Comments received from the Competent Authority, 14/11//2012

Romanian Competent Authorities comments on FVO Draft Report 6306/2012

Ministry of Agriculture and Rural Development (MARD)

General comments on text

5.1 RELEVANT NATIONAL LEGISLATION
Findings

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- Order No 1718/2009 of Ministry of Agriculture and Rural Development (MARD) on the approval of the authorisation and import permits formats on the deliberate release into the environment of genetically modified organisms,
- Order No 1205 /2009 of MARD on the establishment and functioning of the National Register regarding the locations of the release of genetically modified organisms,
- Order No 1160/2010 of MARD on the approval the control procedure of the import, export and transit of genetically modified organisms.

Proposed refomulation:

- Order No 1718/2009 of Ministry of Environment on the approval of the authorisation and import permits formats on the deliberate release into the environment of genetically modified organisms,
- Order No 1205 /2009 of Ministry of Environment on the establishment and functioning of the National Register regarding the locations of the release of genetically modified organisms,
- Order No 1160/2010 of Ministry of Environment and of Ministry of Finance on the approval the control procedure of the import, export and transit of genetically modified organisms.

5.2.3.2 Controls of the deliberate release of GMOs authorised for purposes other than placing on the market (field trial)
Findings

The consent holder needs to register the exact location of the GMO trial with CDA every year and an annual authorisation is issued.

…… Another joint inspection is carried out by the CDA and NEG after harvest to verify whether the entire GMO material has been properly incorporated in the soil.

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The plan did not include GMO controls these years.

Proposed refomulation:

The consent holder needs to register the exact location of the GMO trial with CDA every year and an annual cultivation authorisation is issued.

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Another joint inspection is carried out by the CDA and NEG after harvest to verify whether the entire GMO material has been properly destroyed and incorporated in the soil. An inspection report is drawn up after each visit by each authority. …… ……..
The plan did not include GMO controls these years.
Comment:
Even the inspector declared "The plan did not include GMO controls these years", MARD mention that the control plan included GMO controls.

5.2.4 Controls of GMOs in seed and propagating material

GMO controls of seed processing

"Sampling of seed can also be carried out by the 27 samplers employed by seed companies and approved by the LCCSMS. "

Proposed reformulation:

Sampling of seed lots can also be carries out by 27 authorized samplers under the official supervision employed by seed companies. The authorization is made according to the provisions of EC Directive 66/402/EEC (for maize) by the LCCSMS and TISQ.

Controls carried out for GMO presence in non-GM soyabean seed

"The *de minimis* labelling threshold applied in Romania for adventitious and technically unavoidable presence of authorised GM material in non-GM seed contravene Article 21 of Directive 2001/18/EC and Article 4 of Regulation (EC) No 1830/2003. Therefore, recommendations (2) and (3) of the previous report have not been adequately addressed."

Comment:

In the case of soybean seed, Romania multiplies only conventional varieties which are placed on the market according to the provisions of *Directive 2002/57/EC on the marketing of seed of oil and fibre plants.*

In the last two (2) years we didn't detect any impurification with GM in conventional seed soyabean.

The MARD Order no 232/2010 stipulate for self pollinated species (e.g. soya) a threshold value of 0.5%, this threshold is applied only for authorized GM events, in fact in the case of soyabean the threshold is 0, because until now there are not authorized for cultivation any transformation event.

"GM seed is labelled, although not exactly in line with the wording of Article 4 of Regulation (EC) No 1830/2003."

Comment:

No GM varieties of soyabean are multiplied or marketed in Romania. We propose that the sentence in question to be deleted from the report.

On labeling issue we would like to state again that Romania apply the EU legislation on the marketing of seeds (e.g Directive 66/402/EEC - art. 11a "*In the case of seed of a variety which has been genetically modified, any label or document, official or otherwise, which is affixed to or accompanies the seed lot, under the provisions of this Directive, shall clearly indicate* **that the variety has been genetically modified***")*

National Environment Protection Agency (NEPA)

5.2.3.1 Authorisation of the deliberate release of GMOs for purposes other than placing on the market (field trial)

Legal Requirements

Article 6 of Directive 2001/18/EC specifies the standard authorisation procedure for the deliberate release of GMOs into the environment for any other purpose than for placing on the market. Article 8 regulates the handling of modifications and new information regarding the deliberate release of GMOs. Article 9 specifies the consultation of and information to the public, which MSs shall carry out.

Findings

Authorisation for deliberate release of GMOs into the environment under Part B of Directive 2001/18/EC (field trials) is issued by NEPA.

The CA stated that each application for authorisation of a proposed GMO trial is assessed on a case by case basis.

The notifier submits the application dossier together with the Summary Notification Information Format (SNIF) to NEPA. NEPA submits the SNIF to the European Commission and consults the public. The SNIF is published on the web page of NEPA, the web page and the information board of the local environmental protection agency and the information board of the local municipality.

