

GM herbicide tolerant oilseed rape checklist ENV/08/08-2

Trait or process (WHAT RISK)	Specific monitoring issue identified from an ERA ¹ (WHAT CHARACTER)	Monitoring methods (HOW) ²		Environmental Surveillance system that might be used taking into account the exposure to crop/trait combinations (WHAT SYSTEM ³)	Environment e.g. field, natural habitats applicable to CSM/GS ⁴ (WHERE)	Time for monitoring duration of period, timing applicable to CSM/GS (WHEN)
		CSM ⁵ (if identified by an ERA)	General Surveillance ⁶			
Volunteers in fields	Monitoring of volunteers		Questionnaires or other survey methods	Existing surveillance networks:	In fields and field margins	During the authorisation period, and long term ⁷ if necessary. Specify what long term is or leave out)

¹ ERA – Environmental Risk Assessment

² 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)

³ Suggested to remove this column as it is not "communicating to the notifier"

⁴ GS – General Surveillance

⁵ CSM – Case Specific Monitoring

⁶ One expert suggested that the parameters to be monitored under GS can be monitored through a directed study

⁷ Specify what long term is or leave out

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		CSM ⁵ (if identified by an ERA)	General Surveillance ⁶				
<p>Persistence and Invasiveness & Selective Advantage or Disadvantage</p>	<p>Potential effects due to vertical gene transfer from GM-HT plants to crop plants (volunteers, feral plants) establishment of GMP outside of fields</p> <p><i>(One expert proposed to move feral plants to the next sub-issue and that the GMP be monitored outside the fields)</i></p>	<p>Monitoring the occurrence (establishment) and abundance (frequency) of GM-HT volunteers outside fields, or feral plants</p> <p><i>(Proposal to include monitoring for GMP outside the fields. If there is no increased spread there will be no effects downstream. If increased spread occurs, other studies are required)</i></p>	<p><i>(Divergence of opinion with regard to CSM. It was proposed that Habitat monitoring, the 5th point under mapping and pollen flow all be deleted)</i></p> <p>Habitat monitoring / Land use to identify potential recipient organisms i.e. volunteers and feral plants</p> <ul style="list-style-type: none"> • VDI Part 9 (Assessment of the diversity of ferns and flowering plants – Vegetation surveys) <p>Floristic mapping for clearly detectable (morphological) hybrids or modification of distribution in of volunteers and feral plants</p> <ul style="list-style-type: none"> • Herbicide sprayings • Dot-tests with herbicides • Lateral flow strip • Gene detection methods like PCR, Southern Blotting, micro-arrays, DNA-chip technology • VDI Part 9 (Assessment of the diversity of ferns and flowering plants – Vegetation surveys) <p>If unexpected distribution identify whether GMO (PCR), if positive study plant diversity / plant community and perform additional studies under non-target organisms (Also see vertical gene transfer below)</p> <p>Germination tests with herbicide spraying <i>(Proposal to include Germination Tests)</i></p> <p>Pollen flow¹⁰</p> <ul style="list-style-type: none"> • VDI 4334 Part 3 Technical pollen sampler • VDI 4334 Part 4 Biological pollen sampler 	<p><i>(Divergence of opinion with regard to GS, one expert proposed to delete all GS)</i></p> <p>Volunteer mapping, if unexpected result identify whether GMO (PCR) <i>(Proposal to include volunteer mapping)</i></p> <p>Questionnaires⁹ and other survey methods</p> <p>Large scale surveys in areas with GMP-cultivation</p> <p>Ecological surveys in wider areas, including:</p> <ul style="list-style-type: none"> ▪ Floristic mapping (including phenotypic detecting methods) <ul style="list-style-type: none"> ○ Herbicide sprayings ○ Dot-tests with herbicides ○ Lateral flow strip ▪ Population & plant community monitoring ▪ VDI 4330 Part 9 <p>Germination tests with herbicide spraying <i>(Proposal to include Germination tests)</i></p> <p>Pollen monitoring¹⁰:</p> <ul style="list-style-type: none"> • VDI 4334 Part 3 • VDI 4334 Part 4 <p>Gene detection methods like PCR, Southern blotting, micro arrays, DNA-chip-Technology</p> <ul style="list-style-type: none"> • VDI 4330 Part 5, 7 • ELISA <p><i>(Proposal to exclude or delete pollen monitoring and gene detection methods)</i></p>	<p>Biodiversity monitoring Soil monitoring for seeds <i>(Proposal that soil monitoring be carried out in respect of seeds as opposed to all inclusive soil monitoring)</i></p> <p>Agricultural monitoring (Plant health, variety registration) <i>(Proposal to include plant health/variety registration)</i></p> <p>Human & animal health monitoring <i>(Proposal to exclude on the basis of relevance)</i></p> <p>WISE (system used by the Water Framework Directive) <i>(Proposal to exclude WISE)</i></p> <p>Systems like:</p> <ul style="list-style-type: none"> • French Biovigilance Surveillance • Italian network for pollen monitoring (R.I.M.A.) <p><i>(Proposal to exclude Italian network)</i></p> <p>Routine surveillance programmes suitable for combination of oilseed rape surveillance, e.g. appropriate indicators & parameters like:</p> <ul style="list-style-type: none"> • Feral GM plants • Volunteer GM plants • Crossable wild relatives of oilseed rape <p><i>(Proposal to delete "Feral GM Plants" and "Crossable wild relatives of Oilseed")</i></p>	<p>In fields, field margins, disturbed areas (e.g. roadsides, railroad tracks, loading and storage areas, areas of processing facilities) and natural habitats in representative GMP-growing regions.</p> <p>In representative environments where oilseed rape might survive as volunteer or as feral plants.</p>	<p>During the growing season and after harvest.</p>

