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Floor 3/F5
Department for Environment, Food and Rural Affairs,
Ashdown House, 123 Victoria Street
London SW1E 6DE

Our Ref: BRA02/080
Your Refs: 00/R14/8, 98/R19/18, 01/R33/9

2 August 2002

Dear Dr Smith

**PART VI ENVIRONMENTAL PROTECTION ACT 1990 AND THE GENETICALLY
MODIFIED (DELIBERATE RELEASE) REGULATIONS 1992 AS AMENDED 1995 AND 1997**

**APPLICATION FOR CONSENT REFS: 00/R14/8, 98/R19/18 AND 00/R33/9 – NEW
ANALYSIS OF SEED**

Following the discovery of unexpected transgenic events in seed used in a small-scale agronomy trial at SAC, Aberdeenshire we have carried out further tests as set out below. As a consequence of this we wish to notify you of the presence, at very low levels, of three additional events : Ms1, Rf1 and Rf2 in genetically modified herbicide tolerant spring oilseed rape seed sown under consent application reference numbers 00/R14/8 (held by SAC, Aberdeen) and 98/R19/18 and 00/R33/9 (held by ourselves).

As with the events Ms8 and Rf3 referred to in the above consents these additional events also confer herbicide tolerance to glufosinate ammonium and hybrid system components (see below) and have undergone a full risk assessment according to part C of Directive 90/220.

Although we cannot verify the source of this admixture it appears that it was present in some of the seed of the hybrid line PH96S452 which was sent to the UK, from Belgium, in seed batches in 1999, 2000 and 2002.

None of the produce from the seed batches grown in the UK will, or has, entered the food or feed chain, in accordance with the conditions of our part B consents, and has been grown to SCIMAC guidelines, to which these trials are subject.

Given the management of these trials, the fate of the produce and that these events are earlier versions of exactly the same trait, hence similar to Ms8 and Rf3, we don't believe there is any change to the conclusion of the risk assessment for the above consents nor any impact upon the scientific validity of the trials conducted using this seed. We trust therefore that you agree with our view that the existing controls remain valid and appropriate for those trials currently being grown.

Identifying the presence of Ms1, Rf1 and Rf2

On June 21st 2002 we received an E-mail from the Scottish Agricultural College (SAC) in Aberdeen informing us that a batch of genetically modified herbicide tolerant spring oilseed rape seed contained an unknown event. This was confirmed by another E-mail on July 3rd with information from the inspectorate body SASA that after further analysis of seed samples, the event was different to that covered by the SAC consent (00/R14/8) and also not Ms1Rf1. It had been expected that any admixture was Ms1Rf1 as seed containing this event had previously been handled on the site.

A sample of 250gm was sent to the Bayer Cropscience laboratory's in Belgium for testing in July 2002. The analysis gave similar, although not identical, results to those obtained from the SASA and CSL laboratories which was confirmed to SAC in writing on 18th July (see enclosed). There was presumably a difference in detection levels achievable since both the CSL and SASA laboratories could not detect any presence of Ms1 or Rf1. We identified that 2.8% of the seeds contained sequences *nptII* and pNos. Of that, 93% was Rf2, 6% was Rf1 and 1% was Ms1. Hence, the seed sample contained:

2.60 % : Rf2

0.17 % : Rf1

0.03 % : Ms1

The source and additional use of the seed batches

In addition to analysing the sample from SAC we also used our audit trail to trace other seed batches from the same original seed lot. The seed was multiplied as Basic seed in Belgium in 1997 to produce the hybrid variety, PH96S452. The parent seed was produced in Canada. A sample from the remaining batch, still held in Belgium, has since been analysed to compare with the sample from SAC. The results were almost identical: 92% was Rf2, 7% was Rf1 and 1% Ms1. Hence the seed sample contained:

2.58% : Rf2

0.20% : Rf1

0.03% : Ms1

Four different batches of this seed were sent to the UK for trials purposes :

Date	Batch	Quantity (kg)
March 1999	1	50
March 1999	2	75
March 2000	3	450
March 2002	4	600

The 6kg seed sample delivered to SAC in May 2000 was taken from batch 3 and planted in their trial in 2001 and 2002. The remaining seed from that batch and batches 1, 2 and 4 have been grown on farm scale evaluation sites:

