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The State Secretary of
Infrastructure and the Environment
Mrs W.J. Mansveld
P.O. Box 20901
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KENMERK CGM/150601-02

ONDERWERP Advice on improving the general surveillance of GM crops

Dear Mrs Mansveld,

In Europe holders of authorisations for genetically modified (GM) crops are required to monitor for the occurrence of any unanticipated adverse effects on human health and the environment resulting from the importation or cultivation of a GM crop. This 'general surveillance' is in addition to the exhaustive risk assessment carried out under the centralised procedure for the marketing authorisation of GM crops in the European Union.

General surveillance was instituted to ensure that if any unanticipated adverse effects occur, measures can be taken to protect human health and the environment. Applicants must submit a monitoring plan to satisfy the requirement for general surveillance. As the party responsible for carrying out the environmental risk assessments of applications for marketing authorisation in the Netherlands, COGEM has evaluated many of these monitoring plans. Since 2010 most applicants have submitted the same monitoring plan. Although COGEM considers this monitoring plan to be adequate for the importation of GM maize, soy and cotton, it sees a number of opportunities for improvement, as recommended in previous topic and advisory reports.[1]

- In the present general surveillance (GS) plan, the authorisation holder states that the operators have agreed to provide information relevant to the monitoring of [event] to the authorisation holder. The GS plan could be improved by including a guarantee that operators will monitor for unanticipated effects. In particular, the plan should state that

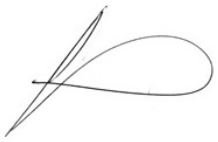
[1] COGEM (2010). General Surveillance. CGM/100226-01

the authorisation holder will provide evidence that the operators do collect this information.

- The GS plan further states that if the authorisation holder identifies any potential unanticipated adverse effects, they will inform the European Commission immediately. COGEM is of the opinion that all Member States should also be directly informed of these effects by the authorisation holder to ensure that appropriate measures to protect human health and the environment can be implemented immediately.
- In the EFSA guidance document, EFSA states that the applicant should make raw data and analysis of monitoring data available to the Competent Authorities and the European Commission. COGEM agrees with this request and points out that the applicant should include a statement on this in the GS plan.

COGEM realises it makes little sense to include these suggestions for improving the GS plan in every advice. Therefore COGEM decided to set out these points in this advisory letter and refer to them where relevant in future advice on permit applications for marketing authorisation. COGEM will continue to critically evaluate the monitoring plans and will inform you of its recommendations where necessary.

Yours sincerely,



Professor Sybe Schaap
Chair of COGEM

c.c. H.P. de Wijs, Head of the GMO Office
J.K.B.H. Kwisthout, Ministry of Infrastructure and the Environment