⁹ Some experts were of the opinion, that (farmer) questionnaires might be useful to provide info on agronomic issues but are not appropriate to detect effects on the environment within fields and in the field margins – it does not provide scientifically sound environmental data

¹⁰ Some experts believe that pollen monitoring should be excluded, one reason being that pollen samplers do not work appropriately (e.g. lack of DNA sensitivity and hazard detection)

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		CSM ⁵ (if identified by an ERA)	General Surveillance ⁶			
		Gene detection methods like PCR, Southern blotting, micro arrays, DNA-chip-Technology <ul style="list-style-type: none"> • VDI 4330 Part 5 Sampling of plant material for the detection of genetically modified nucleic acids, in prep. • VDI 4330 Part 7 PCR-methods for the detection of genetically modified nucleic acids in the environment⁸ • ELISA (protein detection depending on GMP product) 		<i>Rape" and limit surveillance to "Volunteer GM plants")</i>		
Spread, persistence and accumulation of GMHT oilseed rape in the environment	Screening of GMHT oilseed rape / transgenes ¹¹ in appropriate environmental media and organisms (e.g. plants, soil, compost) <i>(Proposal to delete "screening of transgenes" and "soil ,compost" The only risk with naked DNA is horizontal gene transfer and that is already covered under "Potential for gene transfer")</i>	<i>(with the exception of floristic mapping it was proposed that all of the following CSM be deleted)</i> Dot-tests with herbicides Habitat monitoring / Land use to identify potential recipient organisms i.e. volunteers and feral plants <ul style="list-style-type: none"> • VDI Part 9 (Assessment of the diversity of ferns and flowering plants – Vegetation surveys) Floristic mapping for clearly detectable (morphological) hybrids or modification of distribution in of volunteers and feral plants <ul style="list-style-type: none"> • Herbicide sprayings • Dot-tests with herbicides • Lateral flow strip If unexpected distribution identify whether GMO (PCR), if positive study plant diversity / plant community and perform additional studies under non-target organisms (Also see vertical gene transfer below)			In representative fields, field margins and natural habitats where the oilseed rape is grown Road sites, areas of processing facilities. Representative bio-geographical regions. In soil, plants, compost, silage, dung.	During the authorisation period, and long term if necessary. During the growing season and after harvest. Long term observations.

