: none"> <li>▪ Floristic mapping</li> <li>▪ Population &amp; plant community monitoring</li> <li>▪ VDI 4330 Part 9 (Assessment of the diversity of ferns and flowering plants – Vegetation surveys)</li> </ul> <p>Gene detection methods (PCR, Southern blotting, micro-arrays) DNA-Chip-Technology VDI 4330 Part 5, 7</p> <p>Pollen monitoring<sup>13</sup>: Technical pollen sampler VDI 4334 Part 3 Biological pollen sampler VDI 4334 Part 4</p> <p>VDI 4330 Part 11 (Detection of Cry-proteins in soil and plant residues, in prep.)</p> <p>Dot-tests with herbicides</p> <p style="text-align: center;"><i>OR</i></p> <p>Antibody based detection method (ELISA RIA) VDI 4330 Part 11 (Detection of Cry-proteins in soil and plant residues, in prep.)</p>	Existing surveillance networks Biodiversity monitoring Agricultural monitoring (e.g. plant inspection service) Systems like: <ul style="list-style-type: none"> <li>• French Biovigilance Surveillance</li> <li>• Routine surveillance programmes suitable for combination of GMP-Surveillance, e.g. appropriate indicators &amp; parameters like: <ul style="list-style-type: none"> <li>• Feral GMP</li> </ul> </li> </ul>	Fields,/Soil, water and sediment of nearby water bodies	During the authorisation period and long term if necessary

<sup>13</sup> Some experts believe that pollen monitoring should be excluded, one reason being that pollen samplers do not work correctly.

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		CSM <sup>4 5</sup> (if identified by an ERA)	General Surveillance				
Potential for Gene transfer	<p>Vertical to crop plants (volunteers, feral), leading to plants with one or several GM traits</p> <p><i>Feral maize plants are unusual, in any case they are already monitored for under establishment of Bt maize in the environment</i></p>	<p>Monitoring of gene flow: 1. from field to volunteers 2. from field to feral plants, in those areas where Bt maize kernels might survive during winter<sup>6</sup></p> <p><i>(It was suggested to exclude this section in it's entirety on the grounds that gene flow monitoring is not proportional to risk)</i></p>	<p>9</p>	<p>Questionnaires<sup>7</sup> and other survey methods</p> <p>Ecological surveys in wider areas, including: - Floristic mapping for clearly detectable (morphological) hybrids or modification of distribution in volunteers or feral distribution - Population &amp; plant community monitoring</p> <p>Gene detection method (PCR, Southern blotting, micro arrays).</p> <p>VDI 4330 Part 3,7,9</p> <p>Habitat monitoring / Land use to identify potential recipient organisms: volunteers and feral plants, in wider areas</p> <p>Pollen monitoring<sup>10</sup></p> <ul style="list-style-type: none"> <li>• Technical pollen sampler VDI 4334 Part 3</li> <li>• Biological pollen sampler VDI 4334 Part 4</li> </ul>	<p>Existing surveillance networks Biodiversity monitoring Soil monitoring Agricultural monitoring (Plant health, Variety registration) <i>(It was queried how appropriate plant health and variety registration were for GS)</i> Human and animal health monitoring Water Framework Monitoring Systems like:</p> <ul style="list-style-type: none"> <li>• French Biovigilance Surveillance</li> <li>• Routine surveillance programmes suitable for combination of GMP Surveillance, e.g. appropriate indicators &amp; parameters like:                             <ul style="list-style-type: none"> <li>• Feral GMP</li> </ul> </li> </ul>	<p>In representative fields and field margins where Bt-maize is grown, as well roadsides (transportation), and areas of processing facilities.</p> <p>Large scale surveys in areas with GMP-cultivation</p> <p>Large scale surveys in areas outside of GMO growing regions</p>	<p>During the authorisation period, and long term if necessary</p>
	<p>horizontal to micro-organisms in soil, and living on or next to the GMP</p>	<p>Monitoring of gene transfer to microorganisms, e.g. if the gene is not present in microbial communities and the trait confers a selective advantage<sup>6</sup>.</p> <p><i>(Again it was suggested by certain experts to exclude this section in it's entirety on the grounds that there are no relevant monitoring issues. Bt genes or its products do not confer a selective advantage. The genes are already present in abundance. The methodology is undeveloped).</i></p>		<p>In case appropriate methods would be available e.g. gene detection methods for soil microbial communities.</p>		<p>In representative fields where Bt-maize is grown</p>	<p>During the authorisation period and long term if necessary.</p> <p>During the growing season and after harvest</p>

