

FORMAT FOR THE PRESENTATION OF THE RESULT OF DELIBERATE
RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED
HIGHER PLANTS IN ACCORDANCE WITH ARTICLE 10
OF DIRECTIVE 2001/18/EC

1 General information

1.1 European notification number: **B/ES/10/47**

1.2 Member State of notification: **Spain**

1.3 Date of consent and consent number: **29/04/10 Aragon, 12/05/10 Navarra (Resolución 778/2010) and 17/05/10 Andalucía (501/18003)**

2 Report status

2.1 Please indicate whether, according to Article 3 of the present Decision, the current report is:

- the final report
- a post-release monitoring report
- **final**
- intermediary

3 Characteristics of the release

3.1 Scientific name of the recipient organism: ***Zea mays***

3.2 Transformation event(s) (acronym(s) or vectors¹ used (if transformation event identity not available): **pAG3541 – 1 transformation event, VCO-Ø1981-5.**

3.3 Unique identifier, if available: **VCO-Ø1981-5**

3.4 Please provide the following information as well as the field(s) layout:

¹ In the case of small-scale field trials where several lines may be tested, the vectors used should be mentioned, which gives insight into the introduced traits and/or genetic elements. In the case of large-scale trials, the number of events notified is limited to only one or a few events.

Geographical location(s) (administrative region and, where appropriate, grid reference)	Size of the release site(s) (²) (m2)	Identity (³) and approximate number of GM higher plants per event actually released (number of seeds/plants per m2)	Duration of the release(s) (from ... (day/month/year... until... (d/m/y)
EJEA DE LOS CABALLEROS, ZARAGOZA	10 000 m2 2.300 m2 transgenic plants 4.100 m2 non GM (borders and filling)	VCO-Ø1981-5, approximately 17.500 plants.	19/05/2010 sowing 4/11/2009 harvest
MURILLO EL CUENDE, NAVARRA	10 000 m2 1.600 m2 transgenic plants 3000 m2 non GM (borders and filling)	VCO-Ø1981-5, approximately 12.500 plants.	19/05/2010 sowing 5/11/2009 harvest
MURUZABAL DE ANDION, NAVARRA	10.000 m², 1600 m² transgenic plants, 3000 m² non GM (borders and fillings)	VCO-Ø1981-5 approximately 12.500 plants.	31/05/2009 sowing 5/11/2010 harvest
LA LUISIANA, ANDALUCIA	2.500 m², 650 m² transgenic plants 400 m² non GM (borders and fillings) os''	VCO-Ø1981-5 approximately 5.000 plants.	7/06/2010 sowing 29/10/2010 harvest

(²) Specify the size of the GM area and, where appropriate, the size of the non-GM area (e.g. non-GM border)

(³) Vectors used

EJEA DE LOS CABALLEROS:

