

**DEFRA REPORT UNDER PART VI ENVIRONMENTAL PROTECTION ACT 1990 AND THE GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) (ENGLAND) REGULATIONS 2002**

<b>Incident</b>	<b>Unauthorised GM material in spring 2002 sown oilseed rape farmscale trials.</b>								
<b>Consent Holder</b>	Bayer CropScience UK Ltd (formerly Aventis CropScience)								
<b>Address</b>	Hauxton, Cambridge, CB2 5HU								
<b>Contact</b>	The Regulatory Affairs Manager								
<b>Consent number(s)</b>	98/R19/18 and 00/R33/09								
<b>Release Details</b>	Spring Oilseed Rape  Transformed lines for herbicide tolerance to glufosinate ammonium, male sterility and fertility restoration.								
<b>Background</b>	Following a previous incident in August 2002 involving the release of unauthorised material at FSE sites, Ministers instructed the GM Inspectorate to investigate other seedlots sown in 2002. A similar investigation was undertaken by the Scottish Agricultural Science Agency [SASA] GM Inspectorate. Ten sites in England fell into this category and only one site in Scotland								
<b>Sampling &amp; testing</b>	The CSL GM Inspectorate secured samples from two sites in England and SASA drew samples from the harvested seed from the site in Scotland. Official testing of these samples was undertaken on behalf of the Inspectorates. This testing identified the presence of the additional GM elements <i>nptII</i> , <i>Pnos</i> and CaMV 35S promoter in seed of seedlot E5103.								
<b>Identification of additional GM events</b>	Bayer provided a detailed report on 20.06.03 to the Inspectorates, confirming that the GM element <i>nptII</i> (Kanamycin) and CaMV 35S promoter were present as a result of the following GM events:  <table><tr><td>Ms1</td><td>(0.1%),</td></tr><tr><td>Rf1</td><td>(0.1%),</td></tr><tr><td>Rf2</td><td>(4.0%), and</td></tr><tr><td>Topas 19-2</td><td>(1.3%).</td></tr></table> The <i>Pnos</i> GM element is also a component of these GM events.	Ms1	(0.1%),	Rf1	(0.1%),	Rf2	(4.0%), and	Topas 19-2	(1.3%).
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Topas 19-2	(1.3%).								
<b>Verification of Bayer test data</b>	Bayer's test results are consistent with the findings of the GM Inspectorates and provide an explanation of the additional GM elements found in the E5103 seed.								
<b>Risk to human health and the environment</b>	After the reporting of the 2002 case, the Advisory Committee on Releases to the Environment (ACRE) advised on 13.08.02 that the release of the events Ms1, Rf1 and Rf2 does not pose an additional risk to human health or the environment than a conventional oilseed rape variety. On 4.09.03 the Committee considered the additional presence of event Topas 19/2 in lot E5103 in the light of their previous advice. It confirmed that presence of this event irrespective of whether it formed part of a seed admixture or a combination of stacked genes within a hybrid variety did not alter its previous assessment that the release represented no increased risk to human health or the environment.								
<b>Enforcement action</b>	The Inspectorate carried out monitoring visits with respect to harvest and disposal of seed and post trial control procedures. The Inspectorate was satisfied that procedures were in compliance with the consent conditions								
<b>Subsequent action</b>	ACRE has conducted a review of Inspection and Enforcement. The review emphasised that the way in which consent holders should discharge their duty of care is dependent on the risk of the material becoming contaminated with								

adventitious GM presence prior to release. This included a recommendation that seed produced outside containment be tested prior to release. The Department has accepted all of ACRE's recommendations and will implement them in full.

Bayer are revising their internal quality control and quality assurance procedures to prevent future occurrences of adventitious GM presence in their seedlots. Their procedures shall be subject to official scrutiny.

No crops of seedlot E5103 have been grown since the harvest of 2002 or are currently being grown in the UK.

No prosecution will be taken in England against Bayer Cropscience. In Scotland the final decision on whether or not to prosecute will be taken by the Procurator Fiscal, to whom the issue is being referred.