⁸ According to one expert this is not a generic method for detecting a wide range of GMPs

¹¹ 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.

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	<p>Long term and large scale screening of persistence and dispersal of feral plants and / or cultivars and / or wild relatives <i>(It was suggested that this character has already been covered under “Potential effects due to establishment of GMP outside of fields” above, and on this basis should not be included here, therefore proposal to delete the entire row.</i></p> <p><i>Others believed it should be included and proposed the following CSM and GS)</i></p>	<p><i>(It was proposed that all of the following CSM be included)</i></p> <p>Existing surveillance networks</p> <p>Habitat monitoring to focus monitoring on habitat types favoured by feral plants / cultivars /wild relatives</p> <p>Ecological surveys in wider areas, including:</p> <ul style="list-style-type: none"> • Floristic mapping <ul style="list-style-type: none"> ○ VDI 4330 Part 9 ○ Herbicide sprayings ○ Dot-tests with herbicides ○ Lateral flow strip tests • Population & plant community monitoring • Counting the number of individuals <p>Germination tests with herbicide spraying Gene detection methods like PCR, Southern blotting, micro arrays, DNA-chip-Technology</p> <ul style="list-style-type: none"> • VDI 4330 Part 5, 7 • ELISA 	<p><i>(It was proposed that GS reflect that under the 2nd point above)</i></p>	<p><i>(It was proposed that Environmental Surveillance Systems reflect that under the 2nd Point above)</i></p>	<p>In representative oilseed rape - growing regions as well as large scale surveys in areas outside of oilseed rape growing regions.</p> <p>Areas of processing facilities</p> <p>Loading and storage areas</p> <p>Roadsides, railroad tracks representative biogeographical regions</p> <p><i>(It was proposed to include areas of processing facilities, loading and storage areas, roadsides railroad tracks etc)</i></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>
Presence of transgene products in the environment	<p>Quantification of transgene product e.g. in field soils, and water and sediment of nearby water bodies <i>(It was suggested to delete the entire row since HT proteins will most likely not exert an effect on any organism, also, these gene products already exist in soil micro-organisms. Other experts suggested to retain the row)</i></p>	<p>ELISA</p> <p>Southern blots if applicable</p>			<p>Soil, groundwater and surface water and sediments in the regions where the GMP is grown.</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>

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Potential for Gene transfer	Vertical to crop plants (volunteers, feral plants), leading to plants with one or several GM traits	<i>(See "Persistence and Invasiveness & Selective advantage or Disadvantage" Proposal to include the following)</i> Monitoring of Spontaneous stacking of genes	<i>(See "Persistence and Invasiveness & Selective Advantage or Disadvantage" Proposal to include the following)</i> In unexpected distribution of oilseed rape investigate whether cumulative GM traits (if appropriate)				During the authorisation period and long term if necessary

