

## Generic Checklist ENV/08/06

Trait or process		Specific monitor- ing issue identified from an ERA <sup>1</sup>	Monitoring methods (HOW) <sup>2</sup>		Environmental Sur- veillance system that might be used taking into account the expo- sure to crop/trait combinations (WHAT SYSTEM)	Environment e.g. field, natural habi- tats applicable to CSM/GS <sup>3</sup>  (WHERE)	Time for monitoring duration of period, timing applicable to CSM/GS  (WHEN)
(WHAT RISK)		(WHAT CHAR- ACTER)	CSM <sup>4</sup> (if identified by an ERA)	General Surveillance			
<b>Persistence and Invasiveness &amp; selective advantage or disadvantage</b>	volunteers (in fields)	Monitoring of volunteers	Floristic mapping Gene detection method 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 detec- tion of genetically modified nucleic acids in the environment)	Questionnaires and other survey methods  Ecological surveys in wider areas, includ- ing: <ul style="list-style-type: none"><li>Floristic mapping</li><li>Population &amp; plant community monitoring</li><li>VDI 4330 Part 9</li></ul>	Biodiversity monitoring Soil monitoring Agricultural monitoring (Plant health, Variety registration) Human & animal Health monitoring Water Framework Monitoring	In representative environments where the GMP might survive as volunteer, e.g.. agricultural fields and field margins	During the authorisation period, and long term if necessary.  During the growing sea- son and after harvest
	establish- ment of the GMP <sup>6</sup> out- side of fields	Monitoring of established GMP outside fields	Existing surveillance networks, Ecological surveys in wider areas, including: - Floristic mapping - Population & plant community monitoring - Gene detection method VDI 4330 Part 5 + 7 VDI 4330 Part 9 (Assessment of the diversity of ferns and flowering plants - Vegetation surveys, in prep.)	Gene detection method VDI 4330 Part 5 + 7  Pollen monitoring <sup>5</sup> : Technical pollen sampler VDI 4334 Part 3 Biological pollen sampler VDI 4334 Part 4  ELISA VDI 4330 Part 11 (Detection of Cry- proteins in soil and plant residues, in prep.)	Systems like: French Biovigilance Surveillance Routine surveillance pro- grammes suitable for combi- nation of GMP Surveillance, e.g. appropriate indicators & parameters like: <ul style="list-style-type: none"><li>Birds</li><li>Butterflies</li><li>Beetles</li><li>Bees</li><li>Wild relatives of GMP</li><li>Feral GMP plants</li></ul>	Field margins and natural habi- tats in representative GMO- growing regions, Areas of processing facilities Loading and storage areas  Roadsides, Railroad tracks  Large scale surveys in areas outside of GMO-growing re- gions  Large scale surveys in areas outside of GMO-growing re- gions	During the authorisation period, and long term if necessary.  During transport and processing  During the growing sea- son and after harvest

<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> Some experts believe that pollen monitoring should be excluded, one reason being that pollen samplers do not work correctly.<sup>6</sup> GMP = genetically modified plant

Trait or process		Specific monitoring issue identified from an ERA <sup>1</sup>	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)
(WHAT RISK)			CSM <sup>4</sup> (if identified by an ERA)	General Surveillance			
	Spread, persistence and accumulation of GMP in the environment	Screening of GMP/transgenes <sup>7</sup> in appropriate environmental media and organisms (e.g. plants, soil, compost)	Gene detection methods (PCR, Southern blotting, micro arrays). VDI 4330 Part 7  Dot-tests with herbicides  DNA-Chip-Technology  ELISA VDI 4330 Part 11 (Detection of Cry-proteins in soil and plant residues, in prep.)			In representative fields, field margins and natural habitats where the GMP is grown Road sites, areas of processing facilities  Representative biogeographical regions  In soil, plants, compost, silage, dung	During the authorisation period, and long term if necessary.
		Long term and large scale screening of persistence and dispersal of ferals and / or cultivars and / or wild relatives	Floristic mapping Population & plant community monitoring Gene detection methods VDI 4330 Part 5,7,9			In representative GMO-growing regions as well as large scale surveys in areas outside of GMO growing regions	During the growing season and after harvest.
	Presence of GMP products in the environment	Quantification of GM product e.g. in field soils, and water and sediment of nearby water bodies	ELISA (protein detection depending on GMP product) VDI 4330 Part 11 Southern blots if applicable			Soil, water and sediment of nearby water bodies	Long term observations

<sup>7</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.