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Interaction between GMP and target organisms	resistance development in target pests	Monitoring baseline susceptibility & resistance development of target organisms	<p>Changes over time in susceptibility by regular monitoring</p> <ul style="list-style-type: none"> <li>- Probit analysis (LC50, LC90, etc.)</li> <li>- Discriminating dose assay</li> </ul> <p>If changed susceptibility, monitor frequency of resistant alleles: <i>(through increased efficacy of the plants resistance. Divergence of opinion whether to include or exclude 'If changed susceptibility ...')</i></p> <ul style="list-style-type: none"> <li>- F0, F1 or F2 screens</li> <li>- Biochemical and/or molecular tests</li> </ul> <p>Efficacy of resistant plants</p> <p>Population genetics (baseline)</p>	<p><i>(There was divergence of opinion among experts with regard to the Environmental Surveillance systems that might be used. one expert proposed to delete paras 2, 3 and 4 while another proposed to delete first para only)</i></p> <p>Case Specific Monitoring systems</p> <p>Existing IRM plans developed by applicants and some Member States (e.g. Spain, Germany, France)</p> <p>A specific monitoring programme for each Bt toxin, considering also combined genes.</p> <p>Target organisms (depending on gene product and geographic area)</p>	<p>Sampling sites in representative geographical areas where Bt maize is cultivated</p> <p>Bt maize fields, refugees, or neighbouring maize fields (depending on event)</p> <p>Measures on regional (population) level depending on the population genetics and ecology</p>	<p>As long as varieties expressing the toxin are cultivated</p> <p>In intervals testing every 5<sup>th</sup> pest generation</p>
	Build-up of secondary target pests <i>(One expert proposed to delete the entire row as there are either target pests or non-target orgs. Another proposed to just delete "target")</i>	Monitoring abundance and damage caused by secondary target pests <i>(In this instance the word pests relates to those organisms which do not ordinarily cause problems. However once the target pests have been omitted, such secondary pests will increase in number and will become problematic therefore it was proposed to delete the word 'target')</i>	<p>Survey pesticide use. Questionnaires<sup>7</sup> and other survey methods</p> <p>If increased pesticide use, monitor pests</p> <ul style="list-style-type: none"> <li>• Representative examples of pests from different geographical area</li> <li>• Inspection/Assessment of plant damage infestation</li> <li>• Knock off plants</li> <li>• Pheromone trapping</li> </ul> <p>e.g. EPPO diagnostic protocols</p> <p><i>(Divergence of opinion as to whether to include or exclude)</i></p> <p><i>(It was also suggested to monitor pesticide use. If increased pesticide use were demonstrated, then other studies should be performed to determine if the environmental effects were as a result of the GMP)</i></p>	<p><i>(Divergence of opinion whether to include or exclude GS)</i></p> <p>Questionnaires<sup>7</sup> and other survey methods</p> <p>Pest survey</p> <ul style="list-style-type: none"> <li>• Representative examples of pests from different geographical area</li> <li>• Count of damage by infestation</li> <li>• Knock off plants</li> </ul>	<p>Systems like :</p> <ul style="list-style-type: none"> <li>• French Biovigilance Surveillance</li> <li>• Ecological Area Survey</li> </ul> <p>Routine surveillance</p>	<p>Bt maize and non-Bt maize fields</p>