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Potential effects due to vertical gene transfer from GM-HT oilseed rape to wild relatives	<p>a) Monitoring the occurrence (establishment), abundance (frequency) of hybrids with wild relatives</p> <p>b) Monitoring herbicide tolerance of hybrids under selection pressure (herbicide use)</p> <p>c) Monitoring the frequency of sexually compatible species</p> <p><i>(It was suggested to exclude b and c on grounds that they are required only where unexpected and increased distribution has occurred.)</i></p>	<p><i>(Divergence of opinion with regard to extent of CSM. In general agreed that mapping be carried out and then further investigations pursued following a positive outcome. It was also proposed that Germination tests, scale of floristic frequencies, pollen monitoring and gene detection method be deleted)</i></p> <p>Habitat monitoring / Land use to identify potential recipient organisms: feral plants and wild relatives, in wider area.</p> <p>Mapping of distribution of hybridisable relatives and the proportion of hybrids</p> <p>Ecological surveys in wider areas, including:</p> <ul style="list-style-type: none"> • Floristic mapping <ul style="list-style-type: none"> ○ VDI 4330 Part 9 ○ Herbicide sprayings ○ Dot-tests with herbicides ○ Lateral flow strip tests • Population & plant community monitoring • Counting the number of individuals <p>If unexpected distribution of hybridisable relatives identify whether GMO (PCR). If positive study plant diversity / plant community and perform additional studies under non target organisms. If unexpected proportion of hybrids monitor genetic diversity and investigate whether cumulative GM-traits (if appropriate)</p> <p>Germination tests with herbicide spraying</p> <p>Scale of floristic frequencies</p> <ul style="list-style-type: none"> • analysing seed quantity and quality (laboratory tests) <p>Pollen monitoring</p> <ul style="list-style-type: none"> ▪ VDI 4330 Part 3, 4 <p>Gene detection methods (PCR, Southern blotting, micro-arrays) to identify hybrids</p> <ul style="list-style-type: none"> • VDI 4330 Part 5, 7 • ELISA 	<p><i>(Divergence of opinion with regard to extent of GS carried out. One expert suggested deleting everything in GS column. It was otherwise suggested that pollen monitoring and gene detection methods be deleted. Proposal to include Germination tests with herbicide spraying)</i></p> <p>Volunteer mapping, if unexpected result identify whether GMO (PCR)</p> <p>Questionnaires⁹ and other survey methods</p> <p>Large scale surveys in areas with GMP-cultivation</p> <p>Ecological surveys in wider areas, including:</p> <ul style="list-style-type: none"> ▪ Floristic mapping (including phenotypic detecting methods) <ul style="list-style-type: none"> ○ Herbicide sprayings ○ Dot-tests with herbicides ○ Lateral flow strip ○ VDI 4330 Part 9 ▪ Population & plant community monitoring <p>Germination tests with herbicide spraying</p> <p>Pollen monitoring¹⁰:</p> <ul style="list-style-type: none"> • VDI 4334 Part 3 • VDI 4334 Part 4 <p>Gene detection methods like PCR, Southern blotting, micro arrays, DNA-chip-Technology</p> <ul style="list-style-type: none"> • VDI 4330 Part 5, 7 • ELISA 	<p>Existing surveillance networks:</p> <p>Biodiversity monitoring <i>(Proposal to exclude Biodiversity monitoring)</i></p> <p>Soil monitoring for seeds <i>(Proposal that soil monitoring be carried out in respect of seeds as opposed to all inclusive soil monitoring)</i></p> <p>Agricultural monitoring (Plant health, variety registration) <i>(Proposal to include plant health/variety registration)</i></p> <p>Human & animal health monitoring <i>(Proposal to exclude on the basis of relevance)</i></p> <p>WISE (system used by the Water Framework Directive) <i>(Proposal to exclude WISE)</i></p> <p>Systems like:</p> <ul style="list-style-type: none"> • French Biovigilance Surveillance • Italian network for pollen monitoring (R.I.M.A.) <p>Routine surveillance programmes suitable for combination of oilseed rape surveillance, e.g. appropriate indicators & parameters like:</p> <ul style="list-style-type: none"> • Feral GM plants • Volunteer GM plants • Crossable wild relatives of oilseed rape <p><i>(Proposal to delete "Feral GM Plants" and "Crossable wild relatives of Oilseed Rape" and limit surveillance to "Volunteer GM plants")</i></p>	<p>In fields, field margins, disturbed areas (e.g. roadsides, railroad tracks, loading and storage areas, areas of processing facilities) and natural habitats in representative oilseed rape growing regions.</p> <p>Large scale surveys in areas outside of oilseed rape growing regions. <i>(It was proposed to delete this point)</i></p>	<p>During the authorisation period, and long term if necessary.</p> <p>During transport and processing. <i>(It was proposed to delete this point)</i></p> <p>During the growing season and after harvest. <i>(It was proposed to delete and after harvest)</i></p>