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)
Potential for Gene transfer	vertical to crop plants (volunteers, feral), leading to plants with one or several GM traits	Monitoring of gene flow: 1. from field to volunteers 2. from field to feral plants, in those areas where the GMP might survive during winter	Floristic mapping for clearly detectable (morphological) hybrids or modification of distribution in volunteers or feral distribution  Habitat monitoring / Land use to identify potential recipient organisms: volunteers and feral plants, in wider areas  Gene detection methods (PCR, Southern blotting, micro arrays). Pollen flow VDI 4330 Part 3,4,5,7,9	Questionnaires and other survey methods  Ecological surveys in wider areas, including: - Floristic mapping - Population & plant community monitoring Gene detection method VDI 4330 Part 3,7,9  Pollen monitoring: Technical pollen sampler VDI 4334 Part 3 Biological pollen sampler VDI 4334 Part 4	Biodiversity monitoring Soil monitoring Agricultural monitoring (Plant health, Variety registration)	In representative fields and field margins where the GMP is grown, as well road sites (transportation), and areas of processing facilities.  Large scale surveys in areas with GMP-cultivation	
	vertical to wild plants	Monitoring gene transfer from field to wild relatives:  a) establishment and frequency of weedy hybrid plants,  b) Herbicide tolerance of hybrids under selection pressure (herbicide use),  c) frequency of sexually compatible species	Counting the number of individuals  Herbicide sprayings Dot-tests with herbicides  Gene detection methods (PCR, Southern blotting, micro-arrays) to identify hybrid ferals and volunteers  Scale of floristic frequencies <ul style="list-style-type: none"> <li>analysing seed quantity and quality (laboratory tests) analysing seed quantity and quality (laboratory tests)</li> </ul> Floristic mapping Population and plant community monitoring Pollen monitoring VDI 4330 Part 3,4,5,7,9			See also Monitoring of established GMP outside fields Large scale surveys in areas outside of GMP-growing regions	See also Monitoring of established GMP outside fields  Long term observations
	horizontal to micro-organisms in soil, and living on or next to the GMP	Monitoring of gene transfer to microorganisms, e.g. if the gene is not present in microbial communities and the trait confers a selective advantage.	In case appropriate methods would be available e.g. gene detection methods for microbial soil communities.	In case appropriate methods would be available e.g. gene detection methods for soil microbial communities.		In representative fields where the GMP is grown	During the authorisation period and long term if necessary.  During the growing season and after harvest
Interaction between GMP and target organisms	reduced abundance and diversity of weeds or development of new weed species	Monitoring abundance and diversity of weeds	Floristic mapping Population and plant community monitoring VDI 4330 Part 9 Inventory of seed bank  Agronomic (Questionnaires, other methods) surveys	Questionnaires and other survey methods  Ecological surveys in wider areas, including: - Floristic mapping - Population & plant community monitoring	Agricultural monitoring (Plant health, Variety registration)		

Trait or process		Specific monitor- ing issue identified from an ERA <sup>1</sup>	Monitoring methods (HOW) <sup>2</sup>		Environmental Sur- veillance system that might be used taking into account the expo- sure to crop/trait combinations (WHAT SYSTEM)	Environment e.g. field, natural habi- tats applicable to CSM/GS <sup>3</sup>  (WHERE)	Time for monitoring duration of period, timing applicable to CSM/GS  (WHEN)
(WHAT RISK)		(WHAT CHAR- ACTER)	CSM <sup>4</sup> (if identified by an ERA)	General Surveillance			
	resistance development in animals	Monitoring baseline sus- ceptibility & resistance development of target organisms  A specific monitoring programme for each gene product, considering also combined genes.  Target Organisms (de- pending on gene product and geographic area)	Changes over time in susceptibility (LC50) by regular monitoring - Probit analysis (LC50, LC90, etc.) - Discriminating dose assay Frequency of resistant alleles: - F0, F1 or F2 screens - Biochemical and/or molecular tests Efficacy of resistant plants Population genetics (baseline) Frequency of resistance alleles/resistant animals (F2-screen, Sampling & LC50)			Define geographic areas Sampling sites in representative areas (depending on event): Measures on regional (popula- tion) level depending on the population genetics and ecology	
	Resistance development in plants	Monitoring development of resistance in plants	Questionnaires, surveys Floristic mapping Population & plant community monitoring VDI 4330 Part 9				
	secondary pests	Monitoring abundance and damaged caused by secondary-pests  Representative examples of pests, <i>Pests should be listed by geographical areas</i>	Pest survey (e.g. collection by knocking them off plants, count of damage by infestation)			During the period of authorisa- tion, and depending on the re- sults longer term.  During the growing season and after harvest.	
Interaction between GMP and non-target organisms		Monitoring of abundance and diversity of relevant (indicator) species repre- senting a larger set of non-target organisms  Relevant indicators should be defined for representative geographic regions depending on crop/trait combination	Scientifically based methodology appropriate for the case-specific monitoring of indicator organ- isms See Appendix 1: - Representative examples of hypogaeic phyto- phages - Representative examples of hypogaeic preda- tors - 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)	Identification of relevant monitoring objec- tives and parameters which are suitable on non-target organisms in the environment: Surveillance of abundance and/or diversity of relevant (indicator) species representing a larger set of non-target organisms eg: Hypogaeic phytophages Hypogaeic predators Parasitoids Birds Mammals Earth worms (Lumbricidae) Nematodes Springtails (Collembola)	Biodiversity monitoring Soil monitoring Agricultural monitoring (Plant health, Variety registration) Human & animal Health monitoring Water Framework Monitoring  Systems like : French Biovigilance Surveillance Ecological Area Survey	In representative fields and field margins where the GMP is grown, as well as natural habi- tats	