Consent	Year	Grid Reference	Nearest village	County
98/R19/18	1999	SK 968 589	Boothby Graffoe	Lincolnshire
98/R19/18	1999	SU 157 919	Hannington	Wiltshire
98/R19/18	1999	SU 677 980	Shirburn	Oxfordshire
98/R19/18	2000	SK 959 592	Boothby Graffoe	Lincolnshire
98/R19/18	2000	SP 069 360	Laverton	Worcestershire
98/R19/18	2000	TA 265 382	East Newton	Hull
98/R19/18	2000	SP 241 486	Alderminster	Warkshire
98/R19/18	2000	NZ 137 115	Hutton Magna	Yorkshire
98/R19/18	2000	SO 675 313	Kempeley	Gloucestershire
00/R14/8	2001	SAC		Aberdeenshire
00/R14/8	2002	SAC		Aberdeenshire
00/R33/9	2002	SK 600 712	Meden Vale	Nottinghamshire
00/R33/9	2002	TF 944 250	Horningtoft	Norfolk
00/R33/9	2002	TA 221 373	Aldbrough	East Riding of Yorkshire
00/R33/9	2002	TM 102 875	Winfarthing	Norfolk
00/R33/9	2002	SJ 683 255	Hinstock	Shropshire
00/R33/9	2002	NZ 205 365	Oakenshaw	Durham
00/R33/9	2002	TF 216 976	Thorganby	Lincolnshire
00/R33/9	2002	TF 221 888	Ludford	Lincolnshire
00/R33/9	2002	SJ 399 262	Bagley	Shropshire
00/R33/9	2002	SE 820 490	Kilnwick Percy	East Riding of Yorkshire
00/R33/9	2002	SY 788 028	Hilton	Dorset
00/R33/9	2002	TA 065 596	Nafferton	East Riding of Yorkshire
98/R19/18	2002	NJ 746 301	Daviot	Aberdeenshire
98/R19/18	2002	NJ 772 280	Daviot	Aberdeenshire

Any seed left-over from these plantings has been disposed of, by deep landfill, and not carried over from one year to the next.

Similarity of the events Ms1, Ms8, Rf1, Rf2, and Rf3

Our hybrids are obtained by crosses between a female inbred line containing the event Ms8, with a male inbred line containing event Rf3. Ms8 and Rf3 are the up-to-date elite events developed in the framework of the projects named "SeedLink" and "Liberty Link". Male sterile (Ms) lines, that do not produce pollen, and male lines containing a gene restoring the male fertility (Rf) produce hybrids which are also tolerant to the herbicide, glufosinate ammonium.

The first Ms and Rf events created were named Ms1, Rf1 and Rf2. From a combination of lines containing those events, several commercial hybrid varieties have been developed in different parts of the world, amongst which Canada is the most important.

These three events, Ms1, Rf1 and Rf2, contain the gene conferring the resistance to the antibiotic, kanamycin, (the construct containing the pNos and the *nptII* sequences). However, Aventis has subsequently developed transformations using just the *bar* gene (conferring the tolerance to the herbicide glufosinate ammonium) as the unique marker gene. Therefore the events Ms8 and Rf3 were created, without the kanamycin resistance marker gene, but still conferring herbicide tolerance to glufosinate ammonium. Hence the only difference between hybrids containing Ms1, Rf1 or Rf2 and hybrids containing Ms8 and Rf3 is that the latter do not contain the kanamycin resistance cassette.

Lines containing Ms1 and Rf1 have been grown in the UK under both part B and part C consents, and Rf2 under a part B consent, during the previous 5 to 8 years. Indeed all have undergone a full risk assessment according to part C of Directive 90/220 which has led to decisions of placing on the market into the EU, no. COM 97/392/EC and COM 97/393/EC on June 6th 1997.

Future action by Aventis Cropscience

We believe that since this was not a deliberate release of Ms1, Rf1, or Rf2, that they are similar to those events covered by the consent and that both the risk assessment and scientific validity of the trials are unaffected, it is not necessary to take any additional action regarding the trials currently being grown. Hence (subject to hearing from you to the contrary) we propose continuing with the Farm Scale Evaluations while following the conditions of the consent to ensure that no produce enters the food or feed chain and with the usual monitoring of the sites the following season. In addition, we will of course continue to follow the SCIMAC guidelines including adhering to the separation distances defined.

In addition any remaining seed from the batches of spring oilseed rape variety PH96S452, that may contain admixture from these events, will be destroyed. We believe this has already been done at SAC. We have committed to providing a different seed batch for next season which will be subjected to a more rigorous test system that we propose to put in place.

This future testing of seed batches, in addition to confirming the presence of Ms8 and Rf3, will also include analysis to ensure the absence of other events like Ms1, Rf1 and Rf2, subject to certain detection limits. This has already been actioned for next season so that test results will be available prior to planting the crop of winter oilseed rape within the Farm Scale Evaluation programme 2002/3.

I hope that this provides sufficient information to explain the situation and trust that you agree with our assessment. We look forward to your response and in particular confirmation of the actions as detailed above.

Yours sincerely,

Judith Rylott
Head of Product Development