Plano de EJEA 2010																			
Selectivity	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490				
			6	7	8	9	10	11	12	13	14	15	16	17	18				
	Rep 4	LG3490	LG3490	OHC6981-S1-C	OHC6981-S2-C	OHC6981-S3-C	OHC6981-S4-C	OHC6981-S5-C	OHC6981-S1-C	OHC6981-S2-C	OHC6981-S3-C	OHC6981-S4-C	OHC6981-S5-C	NT	HC6981	HC6981	HC6981	LG3490	LG3490
	Rep 3	LG3490	LG3490	OHC6981-S1-C	OHC6981-S2-C	OHC6981-S3-C	OHC6981-S4-C	OHC6981-S5-C	OHC6981-S1-C	OHC6981-S2-C	OHC6981-S3-C	OHC6981-S4-C	OHC6981-S5-C	NT	HC6981	HC6981	HC6981	LG3490	LG3490
	Rep 2	LG3490	LG3490	OHC6981-S3-C	NT	OHC6981-S2-C	OHC6981-S1-C	OHC6981-S4-C	OHC6981-S5-C	OHC6981-S1-C	OHC6981-S2-C	OHC6981-S3-C	OHC6981-S4-C	OHC6981-S5-C	HC6981	HC6981	HC6981	LG3490	LG3490
Testing Event	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	
			12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
	Rep 5	LG3490	LG3490	OHD6981C / 5	9LG3490 / 5	ONAC6936LOT1	OHD6981GL /	OHC6981GL /	9DKC5783 / 5	OHA0 / 5	OHC6981C / 5	OHA6981C / 5	OHC0 / 5						
		11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
	Rep 4	LG3490	LG3490	OHD6981GL /	OHD6986 / 4	OHD6981C / 4	9DKC5783 / 4	9LG3475 / 4	OHC6981C / 4	ONAC6936LOT1	9LG3540 / 4	9PR36K67 / 4	9PR35F38 / 4						
Efficiency	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
	Rep 3	LG3490	LG3490	OHC6981-S1-C	UTC	OHC6981-S1-C	OHC6981-S1-C	OHC6981-S1-C	UTC	OHC6981-S1-C	UTC	OHC6981-S1-C	UTC	OHC6981-S1-C	UTC	OHC6981-S1-C	UTC	OHC6981-S1-C	
		7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
	Rep 2	LG3490	LG3490	OHC6981-S1-C	OHC6981-S2-C	UTC	OHC6981-S1-C	OHC6981-S1-C	UTC	OHC6981-S1-C	UTC	OHC6981-S1-C	UTC	OHC6981-S1-C	UTC	OHC6981-S1-C	UTC	OHC6981-S1-C	
Rep 1	LG3490	LG3490	OHC6981-S2-C	OHC6981-S1-C	OHC6981-S2-C	OHC6981-S2-C	OHC6981-S1-C	UTC	UTC	OHC6981-S2-C	OHC6981-S2-C	OHC6981-S1-C	UTC	UTC	OHC6981-S2-C	OHC6981-S1-C	UTC		
	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	

“Selectivity” and “Testing of events” are yield trials.
 “Efficiency” is a trial about efficiency of the glyphosate.

The “Selectivity” trial is done in one transformation event VCO-Ø1981-5 (4 replications in two moments of the maize crop development).

The “Testing of events” is a trial of observation and yield measurement with the transformation event VCO-Ø1981-5 in 3 experimental varieties treated with conventional maize herbicides or with Gliphosate (5 replications).

“Efficiency” was made to check the efficacy of Gliphosate in the weeds (3 replications, different crop development stages, comparison with plots with no herbicide treatment NT or with conventional herbicide).

Plots with no color are border rows of a conventional maize variety of the same cycle as the transgenic plants.

MURILLO EL CUENDE:

