



**CSL GM Inspectorate seed audit**  
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<b>Seed company</b>				
<b>Representative seen</b>				
<b>Audit date</b>				
<b>Crops audited</b>	Maize	<i>Brassica napus</i>	<i>Brassica rapa</i>	Soya

**A) GENERIC QUESTIONS ABOUT COMPANY PRACTICE**

A1. Does the company operate a 'no GMO' policy? If so, is this across the whole company, at the level of European operations, or just the UK operations?
A2. Is the parent company a biotech company with an active GM crops production programme? If so, is the GM crop programme active in UK operations (i.e. contained use), in European operations and/or across the company?
A3. Does the company operate in accordance with overarching total quality management system/s (e.g. GLP, UKAS, ISO etc)
A4. Does the company (or the company's contractors) operate according to any farm assurance scheme/s, such as the ACCS (Assured Combinable Crops Scheme, TASCC (Trade Assurance Scheme for Combinable Crops)?
A5. Does the company have a formal approach to management of the risks of AGMP in seeds?
A6. Does the company have a nominated person who is responsible for all GM issues? Does this include responsibility for commissioning analytical tests?
A7. Does the company have a contingency plan to be implemented in the event that AGMP is identified in germplasm or seed?
A8. Does the company have a protocol for contacting the GM Inspectorate in the event that AGMP (suspected or confirmed) is identified in seed that is intended for marketing, seed that has been marketed, or trials seed?
A9. Of the crops of interest to the GM inspectorate, are the basic principles of seed production the same for all these crops, e.g. do standard OECD isolation requirements apply to all crops, or are other arrangements in place for certain crops?



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**B) STAGE:** Variety development

Generic controls & risks	Impact (H/M/L)	Probability (H/M/L)	Expected Controls	Adequacy		Application	
				Actual Controls	Initial Evaluation	Examples of tests that might be in used	Test(s) used and result(s)
<b>Generic control</b> B1. Company operates a 'no GMO' policy	n/a	n/a	1. Statement from breeder confirming non-GM status/they don't work with GMOs, including measures taken to ensure germplasm/seeds sourced are non-GM			Up-to-date signed statement, including e.g. procurement protocol, testing protocol &/or certificates	
			2. Protocols to ensure germplasm is only obtained from non-GM suppliers; evidence that is requested			Demonstration that protocols are followed, e.g. up-to-date SOPs, evidence from suppliers that material is GM-free	
			3. <i>Analytical tests capable of detecting GMOs - RFLPs, broad-screen PCR. See also section on GM testing</i>			<i>Negative test results (tests conducted using appropriate primers, appropriate LoDs, etc.)</i>	
			4. Prevailing laws &/or culture in country of origin of seed			Evidence the company have considered this in selecting the breeder, and the breeder has complied with these laws	
B2. Germplasm contaminated at early stage (lab/glasshouse /breeder)	3H	1L	1. Protocols for separation of GM/conv during labwork and glasshouse work (e.g. spatial &/or physical (&/or temporal) separation) - incl. SOPs, TQM system (e.g. GLP, UKAS, ISO, etc), Code of Practice, OECD standards			Demonstration that protocols followed (e.g. up-to-date SOPs, inspection reports, glasshouse trial layout plans, training records, protocols signed to confirm they have been read, satisfactory audit report from official	



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						inspection bodies (e.g. HSE))	
B3. Cross pollination with GM during variety development (glasshouse/small field)	3H	1L	1. Protocols for separation of GM/conv glasshouse and field trials work (e.g. spatial &/or physical (&/or temporal) separation) - incl. SOPs, TQM system (e.g. ISO), Code of Practice, OECD standards			Demonstration that protocols followed (e.g. inspection reports, field trial layout plans, up-to-date SOPs, training records, protocols signed to confirm they have been read)	
B4. Production of breeders seed/Pre-basic/basic - multi-plot issues	3H	1L	1. <i>Policy on selecting land and reputable grower for seed production to ensure no cross pollination with GM crops or volunteers from previous GM crops</i>			<i>Up to date policy available that demonstrates issue has been considered and sets a risk-based time lag between (GM) crop and seed crop. Evidence of how history of land is obtained/maintained</i>	
			2. Protocols for adequate cleaning of drill between plots e.g. SOP for drill cleaning (or use of separate drill)			Records of drill cleaning between GM/conv plots; Training, signed to say read, TQM system - certified; evidence of amount of carry-over in drill	
			3. Protocols for adequate spacing (spatial separation) between GM /conv plots e.g. SOP for separating GM/conv plots			Plan of plot area showing distance between GM/conv; company policy document; Training, signed to say read, TQM system – certified	
			4. Protocols for adequate labelling of GM/conv plots e.g. SOP for labelling plots			SOP for labelling GM/conv plots; evidence that procedures followed	