Trait or process		Specific monitoring issue identified from an ERA <sup>1</sup>	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)
(WHAT RISK)		(WHAT CHARACTER)	CSM <sup>4</sup> (if identified by an ERA)	General Surveillance			
			- Family spectrum, abundance and dominance structure of nematodes - Spectrum of species, abundance and dominance structure of springtails (Collembola)	See above: 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)			
		Monitor abundance and damage caused by secondary non-target diseases.  <i>Diseases should be listed by geographical areas and case-specific for the crop in question? Appendix-1</i> Representative examples of Aphidae, Coleoptera, Hymenoptera, Lepidoptera, Cicadina, Diptera etc.		VDI 4330 Part 13 (Method standards for butterflies, in prep.)		Representative geographical areas	
		Monitoring the spectrum of species, relative frequencies and fitness of species.  Monitoring gene product in water	Methods appropriate to monitor impacts on specific non-target organisms in different environments		WISE (system used by the Water Framework Directive)	In representative field margins where the GMP is grown. Groundwater and surface water in the regions where the GMP is grown	
	Changes of susceptibility to non-target pests & diseases	Monitoring the damage caused by pests.	Pest and diseases survey linked to crops practices Pest survey (e.g. collection by knocking them off plants, count of damage by infestation)			In the fields where the GMP is grown	Annually (at harvest time) during cultivation

Trait or process		Specific monitoring issue identified from an ERA <sup>1</sup>	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)
(WHAT RISK)		(WHAT CHARACTER)	CSM <sup>4</sup> (if identified by an ERA)	General Surveillance			
	Other Impacts on habitat diversity and biodiversity	Monitoring changes in diversity, relative frequencies and fitness at different levels of the food chain, other than the specific items listed before  Monitoring of relevant indicators in order to detect adverse effects on protection targets	Depending on indicators; if applicable, amendment of existing programs by relevant indicators  Large scale observations  Biodiversity indicators	Identification and observation of relevant surveillance programs that provide information relevant to indicators in order to address protection targets.  Compilation and evaluation of available knowledge on unusual effects from existing surveillance and monitoring programmes (e.g. bird monitoring programmes, biodiversity monitoring, butterfly monitoring).  Depending on the usefulness of existing surveillance programmes the cost effective amendment of relevant indicators or the amendment of existing programs by relevant indicators  Large scale observations  Biodiversity indicators.	Link with INSPIRE Directive: - Habitats and biotopes - Species distribution - etc	In representative fields and field margins where the GMP is grown, as well as natural habitats  Representative and/or relevant bio geographical regions	No time limit
Changes in biogeochemical processes		Monitoring relevant soil functions/parameters	Substrate-induced respiration Fumigation-extraction method Infrared carbon dioxide analyser with flow rate indication/determination of oxygen absorption  Total DNA extraction (DGGE)  Germination and growth tests, soil parameter as pH, nutrient content, consistency etc.	Substrate-induced respiration Fumigation-extraction method Infrared carbon dioxide analyser with flow rate indication/determination of oxygen absorption  Total DNA extraction (DGGE) VDI 4330 Part 11 Germination and growth tests, soil parameter as pH, nutrient content, consistency etc.  Identification and observation of relevant surveillance programs that provide information relevant to indicators in order to address protection targets  Compilation and evaluation of available knowledge on unusual effects from existing surveillance and monitoring programmes (e.g. bird monitoring programmes, biodiversity monitoring, butterfly monitoring)  Depending on the usefulness of existing surveillance programs the cost-effective amendment of relevant indicators or the amendment of existing programs by relevant indicators  Large scale observations Biodiversity indicators	Soil monitoring Agricultural monitoring (Plant health, Variety registration) Water Framework Monitoring  INSPIRE Directive	In representative fields where the GMP is grown	During the authorisation period, and long term if necessary.  During the growing season and after harvest

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</sup> (if identified by an ERA)	General Surveillance			
				Biodiversity indicators			
Changes in cultivation practices		Monitor changes in farming practice <sup>8</sup> (e.g. amount and type of pesticides, application of fertilizers, tillage, crop rotation, use of energy)	Practices inquiries  Pesticide use indicators - Link with Directive 91/414 and Thematic Strategy for Pesticides  Farmer Questionnaires <sup>9</sup>		Biodiversity monitoring Soil monitoring Agricultural monitoring (Plant health, Variety registration) Water Framework Monitoring  Systems like: French Biovigilance Surveillance German Bee Monitoring INSPIRE	In representative fields where the GMP is grown  On all the fields of farms	

<sup>8</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?

<sup>9</sup> 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 environmental effects on the environment within fields and in the field margins - it does not provide scientifically sound environmental data