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Interaction between GMP and non-target organisms	Impact on non-target organisms  Monitoring of abundance and diversity of relevant <u>terrestrial</u> (indicator) species representing a larger set of non-target organisms  <i>(Proposal by some experts to include 'terrestrial' Monitoring should be limited to field and field margins until unexpected spread has been demonstrated)</i>	Scientifically based methodology appropriate for the case-specific monitoring of indicator organisms Relevant indicators should be defined for representative geographic regions depending on - crop/trait/ <u>expression pattern</u> combination - <u>the Bt toxin</u> <ul style="list-style-type: none"> <li>Hypogaeic phytophages</li> <li>Other epigaeic phytophages<sup>14</sup></li> <li>Hypogaeic predators</li> <li>Epigaeic predators</li> <li>Parasitoids</li> <li><u>Soil organisms</u></li> </ul> <i>(Proposal to include '.../expression pattern,' 'the Bt toxin' and 'Soil organisms')</i>	Surveillance of abundance and/or diversity of relevant (indicator) species representing a larger set of non-target organisms eg: <ul style="list-style-type: none"> <li>Hypogaeic phytophages</li> <li>Other epigaeic phytophages</li> <li>Hypogaeic predators</li> <li>Parasitoids</li> <li>Birds</li> <li>Mammals</li> <li>Earth worms (Lumbricidae)</li> <li>Nematodes</li> <li>Springtails (Collembola)</li> <li>Myriapoda</li> <li>Bacterial, virus and fungi diseases</li> </ul> Use of available routine environmental surveillance systems for indicator (often protected) non-target organisms if appropriate; Compilation and evaluation of available knowledge on unusual effects from existing surveillance and monitoring programmes (e.g. bird monitoring programmes, biodiversity monitoring, butterfly monitoring) VDI 4330 Part 13 (Method standards for butterflies, in prep.) <sup>15</sup> – <i>proposal by some experts to delete this paragraph.</i>  <i>Proposal to delete 'Birds, Mammals' since they move over a large area</i>	Existing surveillance networks Biodiversity monitoring Soil monitoring Agricultural monitoring (Plant health, Variety registration) Human & animal health monitoring Water Framework Monitoring  Systems like : <ul style="list-style-type: none"> <li>French Biovigilance Surveillance</li> <li>Ecological Area Survey</li> <li>Routine surveillance programmes suitable for combination of GMP surveillance e.g. appropriate indicators &amp; parameters alike <ul style="list-style-type: none"> <li>Birds</li> <li>Butterflies</li> <li>Beetles</li> <li>Bees</li> <li>others</li> </ul> </li> </ul> <i>(Proposal to delete this section. In addition it was queried how appropriate plant health and variety registration systems were for GS)</i>	In representative fields and field margins where Bt-maize is grown (CSM and GS).  For events with high expression of toxin in pollen, monitoring outside fields should be considered. Also, if studies above show unexpected spread of maize, monitor as well as natural habitats (CSM and GS).  <i>(One expert that monitoring should also entail natural habitats and should not be limited to where unexpected spread was demonstrated)</i>	During the period of authorisation, and longer term depending on the results.  CSM for limited period (at least 5 years) and GS during the period of authorisation.

<sup>14</sup> A great number of epigaeic phytophages, in some cases pests, are not target for Bt maize but available indicators (about 100 or more on maize with 30 or more pests included)

<sup>15</sup> Some experts indicate problems with this standard method as it is expensive and cannot be used in a cost effective manner by applicants (alone)

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	<i>(Proposal to remove 'gene product in the water' since Bt protein is already covered under "Presence of GM products in the environment above" - consequently" Detection of toxins in water" should be removed from GS)</i>					
Changes of susceptibility to non-target pests & diseases	Monitoring the damage caused by non-target pests <sup>6</sup> and diseases	<p>9</p> <p>PEST surveys of relevant pests and diseases Inspection/Assessment of plant damage infestation Pheromone trapping e.g. EPPO diagnostic protocols for regulated pests</p> <p><i>(Proposal to include CSM as above)</i></p>	<p>Questionnaires<sup>7</sup> and other survey methods</p> <ul style="list-style-type: none"> <li>• damage caused by pests.</li> <li>• volume, time and frequency of pesticide applications</li> </ul> <p><i>(Proposal to delete "damage caused by pests")</i></p>	<p>Existing Surveillance network Pest surveys linked to crop practices.</p> <p><i>(Proposal to replace "pest surveys linked to crop practices" with "existing surveillance networks")</i></p>	In the fields where Bt-maize is grown	During the period of authorisation
	<p>Monitoring the changes in soil mycodyversity and changes in mycotoxins</p> <p><i>(Proposal to delete changes in mycotoxins as it is not environmentally relevant. It was therefore also proposed to remove "consequences of the mycotoxin" from GS</i></p> <p><i>This was also perceived as monitoring for a benefit. One expert flagged this querying whether the monitoring of beneficial aspects should be included: if included then other beneficial aspects should be considered for such monitoring , if not included then a comment to that effect should be provided in the document. The expert had no opinion as to whether the monitoring of benefits should be included/excluded.)</i></p>	<p>9</p>	<p>Survey of soil mycota species <u>and consequences of the mycotoxin</u>.</p>	<p><u>Existing Surveillance networks</u> Pest surveys linked to crop practices</p> <p>Existing Surveillance network systems like</p> <ul style="list-style-type: none"> <li>• French Biovigilance Surveillance</li> <li>•</li> </ul> <p><i>(proposal to include "Existing Surveillance Networks")</i></p>	<p>In adjacent or near adjacent fields where Bt-maize and non-Bt maize are grown (<u>ideally isogenic maize planted on the same date</u>)</p> <p><i>(Proposal to delete " ideally isogenic maize planted on the same date")</i></p>	During the period of authorisation
Other Impacts on habitat diversity and biodiversity	Monitoring changes in diversity of habitats and biota, <u>relative frequencies and fitness</u> at different levels of the food chain,	<p>9</p> <p>Depending on indicators, if applicable, amendment of existing programmes by relevant indicators</p>	<p>Identification and observation of relevant surveillance programs that provide information relevant to indicators <u>in order to address adverse effects on the environment and on protection targets.</u></p>	<p>Link with INSPIRE Directive:</p> <ul style="list-style-type: none"> <li>- Habitats and biotopes</li> <li>- Species distribution</li> <li>- etc</li> </ul>	In representative fields and field margins where Bt-maize is grown, <u>as well as natural habitats</u>	No time limit