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B5. Volunteers in breeders/pre-basic seed crops	3H	1L	1. Protocols for temporal separation of GM/conv (or land NEVER used to grow GM lines?) e.g. SOP/QA procedures in excess of OECD/statutory purity controls/Statutory crop inspection reports			Rotation data; inspection records (e.g. statutory crop inspection report); volunteer numbers. Training forms (for SOPs) signed to say competent, TQM system certified	
			2. Consideration given to isolation from current & former GM trial sites (in UK, e.g. FSE trials for OSR)			Policy on isolation from GM trials, evidence that locations of trials are known relative to company's seed crops	
			3. Protocols for spatial separation of GM/conv fields (e.g. spatial &/or physical (&/or temporal) separation) - incl. SOPs, TQM system (e.g. GLP, ISO, etc), Code of Practice, OECD standards			SOP/QA procedures in excess of OECD/statutory purity controls/Statutory crop inspection report	
			4. Procedures to prevent or minimise GM seed spillage			Inspection records (e.g. statutory crop inspection report), volunteer numbers, training forms signed to say competent, TQM system certified, GM test results	
			5. Procedures for effective GM volunteer control (before flowering)			Inspection records (e.g. statutory crop inspection report), volunteer numbers, training forms signed to say competent, TQM system certified, GM test results	



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**C) STAGE: Sowing a seed crop for certification**

Generic controls & risks	Impact (H/M/L)	Probability (H/M/L)	Expected Controls	Adequacy		Application	
				Actual Controls	Initial Evaluation	Examples of tests that might be in place	Actual tests in place
<b>C1. Generic controls</b>	n/a	n/a	1. Policy on procurement of seeds, in particular policy for ensuring freedom from AGMP in seed from countries deemed to be at risk			Up to date policy, evidence that it is being adhered to - purchase records, procurement checklist	
			2. Policy on selecting land and reputable grower for seed production to ensure no cross pollination with GM crops or volunteers from previous GM crops			Up to date policy available that demonstrates issue has been considered and sets a risk-based time lag between (GM) crop and seed crop. Evidence of how history of land is obtained/maintained	
			3. Adherence to statutory certification (monitoring) procedures regarding purity			Crop inspection reports showing number of off-types (a high number of off-types may suggest inadequate procedures followed - but not evidence of GMO)	
			4. Analytical tests capable of detecting GMOs, e.g. broad-screen PCR, lateral flow kits for common GMOs; growing-out tests to detect off-types			Negative test results (tests conducted using appropriate primers, appropriate LoDs, etc)	



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C2. Admix in drill - quality control - same SLRN, etc.	3H	1L	1. Drilling machinery dedicated to conventional seeds only			Protocol/contract for drill use; IP standards; contractual assurances between grower and seed company. Records showing seed type, SLRN, quantity of seed sown & confirming conventional status	
			2. Protocols stating that conventional-only growers used to produce seed crops (Note: not necessary if grower is located in country where there is no commercial GM production)			Demonstration that protocols followed (e.g. declaration from grower stating that they do not produce GM crops, or have separate GM/conv drills)	
			3. Protocols to ensure GM seed is not accidentally loaded into the drill intended for sowing a conventional seed crop			Demonstration that protocols followed (e.g. up-to-date SOPs, training records, protocols signed to confirm they have been read, log showing SLRN and quantity of seed sown)	
C3. Admix in drill - "carryover"	2M	1L	1. Protocols for adequate cleaning of drill (inside and out e.g. coulters) between fields/seed lots e.g. SOP for drill cleaning (or use of separate drill for GM/conv)			Records of drill cleaning between GM/conv plots; Training forms signed to show competence, evidence of amount of drill carry-over in drill	



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**D) STAGE:** Growing and flowering crop

Generic controls & risks	Impact (H/M/L)	Probability (H/M/L)	Expected Controls	Adequacy		Application	
				Actual Controls	Initial Evaluation	Examples of tests that might be in place	Actual tests in place
<b>D1. Generic controls</b>	n/a	n/a	1. Contract with grower specifying conditions for management of the risk of contamination with GMOs (not necessary if seed originates from a country where there is no commercial GMO cultivation)			Current contract including reference to isolation from other GM crops, GM volunteers, GM conspecifics, related relatives, ferals and GM trials. Evidence of how contract is managed	
			2. Field inspections to check isolation			Records from field visits	
D2. Cross-pollination with GM volunteer	3H	1L	1. Control of volunteers during seed production			Contract with grower detailing expected frequency of field visits. Records of field visits	
D3. Cross-pollination with GM conspecific during certified seed production	2M	3H 2M 1L	1. SOP detailing minimum isolation distance. Evidence that users of SOP are appropriately trained and refer to the document, through training records.			Up to date SOP signed and dated. Evidence of field visits showing distances to nearby crops	
			2. <i>Field inspections to check compliance with isolation distances</i>			<i>Records from field visits</i>	
			3. Removal of crops occurring within area less than permitted isolation distance			Records from field visits	