Efficiency	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490
	8	9	24	25	40	41	56								
	HC6981	HC6981	HC6981	HC6981	HC6981	HC6981	HC6981								
Rep 3	0HC6981-S1-GY1	UTC	0HC6981-S1-GY1.5	0HC6981-S1-GY2	UTC	0HC6981-S1-GY3	0HC6981-S1-CT1								
	7	10	23	26	39	42	55								
	6	11	22	27	38	43	54								
Rep 2	0HC6981-S2-GY1	0HC6981-S2-GY1.5	0HC6981-S2-GY2	UTC	0HC6981-S2-GY3	0HC6981-S2-GY1.5	0HC6981-S2-CT1								
	5	12	21	28	37	44	53								
	4	13	20	29	36	45	52								
Rep 1	0HC6981-S1-GY1	0HC6981-S2-GY1.5	0HC6981-S1-CT1	0HC6981-S2-GY3	UTC	0HC6981-S2-GY1.5	0HC6981-S2-CT1								
	3	14	19	30	35	46	51								
	2	15	18	31	34	47	50								
Testing Event															
	12	13	36	37	60	61	84	85	108	109					
Rep 5	0HA6981C / 5	9DKC5783 / 5	9LG3475 / 5	9PR35F38 / 5	0HA6981GL / 5	0HD6981C / 5	0ND6986 / 5	9PR36K67 / 5	9AALLEXXIA / 5	0HC6981C / 5					
	11	14	39	38	59	62	89	86	107	110					
	10	15	34	39	58	63	82	87	106	111					
Rep 4	9LG3475 / 4	9PR35F38 / 4	0HA6981C / 4	0HD6981C / 4	0NA6936LOT1 / 4	0HA0 / 4	0HA6981GL / 4	9AGRISTER / 4	9PR36K67 / 4	0HD6981GL / 4					
	9	16	33	40	57	64	81	88	105	112					
	8	17	32	41	56	65	80	89	104	113					
Rep 3	0HC6981C / 3	0HA6981C / 3	0HD6981C / 3	0HD6981GL / 3	9PR36K67 / 3	9LG3490 / 3	9ALG3540 / 3	9AALLEXXIA / 3	0NA6936LOT1 / 3	0HD6981C / 3					
	7	18	31	42	55	66	79	90	103	114					
	6	19	30	43	54	67	78	91	102	115					
Rep 2	9LG3490 / 2	0HA6981C / 2	0HD6981C / 2	0HC0 / 2	0ND6986 / 2	0HC6981GL / 2	9LG3540 / 2	9AGRISTER / 2	0NA6936LOT1 / 2	0HD6981GL / 2					
	5	20	29	44	53	68	77	92	101	116					
	4	21	28	45	52	69	76	93	100	117					
Rep 1	9DKC5783 / 2	0HC6981C / 2	9AALLEXXIA / 2	9PR35F38 / 2	0HA0 / 2	0HD6981C / 2	9PR36K67 / 2	0HA6981GL / 2	9LG3475 / 2	0HD6981GL / 2					
	3	22	27	46	51	70	75	94	99	118					
	2	23	26	47	50	71	74	95	98	119					
	1	24	25	48	49	72	73	96	97	120					

“Testing of events” is a yield trial.

“Efficiency” is a trial about efficiency of the glyphosate.

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Plots with no color are border rows of a conventional maize variety of the same cycle as the transgenic plants.