NEPA consults the Bio-safety Commission which is an inter-disciplinary scientific body composed of 12 permanent members and four substitutes from public institutions. Each notification for GMO trial shall contain a risk assessment aiming to identify and evaluate, on a case by case basis, the potential adverse effects of the GMO, both direct and indirect, immediate or delayed, on human health and on the environment. The Bio-safety Commission evaluates the risk assessment submitted by the notifier and issues a scientific opinion, which is submitted to NEPA. NEPA also consults with MARD for approval. The comments submitted by the public during the public consultation are considered by NEPA when the authorisation decision is made. The socio-economic aspects (e.g.whether neighbours would be against), and the characteristics of the biodiversity of the intended location of the GMO trials (e.g. it is not in a protected area) are also taken into account.

NEPA issues the authorisation in the cases where the notification is in compliance with Directive 2001/18/EC and the necessary approvals have been received from MARD. The authorisation is generally valid for more than one year.

The authorisation includes, among other things, the description, the detection and identification methods of the GMO, the conditions of the release, the locations of the trial, the obligations of the consent holder and the validity of the authorisation.

The obligations of the consent holder include requirements regarding isolation distances, training of personnel, waste management and cross border movement of the GM material, monitoring, reporting, labelling and co-operation with MARD and NEG.

NEPA manages a register, accessible to the public via the internet, of the notifications received and rejected by them and the authorisations issued for GMO trials. The

location of the trials is also recorded in the register. The risk assessment submitted by the notifier, the SNIF and the scientific opinion are published on NEPA's website (www.anpm.ro).
There were seven and four new authorisations issued for GMO trials in 2010 and 2012,
respectively. No authorisations were issued in 2011 due to the unavailability of the Bio-safety Commission during its reconstitution.
Once a trial has been terminated, the consent holder has to submit a report, which NEPA checks to see whether the authorisation conditions have been fully followed.

COMMENT

In mid-December, the consent holders submit to NEPA the monitoring reports. After analyzing and verifying NEPA forwards them to EC via JRC according to the reporting obligations. The Format of the Report for field trials is according to the requirements of the MO No 606/2005 on the approval of the format for presenting the results of the deliberate release into environment of genetically modified higher plants for purposes, other than placing on the market (transposing Commission Decision 2003/701/EC).

Conclusions

A system for authorisation regarding the deliberate release of GMO for trial purposes is in place in line with Directive 2001/18/EC.

5.2.3.2 Controls of the deliberate release of GMOs authorised for purposes other than placing on the market (field trial)

Legal Requirements

Article 6(8) of Directive 2001/18/EC requires that the notifier may proceed with the release only when he has received the written consent of the CA, and in conformity with any conditions required in this consent. Article 6(9) requires MSs to ensure that no material derived from GMOs which are deliberately released in accordance with part B is placed on the market, unless in accordance with part C. Article 10 specifies the reporting by notifiers on releases to the CA after the completion of the GMO release.

Findings

The consent holder needs to register the exact location of the GMO trial with CDA every year and an annual cultivation authorization is issued. A map of the location of the trial is included in the documentation submitted by the consent holder. The CDA submits the data regarding the locations of the GMO trials to the NEPA, at their request, each year. NEPA uses these data to maintain their database of environmentally protected areas.

GMO trials of maize and soya bean were carried out involving 17 and 11 GMO events in 2010 and 2011, respectively. In 2012, only GM maize trials have been performed involving three GMO events.
A thematic instruction for controls is issued by the MARD each year. This guidance includes details of controls regarding GMO trial including timing of inspections. It is addressed to the CDA.Official controls of GMO trials are carried out by the CDA and NEG of the location of the trial. There were 37 and 42 inspections carried out in 2010 and 2011, respectively. In 2012, 14 inspections have been performed by the time of the audit. Non-compliances have not been identified.
The audit team visited GM maize trials performed under two authorisations by the State Institute for Variety Testing and Registration (ISTIS) in Calarasi county and a GM maize trial carried out by a farmer in Timis county. A partnership agreement was signed between the performer of the trial and the consent holder in each case.
The trial in Calarasi county is inspected three times a year. Inspectors explained that inspections are carried out after sowing, during the growing season and after harvest by the CDA and the NEG. The CDA stated that they check the isolation distances between the GM maize and maize grown in the neighbourhood. The consent holder stated that they obtain a prior agreement of the neighbouring farmers in order to respect at least 200 m isolation distance prior to sowing. The NEG and the CDA inspectors are present when the leftover of the GM seed is destroyed after sowing. They check whether the seed is duly buried in the GMO field. During the growing season the CDA inspectors checks the vegetative status of the crop. Another joint inspection is carried out by the CDA and NEG after harvest to verify whether the entire GMO material has been properly destroyed and incorporated in the soil. An inspection report is drawn up after each visit by each authority.
The CDA controls of the GMO trial visited in Timis county followed the same principle as in Calarasi. However, the NEG inspector did not carry out inspections in 2011 and 2012 at the time of sowing.
The inspector stated that they operate based on a centrally prepared control plan. The plan did not include ad-hoc GMO controls these years. They can inspect trials based on notification requests to do so from consent holders.
An inspection was carried, based on the notification received from the farmer after harvest in 2011. The conditions of the consent were checked including verification of the surface of the GMO trial and isolation distances. Similar inspections are planned in 2012.

Conclusions
The GMO trials are inspected at an appropriate frequency and it is verified that the conditions of the consent are met.