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	CSM <sup>4 5</sup> (if identified by an ERA)	General Surveillance				
	<p>other than the specific items listed before</p> <p>Monitoring of relevant indicators <u>in order to detect adverse effects on protection targets</u></p> <p><i>(Proposal to replace "relative frequencies and fitness" with "habitats and biota"</i> <i>Proposal to delete " in order to detect adverse effects on protection targets")</i></p>	<p>Large scale observations</p> <p>Relative frequencies of relevant biodiversity indicator species at different levels in the food chain</p> <p>Habitat monitoring</p> <p><i>(Proposal to include CSM as above)</i></p>	<p>Compilation and evaluation of available <u>knowledge data</u> on unusual effects from existing surveillance and monitoring programmes (e.g. bird monitoring programmes, biodiversity monitoring, butterfly monitoring).</p> <p>Depending on the usefulness of existing surveillance programmes the cost effective amendment of relevant indicators or the amendment of existing programs by relevant indicators</p> <p>Large scale observations Biodiversity indicators.</p> <p><i>(Proposal to include " in order to address adverse effects on the environment and on protection targets"</i> <i>Proposal to replace "knowledge" with "data")</i></p>		<p>Studies in natural habitats can be requested after unexpected results from the monitoring of GMP presence outside fields</p> <p><u>Representative and/or relevant bio geographical regions</u></p> <p><i>(Proposal to delete " as well as natural habitats" and " Representative and/or relevant bio geographical regions"</i> <i>Proposal to include " Studies in natural habitats can be requested after unexpected re-sults from the monitoring of GMP presence outside fields")</i></p>	
Changes in biogeochemical processes	Monitoring relevant soil functions/parameters <sup>6</sup>	<p><b>9</b> <i>(One expert indicated that CSM should be the same as GS depending on the Bt toxin being expressed. All of the following CSM techniques were proposed for inclusion)</i></p> <p>Substrate-induced respiration</p> <p>Fumigation-extraction method</p> <p>Infrared carbon dioxide analyser with flow rate indication/determination of oxygen absorption</p> <p>Total DNA extraction (DGGE)</p> <p>VDI 4330 Part 11</p> <p>Germination and growth tests, soil parameter as pH, nutrient content, consistency etc.</p> <p>Micro-arrays</p> <p>Cloning the soil metagenome, using e.g. Bacterial Artificial Chromosomes (<i>Rondon et al, 2000</i>) to assess the genetic and functional diversity</p> <p>Italian index QBS to assess soil biological quali-</p>	<p><i>(There was diverging opinion on the extent of GS that should be carried out)</i></p> <p><i>(It was proposed that the following GS be included)</i></p> <p>Physical, chemical and biological indicators such as soil organic matter, soil structure, depth of soil, infiltration and bulk density; water holding capacity, pH; electrical conductivity; extractable N-P-K, microbial biomass C and N; potentially mineralizable N; soil respiration.etc.</p> <p>Italian index QBS to assess soil biological quality (<i>Parisi et al., 2003; Gardi et al., 2003</i>), or the Maturity Index, or the Weighted Coenozoic Index)</p> <p>Large scale observations</p> <p>Biodiversity indicators</p> <p><i>(the following GS be retained)</i></p> <p>Germination and growth tests, soil parameter as pH, nutrient content, consistency etc.</p> <p>Compilation and evaluation of available</p>	<p><u>Existing Surveillance network</u></p> <p>Soil monitoring</p> <p>Agricultural monitoring (<u>Plant health, Variety registration</u>)</p> <p>Water Framework Monitoring <i>(It was queried by one expert whether Water Framework Monitoring addressed soil parameters)</i></p> <p>INSPIRE Directive</p> <p><i>(It was proposed to include "Existing Surveillance Networks" It was proposed to delete "Plant health and variety registration" for aforementioned reasons)</i></p>	In representative fields where Bt-maize is grown	During the authorisation period, and long term if necessary.