MURUZÁBAL DE ANDIÓN

Plan 2010 CHAIR Andion														
Efficiency	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490
	8	9	24	25	40	41	56							
	HC6981	HC6981	HC6981	HC6981	HC6981	HC6981	HC6981							
Rep 3	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490
	7	10	21	26	39	42	55							
	8	11	22	27	40	43	56							
Rep 2	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490
	6	12	23	28	41	44	57							
	7	13	24	29	42	45	58							
Rep 1	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490
	3	14	25	30	43	46	59							
	4	15	26	31	44	47	60							
	5	16	27	32	45	48	61							
	6	17	28	33	46	49	62							
	7	18	29	34	47	50	63							
	8	19	30	35	48	51	64							
	9	20	31	36	49	52	65							
	10	21	32	37	50	53	66							
	11	22	33	38	51	54	67							
	12	23	34	39	52	55	68							
	13	24	35	40	53	56	69							
	14	25	36	41	54	57	70							
	15	26	37	42	55	58	71							
	16	27	38	43	56	59	72							
	17	28	39	44	57	60	73							
	18	29	40	45	58	61	74							
	19	30	41	46	59	62	75							
	20	31	42	47	60	63	76							
	21	32	43	48	61	64	77							
	22	33	44	49	62	65	78							
	23	34	45	50	63	66	79							
	24	35	46	51	64	67	80							
	25	36	47	52	65	68	81							
	26	37	48	53	66	69	82							
	27	38	49	54	67	70	83							
	28	39	50	55	68	71	84							
	29	40	51	56	69	72	85							
	30	41	52	57	70	73	86							
	31	42	53	58	71	74	87							
	32	43	54	59	72	75	88							
	33	44	55	60	73	76	89							
	34	45	56	61	74	77	90							
	35	46	57	62	75	78	91							
	36	47	58	63	76	79	92							
	37	48	59	64	77	80	93							
	38	49	60	65	78	81	94							
	39	50	61	66	79	82	95							
	40	51	62	67	80	83	96							
	41	52	63	68	81	84	97							
	42	53	64	69	82	85	98							
	43	54	65	70	83	86	99							
	44	55	66	71	84	87	100							
	45	56	67	72	85	88	101							
	46	57	68	73	86	89	102							
	47	58	69	74	87	90	103							
	48	59	70	75	88	91	104							
	49	60	71	76	89	92	105							
	50	61	72	77	90	93	106							
	51	62	73	78	91	94	107							
	52	63	74	79	92	95	108							
	53	64	75	80	93	96	109							
	54	65	76	81	94	97	110							
	55	66	77	82	95	98	111							
	56	67	78	83	96	99	112							
	57	68	79	84	97	100	113							
	58	69	80	85	98	101	114							
	59	70	81	86	99	102	115							
	60	71	82	87	100	103	116							
	61	72	83	88	101	104	117							
	62	73	84	89	102	105	118							
	63	74	85	90	103	106	119							
	64	75	86	91	104	107	120							
	65	76	87	92	105	108	121							
	66	77	88	93	106	109	122							
	67	78	89	94	107	110	123							
	68	79	90	95	108	111	124							
	69	80	91	96	109	112	125							
	70	81	92	97	110	113	126							
	71	82	93	98	111	114	127							
	72	83	94	99	112	115	128							
	73	84	95	100	113	116	129							
	74	85	96	101	114	117	130							
	75	86	97	102	115	118	131							
	76	87	98	103	116	119	132							
	77	88	99	104	117	120	133							
	78	89	100	105	118	121	134							
	79	90	101	106	119	122	135							
	80	91	102	107	120	123	136							
	81	92	103	108	121	124	137							
	82	93	104	109	122	125	138							
	83	94	105	110	123	126	139							
	84	95	106	111	124	127	140							
	85	96	107	112	125	128	141							
	86	97	108	113	126	129	142							
	87	98	109	114	127	130	143							
	88	99	110	115	128	131	144							
	89	100	111	116	129	132	145							
	90	101	112	117	130	133	146							
	91	102	113	118	131	134	147							
	92	103	114	119	132	135	148							
	93	104	115	120	133	136	149							
	94	105	116	121	134	137	150							
	95	106	117	122	135	138	151							
	96	107	118	123	136	139	152							
	97	108	119	124	137	140	153							
	98	109	120	125	138	141	154							
	99	110	121	126	139	142	155							
	100	111	122	127	140	143	156							
	101	112	123	128	141	144	157							
	102	113	124	129	142	145	158							
	103	114	125	130	143	146	159							
	104	115	126	131	144	147	160							
	105	116	127	132	145	148	161							
	106	117	128	133	146	149	162							

LA LUISIANA

“Testing of events” is a yield trial.