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Horizontal to micro-organisms in soil, and living on or next to the GMP	<i>(HT genes pat and EPSPS are already present in soil micro-organisms and therefore no relevant monitoring issues here)</i>					
Interaction between GMP and target organisms	<p>Reduced abundance and diversity of weeds or development of new weed species</p> <p>Monitoring abundance and diversity of weeds and their fitness if an increased number is detected <i>(Question mark over inclusion of this point as unclear which legislation this should be dealt with)</i></p> <p><i>Also suggested it should go under wider biodiversity – NTO effects. Weed resistance development is an indirect effect of the herbicide use. This is an overlap to 91/414)</i></p>	<p>Floristic mapping</p> <ul style="list-style-type: none"> • VDI 4330 Part 9 <i>(proposal to delete)</i> • Population and plant community monitoring <i>(proposal to include)</i> <p>Inventory of seed bank</p> <p>Agronomic (Questionnaires⁹, other methods) surveys <i>(proposal to delete)</i></p> <p>Monitoring seed feeding insects</p> <p><i>(One expert proposed the exclusion of CSM on grounds there was no target organism)</i></p>	<p>Questionnaires⁹ and other survey methods</p> <p>Ecological surveys in wider areas, including:</p> <ul style="list-style-type: none"> • Floristic mapping • Population & plant community monitoring • Counting the number of individuals <p><i>(Proposal to delete GS or retain with the inclusion of "Counting the number of individuals")</i></p>	Agricultural monitoring <i>(Proposal to delete)</i>	In representative where the oilseed rape is grown	<p>During the authorisation period and long term if necessary.</p> <p>During the growing season and after harvest <i>(Proposal to delete)</i></p>

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Tolerance development in plants	<p>Monitoring development of herbicide tolerance in weeds¹²</p> <p>Monitoring changes in composition and abundance of weed flora – <i>(The monitoring of changes in composition and abundance of weed flora is monitored above under “Reduced abundance and diversity of weeds...” therefore suggested to delete)</i></p> <p><i>(On grounds that “Tolerance development in plants” belongs to Dir 91/414, one expert proposed no CSM, and only Questionnaires/surveys under GS, in the fields and field margins for the authorisation period and longer if necessary)</i></p> <p><i>One expert suggested to delete all monitoring with the exception of questionnaires/surveys</i></p>	<p>Questionnaires⁹, surveys</p> <p>Floristic mapping</p> <ul style="list-style-type: none"> • VDI 4330 Part 9 • Herbicide sprayings • Dot-tests with herbicides • Lateral flow strip tests <p>Population & plant community monitoring</p> <ul style="list-style-type: none"> • VDI 4330 Part 9 <p>Germination tests with herbicide spraying</p> <p>Gene detection methods where above methods show positive results (PCR, Southern blotting, micro arrays, DNA-Chip-Technology).</p> <ul style="list-style-type: none"> • VDI 4330 Part 5, 7 • ELISA 	<p>Questionnaires⁹ and other survey methods</p> <p>Ecological surveys in wider areas, including:</p> <p>Floristic mapping</p> <ul style="list-style-type: none"> • Population & plant community monitoring • Herbicide sprayings • Dot-tests with herbicides • Lateral flow strip tests <p>Germination tests with herbicide spraying</p> <p>Gene detection methods (PCR, Southern blotting, micro arrays, DNA-Chip-Technology).</p> <ul style="list-style-type: none"> • VDI 4330 Part 5, 7 • ELISA 	Agricultural monitoring	In fields and field margins.	During the authorisation period and long term if necessary.