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			4. Pollen barriers/sacrificial rows			Protocol for sowing barrier in SOP. Evidence from field inspections – detailing species, establishment, height, flowering synchronicity (if same species), etc.	
D4. Cross-pollination with related GM crops	2M	1L	1. SOP detailing related crops and minimum isolation distances. Evidence that users of SOP are appropriately trained and refer to the document, through training records			Up to date SOP - signed and dated. Evidence that users of SOP are appropriately trained and refer to the document, through training records	
			2. <i>Field inspections to check compliance with isolation distances</i>			<i>Records from field visits</i>	
D5. Cross-pollination from GM trials	2M 1L	1L	1. Policy on isolation from current and former GM field trial sites			Up to date policy with history of GM trials for compatible crops appended or protocol for obtaining such information	
D6. Cross-pollination with ferals	1L	2M 1L	1. Risk assessment regarding establishment of ferals in country of seed origin			Up to date risk assessment	
D7. Cross-pollination with wild relatives	1L	1L	1. Risk assessment regarding occurrence of wild relatives in country of seed origin			Up to date risk assessment	



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**E) STAGE: Harvest**

Generic controls & risks	Impact (H/M/L)	Probability (H/M/L)	Expected Controls	Adequacy		Application	
				Actual Controls	Initial Evaluation	Examples of tests that might be in place	Actual tests in place
<b>E1. Generic controls</b>	n/a	n/a	1. Harvesting machinery dedicated to conventional crops only			Protocol/contract & SOP for machinery use; IP standards; contractual assurances; machinery logs; harvesting records showing seed type & confirming conventional status	
			2. Analytical tests capable of detecting GMOs, e.g. broad-screen PCR, lateral flow kits for common GMOs			Negative test results (tests conducted using appropriate primers, appropriate LODs, etc)	
<b>E2. Admix in harvester - carryover</b>	2M 1L	2M	1. Policy & protocols in place to ensure GM and conventional crops are harvested separately			Evidence of policies and protocols to ensure separation, plus evidence that these are adhered to	
			2. IP protocols &/or SOPs to ensure harvester is thoroughly cleaned between crops			Evidence that IP protocols are followed, e.g. chain of evidence, signatures to confirm SOPs have been seen & are being used	
			3. Minimum requirements for cleaning harvester - frequency, critical points to focus on, minimum time to be spent on it etc.			Provision of protocols, evidence that protocols are being adhered to	
			4. Minimum running time for harvester to empty between individual fields			Evidence that minimum running time is adhered to	



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E3. Contamination with seed from volunteers	1L	1L	1. Protocol to ensure seed bank is cleaned before seed crop is sown i.e. cultivation and herbicide application regime			Show protocol and evidence that it is followed. Especially e.g. when seed has been contracted for bulking in different countries	
			2. Inspections of growing crop			Inspection records (signed, dated etc)	



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**F) STAGE:** Transport

Generic controls & risks	Impact (H/M/L)	Probability (H/M/L)	Expected Controls	Adequacy		Application	
				Actual Controls	Initial Evaluation	Examples of tests that might be in place	Actual tests in place
F1. Generic controls	n/a	n/a	1. Transport machinery dedicated to conventional material only			Protocol/contract & SOP for vehicle use; IP standards; contractual assurances on transport between seed producer and company; transport log showing seed type, quantity of seed & confirming conventional status	
			2. SOP &/or IP protocol for cleaning transport equipment between loads to prevent admixture - minimum standards to be observed and mechanisms for checking cleanliness			Evidence that IP protocols are followed, e.g. chain of evidence, signatures to confirm SOPs have been seen & are being used incl. signed cleaning records; machinery logs & records	
F2. Admix during transport field to farm on trailers	1L	1L	1. Suitable vehicle/ container used to transport seed			Protocol/contract establishing minimum vehicle standards; farm inspections; IP standards	
F3. Admix during on-farm drying	1L	1L	1. Drying equipment dedicated to drying of conventional material only			Protocol/contract & SOP for dryer use; IP standards; contractual assurances; farm inspections; dryer records showing seed type & quantity & confirming conventional status	