Testing Event		Andalucia							
		LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490
		10	11	30	31	50	51	70	
Rep 4	LG3490	9AGRISTER / 4	0HC6981GL / 4	9DKC5783 / 4	0HDD / 4	9LG3490 / 4	0HA6981GL / 4	9PR35F38 / 4	LG3490
		9	12	29	32	49	52	69	
	LG3490	0HCO / 4	0HC6981C / 4	0HD6981GL / 4	0HA0 / 4	0HA6981C / 4	0HD6981C / 4	9PR36K67 / 4	LG3490
		8	13	28	33	48	53	68	
Rep 3	LG3490	9PR35F38 / 3	0HA0 / 3	9DKC5783 / 3	0HC6981GL / 3	9LG3490 / 3	9AGRISTER / 3	0HC6981C / 3	LG3490
		7	14	27	34	47	54	67	
	LG3490	0HD6981C / 3	0HA6981C / 3	9PR36K67 / 3	0HCO / 3	0HA6981GL / 3	0HD6981GL / 3	0HDD / 3	LG3490
		6	15	26	35	46	55	66	
Rep 2	LG3490	0HCO / 2	9DKC5783 / 2	0HC6981GL / 2	9LG3490 / 2	0HC6981C / 2	9PR35F38 / 2	0HD6981GL / 2	LG3490
		5	16	25	36	45	56	65	
	LG3490	0HA6981GL / 2	9PR36K67 / 2	0HA0 / 2	0HD6981C / 2	0HDD / 2	0HA6981C / 2	9AGRISTER / 2	LG3490
		4	17	24	37	44	57	64	
Rep 1	LG3490	0HA0 / 1	0HA6981GL / 1	0HCO / 1	9AGRISTER / 1	9PR36K67 / 1	0HC6981GL / 1	9LG3490 / 1	LG3490
		3	18	23	38	43	58	63	
	LG3490	0HDD / 1	0HD6981C / 1	0HA6981C / 1	0HC6981C / 1	9DKC5783 / 1	9PR35F38 / 1	0HD6981GL / 1	LG3490
		2	19	22	39	42	59	62	
	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490	LG3490
		1	20	21	40	41	60	61	

The “Testing of events” is a trial of observation and yield measurement with the transformation event VCO-Ø1981-5 in 3 experimental varieties treated with conventional maize herbicides or with Gliphosate (5 replications).

“Efficiency” was made to check the efficacy of Gliphosate in the weeds (3 replications, different crop development stages, comparison with plots with no herbicide treatment NT or with conventional herbicide).

Plots with no color are border rows of a conventional maize variety of the same cycle as the transgenic plants.

4 Any kind of product that the notifier intends to notify at later stage

4.1 Does the notifier intend to notify the released transformation event(s) as product(s) for placing on the market under Community legislation(s) at a later stage?

4.2 Yes **Unknown to date**

If yes, indicate the country (ies) of notification:.....

If yes, specify for which use(s):

- Import.
- Cultivation (e.g.; seed/planting material production).
- Food.
- Feed.
- Pharmaceutical use (or processing for pharmaceutical use).
- Processing for pour.
 - Food use
 - Feed use
 - Industrial use.
- Others (specify):

5 Type(s) of deliberate release(s)

Please select the main type(s) (in boxes) as well as subtype(s) of the release(s). In the case of multi-sites, multi-events and/or multi-annual release(s), please provide a general overview of the type(s) of deliberate release(s) which has/have been carried out for the full duration of the consent. Please tick the appropriate type(s):

5.1 Deliberate release(s) for research purposes

5.2 Deliberate release(s) for development purposes

- Event screening.
- Proof of concept ².

² For example, testing the new trait under environmental conditions.

- Agronomic performances (e.g. efficiency/selectivity of plant protection product, yield capacity, ~~germination capacity~~, crop establishment, plant vigour, plant height, ~~susceptibility to climatic factors/diseases, etc.~~) (specify). X
- Altered agronomic properties (e.g. disease/pest/drought/frost-resistance, etc.) (specify).
- Altered qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc.) (specify).
- Stability of the expression.
- Multiplication of lines.
- Hybrid vigour study.
- Molecular farming³.
- Phyto-remediation.
- Others : (specify)

5.3 Official testing

- Variety registration on a national variety catalogue
 - DUS (=Distinctness, Uniformity and Stability)
 - VCU (=Value of Cultivation and Use)
- Others: (specify):

5.4 Herbicide authorization

5.5 Deliberate release(s) for demonstration purposes

5.6 Seeds multiplication

5.7 Deliberate release(s) for biosafety/risk assessment research

³ « Molecular farming » means the production of substances (for instance, proteins, pharmaceuticals) by plants, which have been genetically modified for a particular trait. “Molecular farming” could be defined as well as the production of plant-synthesised pharmaceuticals, plant-made pharmaceuticals, plant-based proteins production, etc.