Trait or process  (WHAT RISK)	Specific monitoring issue identified from an ERA <sup>1</sup>  (WHAT CHARACTER)	Monitoring methods (HOW) <sup>2</sup>		Environmental Surveillance system that might be used taking into account the exposure to crop/trait combinations (WHAT SYSTEM)	Environment e.g. field, natural habitats applicable to CSM/GS <sup>3</sup>  (WHERE)	Time for monitoring duration of period, timing applicable to CSM/GS  (WHEN)
		CSM <sup>4 5</sup> (if identified by an ERA)	General Surveillance			
		<p>ty ((Parisi et al., 2003; Gardi et al., 2003), or the Maturity Index, or the Weighted Coenozoic Index)</p> <p>Organic matter turnover/decomposition.</p> <p>Soil community composition, different functional groups</p> <p><i>(One expert was opposed to the inclusion of the 'very specific methods' listed here on the grounds that "the value of the methods has not been discussed in detail and it gives the wrong impression that every method is useful. Some of the methods are related to NTO effects and not to biogeochemical processes" The expert proposed to keep footnote 9 and the text "Depending on indicators, if applicable, amendment of existing programmes by relevant indicators")</i></p>	<p><u>knowledge data</u> on unusual effects from existing surveillance and monitoring programmes (e.g. bird monitoring programmes, biodiversity monitoring, butterfly monitoring). <i>(Proposal to replace knowledge with data)</i></p> <p>Depending on the usefulness of existing surveillance programmes the cost effective amendment of relevant indicators or the amendment of existing programs by relevant indicators</p> <p><i>(and the following GS be deleted )</i></p> <p>Identification and observation of relevant surveillance programs that provide information relevant to indicators in order to address protection targets.</p> <p>Substrate-induced respiration</p> <p>Fumigation-extraction method</p> <p>Infrared carbon dioxide analyser with flow rate indication/determination of oxygen absorption</p> <p>Total DNA extraction (DGGE)} VDI 4330 Part 11 – <i>It was queried by one expert whether these methods were relevant for soil function parameters</i></p>			

Trait or process  (WHAT RISK)	Specific monitoring issue identified from an ERA <sup>1</sup>  (WHAT CHARACTER)	Monitoring methods (HOW) <sup>2</sup>		Environmental Surveillance system that might be used taking into account the exposure to crop/trait combinations (WHAT SYSTEM)	Environment e.g. field, natural habitats applicable to CSM/GS <sup>3</sup>  (WHERE)	Time for monitoring duration of period, timing applicable to CSM/GS  (WHEN)
		CSM <sup>4 5</sup> (if identified by an ERA)	General Surveillance			
Changes in cultivation practices	Monitor changes in farming practice <sup>16</sup> (e.g. amount and type of pesticides, application of fertilizers, tillage, crop rotation, use of energy) <sup>6</sup>	<p>9 Type, frequency and volume of pesticide applications per unit of agricultural land</p> <p><i>(Proposal to include CSM as above)</i></p>	<p>Practices inquiries</p> <p>Pesticide use indicators - Link with Directive 91/414 and Thematic Strategy for Pesticides</p> <p>Farmer Questionnaires<sup>7</sup></p> <p><i>(Proposal to delete GS with the exception of Farmer Questionnaires)</i></p>	<p><i>(It was proposed to include the following surveillance systems)</i></p> <p>Existing Surveillance network German Bee Monitoring INSPIRE</p> <p><i>(One expert was unsure as to the relevance of German Bee Monitoring and INSPIRE)</i></p> <p>Existing monitoring programmes</p> <p><i>(It was proposed to delete the following Surveillance systems)</i></p> <p>Biodiversity monitoring Soil monitoring Agricultural monitoring (Plant health, Variety registration) Water Framework Monitoring</p> <p>Systems like: French Biovigilance Surveillance</p>	In representative fields where Bt-maize is grown	<p>During the authorisation period, and long term if necessary.</p> <p><i>(It was proposed to delete "and long term if necessary")</i></p>

<sup>16</sup> Some experts considered this point controversial owing to the interplay between Directive 91/414 and Directive 2001/18/EC. Is the monitoring of these effects covered by Directive 2001/18 or Directive 90/414?