¹² Some experts regard this outside the scope of Directive 2001/18/EC and within the scope of Dir 91/414/EEC

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<p>Impact on non-target organisms</p> <p>Interaction between GMP and non-target organisms</p>	<p>Monitoring of abundance and diversity of relevant terrestrial (indicator) species representing a larger set of non-target organisms</p> <p>Monitoring the spectrum of species, relative frequencies and fitness of species. <i>(One expert suggested it was sufficient to measure abundance since fitness is more difficult to measure. Otherwise suggested that this point and the next point "Monitoring gene product in water" be deleted)</i></p> <p>Monitoring gene product in water.</p> <p><i>Relevant indicators should be defined for representative geographic regions depending on crop/trait combination</i></p>	<p><i>(Divergence of opinion s to whether CSM should be included or excluded in its entirety. One expert indicated it was sufficient to monitor weeds)</i></p> <p>Scientifically based methodology appropriate for the case-specific monitoring of indicator organisms specifically weeds as indicators for wider biodiversity being the most important group and endpoint</p> <p>See Appendix 1 and Scholte and Dicke 2005¹³</p> <ul style="list-style-type: none"> • Representative examples of hypogaeic phytophages • Representative examples of hypogaeic predators • Representative examples of epigaeic predators • Representative examples of parasitoids • Frequencies and reproduction rate of small birds • Frequencies of small mammals • Diversity, abundance and dominance structure of earth worms (Lumbricidae) • Family spectrum, abundance and dominance structure of nematodes • - Spectrum of species, abundance and dominance structure of springtails (Collembola) 	<p>Identification of relevant monitoring networks and systems or objectives and parameters which are suitable for non-target organisms in the environment: Surveillance of abundance and/or diversity of weeds as relevant (indicator) species and if available also other non-target organisms e.g.:</p> <ul style="list-style-type: none"> • Hypogaeic phytophages • Epigaeic phytophages <i>(inclusion proposed)</i> • Hypogaeic predators • Epigaeic predators <i>(inclusion proposed)</i> • Parasitoids • Birds • Mammals • Earthworms (Lumbricidae) • Nematodes • Springtails (Collembola) • Myriapoda • Bacterial virus and fungi diseases <p><i>(Proposal to delete birds and mammals since they move over large areas. Proposal to include Myriapoda and Bacterial virus and fungal diseases)</i></p> <p>See above:</p> <ul style="list-style-type: none"> • 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.) <p><i>(Proposal to delete these 3 bullet points and to introduce the following point)</i></p> <p>Methods appropriate to monitor impacts on specific non-target water orgs in different environments</p>	<p>Existing Surveillance networks</p> <p>Biodiversity monitoring</p> <p>Soil monitoring</p> <p>Agricultural monitoring (Plant health, Variety registration)</p> <p>Human & Animal Health monitoring</p> <p>Water Framework Monitoring</p> <p>Systems like:</p> <ul style="list-style-type: none"> • French Biovigilance Surveillance • Ecological Area Survey <i>(It was suggested to include all of the above in favour of the following)</i> <p>Routine Surveillance Programmes including e.g. appropriate indicators & parameters like</p> <ul style="list-style-type: none"> ○ Feral GM Plants ○ Volunteer GM Plants ○ Crossable wild relatives of oilseed rape ○ Birds ○ Butterflies ○ Beetles ○ Bees 	<p>In representative fields and field margins where the GMP is grown. If studies above show unexpected distribution of feral OSR or hybrids monitor also natural habitats</p> <p>Representative geographical areas.</p>	<p>During the authorisation period and long term if necessary.</p>
<p>¹³ Scholte and Dicke (2005): Effects of insect resistant transgenic crops on non-target arthropods: first step in pre-market risk assessment studies (http://www.cogem.net/onderzoeksrapporten-detail.aspx?pageid=14&loc=2&version=&mode=&munid=18&id=80)</p>						