- Vertical gene transfer studies.
 - Out-crossing with conventional crops
 - Out-crossing with wild relatives
- Horizontal gene transfer studies (gene transfer to micro-organisms).
- Management of volunteers.
- Potential changes in persistence or dispersal.
- Potential invasiveness.
- Potential effects on target organisms.
- Potential effects on non-target organisms.
- Observation of resistant relatives.
- Observation of resistant insects.
- Others: (describe)
-

5.8 Other(s) type(s) of deliberate release(s):
 (describe) :

6 Method(s), result(s) of the release, management and monitoring Measure(s) in respect of any risk to human health or the environment.

6.1 Risk management measure(s)

Please report the risk-management measures, which have been used to avoid or minimise the spread of the GMO(s) outside the site(s) of release, and in particular those measures:

- Which were not originally notified in the application,
- Which were applied in addition to the conditions in the consent,
- Which the consent required only under certain conditions (e.g. dry periods, flooding),
- For which the consent allowed the notifier a choice among different measures.

Tick the examples where appropriate:

6.1.1 Before the sowing/planting:

- Clear labelling of the GM seeds (distinct from other seeds/tubers/etc.) (describe).
The GMO seeds were placed in individual envelopes of 100 seeds, each envelope labeled with the corresponding transformation event code VCO-Ø1981-5 and the name of the experimental variety..
- Segregation during the processing and transport of the seed/planting material (describe the method involved; provide example(s) of containment to prevent spillage during the processing and transport).
The envelopes were placed, in the sowing order in cardboard boxes then in a polypropylene bag, sealed before transport. The seeds preparation was done in the Laboratory of Limagrain in France. Transport was made in a Limagrain car by persons aware of the nature of the seeds.
- Destruction of superfluous seeds/planting material (describe the method involved).
After sowing, the remaining seeds were brought back to the laboratory for destruction. The planter was carefully cleaned on the experimental field (in the borders).
- Temporal isolation (specify).
No temporal isolation.
- Rotation (specify the previous crop).
Ejea de los Caballeros: Sunflower.
Murillo el Cuende: cereal.
Muruzábal de Andi3n cereal
Luisiana: cereal
- Other(s): (specify)

6.1.2 During the sowing/planting activities:

- Method of sowing/planting.
Planting was using a sowing machine for experimental trials. A system of auto cleaning send the remaining seeds in a container where the seeds are collected.
- Emptying and cleaning of the sowing machinery on the field of release.
The sowing machine was cleaned on the release site; remaining seeds were collected after opening the sowing elements.
- Segregation during the sowing (provide example of containment to prevent spillage during the sowing/planting).
Each bag of seeds was open only on the release site; after control of the label and of the position of the plot (using a map/design of the assay), the seeds were poured into the sowing elements.
- Other(s): (specify)

6.1.3 *During the period of release:*

- Isolation distance (x meters)
 - From sexually compatible commercial plant species.
 - Ejea de los Caballeros: 240 m from maize
 - Murillo el Cuende: 800 m from maize
 - Muruzábal de Andi6n 510 m from maize
 - La Luisiana 600 m from maize
 - From sexually compatible wild relatives.
Maize has no wild relatives in Spain
- Border rows (with the same crop or a different one, with a non-transgenic crop, x meters, etc).
At least 8 border rows of non GM maize.
- Cage/net/fence/signpost (specify).
No
- Pollen trap (specify).
No
- Removal of GM inflorescences before flowering (indicate the frequency of removal).
No
- Removal of bolters/relatives/hybrid partners (indicate the frequency of the removal, x metres around the GM field, etc).
No
- Other(s): (specify).....