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			2. SOP/protocol to ensure drying machinery is thoroughly cleaned between GM and non-GM seeds			Protocol/SOP signed to confirm read, staff training records; machinery logs	
F4. Admix in storage on farm	1L	1L	1. Dedicated area for storage of conventional seeds only			Protocol/contract & SOP for silo use; IP standards; contractual assurances; farm inspections; farm records showing seed type, quantity & confirming conventional status	
			2. SOP/protocol for ensuring GM seeds and conventional seeds do not mix			Protocol/SOP signed to confirm read, staff training records; machinery logs	
			3. Storage facility appropriate for type of seed			Facilities meet standards of IP/assurance schemes / company requirements	
F5. Admix transport farm to processing	1L	1L	1. Transport equipment dedicated to transport of conventional material only			Protocol/contract & SOP for vehicle use; IP standards; contractual assurances on transport between seed producer and company; records showing seed type & quantity & confirming conventional status	



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**G) STAGE:** Processing

Generic controls & risks	Impact (H/M/L)	Probability (H/M/L)	Expected Controls	Adequacy		Application	
				Actual Controls	Initial Evaluation	Examples of tests that might be in place	Actual tests in place
<b>G1. Generic controls</b>  <ul style="list-style-type: none"> <li>▪ Bagging, re-bagging</li> <li>▪ Admix in domestic processing plant (silos, elevators, sieves, conveyors, etc.)</li> <li>▪ Admix in further processing, e.g. coating abroad</li> </ul>	3H	2M	1. Evidence is required that seed is free of GMOs prior to accepting in processing plant			Declarations from seed owner; GM testing certificates	
		1L	2. Spatial isolation of GM and non-GM processing			SOP to ensure dedicated GMO-free plant does not accept GMO seeds for processing	
	2M	2M	3. Temporal isolation of GM and non-GM processing			Schedules for GM and non-GM processing and evidence that they are observed	
		1L	4. Standard operating procedures to ensure processing plant is thoroughly cleaned between GM and non-GM seeds			Evidence that SOP is seen and used	
	2M	2M	5. Post-processing GMO testing – analytical tests capable of detecting GMOs, e.g. broad-screen PCR, lateral flow kits for common GMOs			<i>Negative test results. Tests conducted using appropriate primers, appropriate LODs, etc</i>	
		1L					



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**H) CROP SPECIFIC ISSUES**

Risk	Impact (H/M/L)	Probability (H/M/L)	Expected Controls	Adequacy		Application	
				Actual Controls	Initial Evaluation	Examples of tests that might be in place	Actual tests in place

(Continue if necessary)



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**ANALYTICAL TESTING****1) Commissioning analytical tests**

Does the company have a policy on analytical testing for AGMP? If so, is the policy known and understood by all managers of the seed marketing programmes?	
Does the company conduct its own analytical tests?	
Does the company have a nominated laboratory at which all analytical tests are commissioned? If so, does this laboratory have a generic contract with the company for tests, or do offices negotiate their own?	
Is there one person within the UK company/local office responsible for commissioning analytical tests? If not, do individual managers commission tests?	
Does the company issue guidelines to managers for commissioning analytical tests?	
At which stages of the seed production process are tests commissioned? (If different for different crops, state this)	
Does the company receive actual results of tests from the testing laboratory, or summarised results?	
Do all persons commissioning GM tests have a copy of CSL seed audit guidance documents? Is the CSL guidance useful – how could it be made more useful?	



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**2) Essential requirements for analytical tests:** refer to GM Inspectorate guidance for details

Seed lot reference number / crop ID present on certificate? If not, can the certificate be easily linked with the sample tested?	
Sample size (e.g. minimum 3000 seeds)	
DNA or protein based test/s?	
Qualitative or quantitative test/s?	
Appropriate negative and positive controls included	
LOD	
LOQ (RT-PCR only)	
Promoter sequence/s	
Terminator sequence/s	
Marker gene/s	
Specific genetic element/s	
Tests to eliminate environmental contamination	
Assessment of how many GM lines covered?	
If junction primers used, for which specific traits?	
Standard / accreditation scheme followed?	
Results of test/s	
Operating parameters of tests (e.g. $\pm$ confidence limits)	
<b>ASSESSMENT</b>	



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**3) Overall assessment of analytical testing regime**

<b>Signed:</b> ..... (Lead auditor)	<b>Date:</b> .....
<b>Signed:</b> ..... (Second auditor)	<b>Date:</b> .....