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Changes of frequency of / susceptibility to non-target pests & diseases <i>(Proposal to amend "Changes of susceptibility to NT pests..." to "frequency of NT pests...")</i>	Monitoring the abundance and damage caused by pests Monitoring the frequency and damage caused by diseases <i>Pests and diseases should be listed by geographical areas and case-specific for the crop in question (Appendix-1)</i>	Pest and diseases survey linked to crops practices Pest/disease surveys (e.g. collection by knocking them off plants, count of damage by infestation) <i>(Proposal to delete CSM)</i>	Questionnaire and other survey methods <ul style="list-style-type: none"> • Volume, time and frequency of pesticide application • Pest and diseases survey linked to crops practices • Pest/disease surveys (e.g. collection by knocking them off plants, count of damage by infestation) <i>(Proposal to include GS as above, Questionnaire and survey of pesticide use only should be sufficient, If pesticide use increases then other studies will become of interest)</i>	Pest surveys linked to crop practices <i>(proposed for inclusion)</i>	In the fields where the GMP is grown.	During the authorisation period and long term if necessary. Annually during cultivation.

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			CSM ⁵ (if identified by an ERA)	General Surveillance ⁶			
	<p>Other Impacts on habitat diversity and biodiversity</p> <p><i>(One expert suggested to delete this on the grounds that it is speculative; in the unlikely event that there would be such an effect, it would be difficult to establish that there would be a cause effect relationship)</i></p>	<p>Monitoring changes in diversity, relative frequencies and fitness at different levels of the food chain, other than the specific items above</p> <p>Monitoring of relevant indicators in order to detect adverse effects on protection targets</p>	<p>Defining indicators for CSM of habitat diversity and wider biodiversity (e.g. weeds as most important group and endpoint); if applicable, amendment of existing programs by relevant indicators</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>(It was proposed that all CSM be deleted with the exception of the following " Defining indicators for CSM of habitat diversity and wider biodiversity (e.g. weeds as most important group and endpoint)")</i></p>	<p>Identification and observation of relevant surveillance programs that provide information relevant to indicators in order to address adverse effects on the environment and on protection targets.</p> <p>Compilation and evaluation of available knowledge on unusual effects from existing surveillance and monitoring programmes (e.g. bird monitoring programmes, biodiversity monitoring, butterfly monitoring <i>(Proposed to delete these examples)</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>Large scale observations of landscape habitats and biodiversity structure</p> <p>Biodiversity indicators</p> <p><i>(It was proposed to include the following GS altho' with regard to the first point one expert suggested to delete "...at different level of the food chain")</i></p> <p>Relative frequencies of relevant biodiversity indicator species at different levels in the food chain</p> <p>Indicator organism surveys in selected areas, including:</p> <ul style="list-style-type: none"> • Floristic mapping <ul style="list-style-type: none"> ◦ VDI 4330 Part 9 • Population & plant community monitoring • Counting the number of individuals 	<p><i>(Proposed to delete the following)</i></p> <p>Link with INSPIRE Directive:</p> <ul style="list-style-type: none"> • Habitats and biotopes • Species distribution • etc. 	<p><i>(Proposed to delete the following)</i></p> <p>In representative fields and field margins where the GMP is grown, as well as natural habitats.</p> <p>Representative and/or relevant bio geographical regions.</p>	<p><i>(Proposed to delete the following)</i></p> <p>No time limit.</p>