6.1.4 *At the end of the release:*

- Harvest/destruction methods (of crop or part of it) / other means (e.g.: sampling) (describe).
- Harvest / destruction before the ripeness of the seeds.
Grain harvest by a combine having weight meter unit and water content measurement unit. Later the grain is recovered from the machine and buried in the liberation site in presence of technicians from the “Comunidad Aut6noma” that is the Local Competent Authorities.
- Effective removal of plant parts.
Chopping of the plant parts and bury in the liberation site.
- Segregated storage and transport of crop/waste (provide examples of containment to prevent spillage of collected seeds/crops/wastes).
Cob samples were hand harvested, placed in bags, each bag labelled with the identification of the plot from which the cobs were taken, (location, trial, genotype, identification that it is GMO with the event code, indication it is not to be used for animal or human consumption) and transported to the Limagrain laboratory in France by Limagrain vehicle and by Limagrain personal.

- Clean up of machinery on the release site.
The combine is cleaned of rests of grain and other plant material in the liberation site, the residues are buried in place.
- Destination of the waste, treatment of waste/ surplus yield/plant residues (describe).
Buried on the experimental release site.
- Post-harvest treatment and cultivation measures on the release site (describe the method for preparing and managing the release site at the end of the release, including cultivation practices).
Soil preparation for next crop that is not maize.

Other(s): (describe):

6.1.5 *Post-harvest measures:*

Please indicate which measures were taken on the release site after harvest:

Frequency of visits (average) **Monthly**.

- Subsequent crop (specify).
Ejea de los Caballeros: Sunflower due to be sown in April-May

Murillo el Cuende: not sown, probable use next season to repeat the trial if aproved by the competent authority.

Muruzábal de Andión, cereal

La Luisiana: fallow.

- Crop rotation (specify).
- Fallow/no crop (specify).
- Superficial soil work / no deep ploughing.
- False-sowing beds.
- Control of volunteers (specify intervals and duration).
- Appropriate chemical treatment(s) (specify).
- Appropriate soil treatment(s) (specify).
- Other(s) (specify)

6.1.6 *Other(s) measure(s): (describe)*

The monthly visits make sure there is no re-grown of maize. Not found till now.

6.1.7 *Emergency plan(s).*

Indicate:

a) If the release proceeded as planned:

- Yes X
- No (describe for which reason, e.g. vandalism, climatic conditions, etc.) No incidence to report

b) if measures according to the emergency plan(s) (Article 6(2)(a)(vi) and Annex III.B of Directive 2001/18/EC) had to be taken:

- No X
- Yes (describe)

6.2 Post-release monitoring measures

Due to the fact that the current report format can be used for the final and post-release monitoring report(s), the notifier is asked to clearly make the difference between both types of report through this section 2 of Chapter 6. Please indicate whether

- **The post-release monitoring plan will start** (in the case of a final report, after the last harvest of the GM higher plants).
- **The post-release monitoring plan is ongoing** (in the case of an intermediary post-release monitoring report).

The monitoring plan post-release goes on. The monthly visits have nothing to report till now.

- **The post-release monitoring plan has been completed** (in the case of the final post-release monitoring report).
- **No post-release monitoring plan has to be fulfilled.**

The results of this monitoring are meant to confirm or invalidate earlier assumptions in the risk assessment.

According to the aforementioned cases, please indicate which monitoring measure(s) will be/are/were taken and where (on the release site/near the site (e.g. on fields edges)). Please be aware that all post-release monitoring measures taken during the whole post-release period shall be indicated here.

Specify:

- Monitoring measures within site

Duration: **one year**

Frequency of visits (average): **monthly**

- Observation of resistant relatives.
- Observation of resistant insects.
- Control of volunteers (specify intervals and duration).
Control of volunteers for one year monthly, nothing to report till now.
- Monitoring of gene flow (specify).
- Appropriate chemical treatment(s) and/or soil treatment(s).
- Others (specify).

- Monitoring measures of adjacent areas:

Duration: **One year, at the same time of the visits to the release site, to date no incidence or re-growth to report in the adjacent plots.**

Frequency of visits (average): **monthly**

Area monitored:

- Observation of resistant relatives.
- Observation of resistant insects.
- **Control of volunteers X**
and/or monitoring of feral populations (specify intervals and duration).
- Monitoring of gene flow (specify).
- Appropriate chemical treatment(s) and/or soil treatment(s).
- Others (specify).

6.3 Plan for observation(s)/methods(s) involved

In this section the observation plan and the methods used to collect the effects which have to be reported under the next section (section 6.4) need to be specified. Any amendments or modifications to the plan as proposed in the application and the SNIF⁴ part B need to be specified in detail.

During the time between the notification and the final report submission, new scientific insights or methods may be developed which cause a change in the methods used. In particular these modifications need to be specified under this section.

During the field trial observations made do not lead to change the conclusions of the risk assessment made in the application. No changes were found, as compared to conventional maize in terms of persistence or invasiveness, advantages, potential of transfer of genetic

⁴ Summary notification information format (=SNIF)

material, or biological interactions, etc. The only difference found was the tolerance to the herbicide glyphosate which is the trait introduced into this transgenic maize plants.

6.4 Observed effect(s)

6.4.1 Explanatory note.

All results of the deliberate release(s) in respect of any risk for human health or the environment shall be stated, without prejudice to whether the results indicate that any risk is increased, reduced or remains unchanged.

The main objectives of the information given in this section are:

- to confirm or invalidate any assumption regarding the occurrence and impact of potential effect(s) of the GMO(s) which was/were identified in the environmental risk assessment,
- to identify effect(s) of the GMO(s) which was/were not anticipated in the environmental risk assessment.

The observed **effect(s)/interaction(s)** of the GMO(s)

- with respect to any risk to human health,
- with respect to any risk to the environment

shall be reported under this section.

Particular attention shall be drawn to unexpected and unintended effect(s).

Nothing has been detected in effects over the human health or environment, different to the effects related to a normal maize cultivation in the relative to agriculture land preparation, etc. No unexpected or unintended effect to report.

Indications as regards the effects, that the notifier may have to report, are provided hereunder. The effects have obviously to be considered in the light of the crop, the new trait, the receiving environment as well as the conclusions of the environmental risk assessment, which is carried out on a case-by-case basis.

In order to structure the information and to facilitate an efficient search within the given information, the notifier shall use, as far as possible, specific keywords to fill in the text fields under Chapter 6, especially sections 6.4.2, 6.4.3 and 6.4.4. A most updated list of those specific keywords is available on the Internet at: <http://gmoinfo.jrc.it>.

6.4.2 Expected effect(s)

This section concerns « expected effects », that is to say, potential effects which were already identified in the environmental risk assessment of the notification and could therefore be anticipated.

Notifiers should supply data from the deliberate release(s) which validate the assumptions made in the environmental risk assessment.

6.4.3 *Unexpected effect(s)*⁵

“Unexpected effects” refer to effects on human health or the environment which were not foreseen or identified in the environmental risk assessment of the notification. This part of the report should contain any information with regard to unexpected effects or observations relevant for the initial environmental risk assessment. In case of any observed unexpected effects or observations, this section should be as detailed as possible to allow a proper interpretation of the data.

6.4.4 *Other information*

Notifiers are encouraged to supply information, which is outside the scope of the notification but which might be relevant to the field trials in question. This may also include observations of beneficial effects.

Nothing could be detected in relation to biodiversity in general different to what can happen with a normal non GMO maize cultivation.

7 **Conclusion**

In this chapter, the notifier should specify the conclusions drawn and the measures taken or to be taken on the basis of the results of the release with regard to further release(s) and where appropriate, make reference to any kind of product the notifier intends to notify at a later stage.

The conclusions of the ERA made for the 2010 trials are not to be modified as no observation leads to change the conclusions.

DATE: Elorz 29 noviembre de 2010.

Enrique Sánchez-Monge

⁵ Without prejudice to Article 8 OF Directive 2001/18/EC as regards handling of modifications or new information.