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Trait or process (WHAT RISK)	Specific monitoring issue identified from an ERA ¹ (WHAT CHARACTER)	Monitoring methods (HOW) ²		Environmental Surveillance system that might be used taking into account the exposure to crop/trait combinations (WHAT SYSTEM ³)	Environment e.g. field, natural habitats applicable to CSM/GS ⁴ (WHERE)	Time for monitoring duration of period, timing applicable to CSM/GS (WHEN)	
	CSM ⁵ (if identified by an ERA)	General Surveillance ⁶					
		<p>Monitoring relevant soil functions/parameters, to detect the potential transgene accumulation and changes in the soil communities</p> <p><i>(It was suggested to delete monitoring for transgene accumulation as EPSPS accumulation is not relevant. In this case this character would read "Monitoring relevant soil functions/parameters to detect changes in the soil")</i></p>	<p><i>(Divergence of opinion as to whether CSM should be included or excluded in its entirety)</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>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 quality (<i>Parisi et al., 2003; Gardi et al., 2003</i>), 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>(Divergence of opinion as to the extent of GS monitoring carried out. It was proposed to delete all with the exception of Farmer Questionnaire, Germination and growth tests, Soil monitoring systems (first bullet point), large scale observations and biodiversity indicators)</i></p> <p>Identification and observation of relevant surveillance programs that provide information relevant to indicators in order to address protection targets</p> <p>Farmer Questionnaires⁹ and other survey methods</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><u>Germination and growth tests, soil parameter as pH, nutrient content, consistency etc.</u> <u>Soil monitoring systems</u> using e.g.</p> <ul style="list-style-type: none"> • Cloning the soil metagenome using e.g. Bacterial Artificial Chromosomes (<i>Rondon et al, 2000</i>) to assess the genetic and functional diversity • 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>Compilation and evaluation of available knowledge 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 programs the cost-effective amendment of relevant indicators or the <u>amendment of existing programs by relevant indicators</u></p>	<p>Existing Surveillance Networks <i>(proposal to include)</i></p> <p>Soil monitoring</p> <p>Agricultural monitoring (Plant health, Variety registration)</p> <p>Water Framework Monitoring</p> <p>INSPIRE Directive</p>	<p>In representative fields where the GMP is grown.</p>	<p>During the authorisation period, and long term if necessary.</p> <p>Before (baseline), During the growing season and potentially after harvest with appropriate reference/control <i>(proposal to delete)</i></p>

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Trait or process (WHAT RISK)	Specific monitoring issue identified from an ERA ¹ (WHAT CHARACTER)	Monitoring methods (HOW) ²		Environmental Surveillance system that might be used taking into account the exposure to crop/trait combinations (WHAT SYSTEM ³)	Environment e.g. field, natural habitats applicable to CSM/GS ⁴ (WHERE)	Time for monitoring duration of period, timing applicable to CSM/GS (WHEN)
		CSM ⁵ (if identified by an ERA)	General Surveillance ⁶			
				amendment of existing programmes by relevant indicators <u>Large scale observations</u> <u>Biodiversity indicators</u>		
Changes in cultivation practices	<p>Monitor changes in farming practice¹⁴ (e.g. amount, frequency and type of herbicides/pesticides, application of fertilizers, tillage, crop rotation, use of energy)</p> <p>Monitoring development of herbicide tolerance in weeds (<i>proposal to include</i>)</p>	<p><i>(It was proposed to delete all CSM)</i></p> <p>Practices inquiries</p> <p>Volume, time and area of herbicide application</p> <p>Pesticide use indicators - Link with Directive 91/414 and Thematic Strategy for Pesticides</p> <p>Farmer Questionnaires⁹</p>	<p><i>(It was proposed to include GS as follows)</i></p> <p>Practices inquiries</p> <p>Pesticide use indicators - Link with Directive 91/414 and Thematic Strategy for Pesticides</p> <p>Farmer Questionnaires⁹</p> <p>Weed mapping</p> <ul style="list-style-type: none"> • Herbicide sprayings • Dot-tests with herbicides 	<p>Existing Surveillance Networks (<i>proposal to include</i>)</p> <p>Biodiversity monitoring</p> <p>Soil monitoring</p> <p>Agricultural monitoring (Plant health, Variety registration)</p> <p>Water Framework Monitoring</p> <p>Systems like:</p> <ul style="list-style-type: none"> • French Biovigilance • Surveillance • German Bee Monitoring • INSPIRE Directive 	<p>In representative fields where the GMP is grown .</p> <p>On all the fields of farms.</p> <p>Nearby water reservoirs and their sediments and drainage basins</p>	<p>During the authorisation period, and long term if necessary.</p> <p>Before (baseline), during the growing season and after harvest. (<i>proposal to delete</i>)</p>

¹⁴ 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?