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EUROPEAN COEXISTENCE BUREAU

SUMMARY CONCLUSIONS OF THE FOURTH PLENARY MEETING OF THE TECHNICAL WORKING GROUP FOR MAIZE OF 6-7 OCTOBER 2010 SEVILLE, SPAIN

The main objectives of the Fourth Plenary Meeting of the Technical Working Group for Maize (TWG Maize) were:

- To discuss and agree on the issues to be included in the Best Practice Document on monitoring and its structure (based on input received)
- To identify knowledge gaps (if any)
- To agree on a work programme
- To discuss Portuguese approach to coexistence and its monitoring (including field visit)

TWG Maize members representing FR, LU, NL, PL, PT, RO, SI, UK, the European Coexistence Bureau (ECoB) staff and other IPTS staff, as well as representatives from DG SANCO and DG AGRI, participated in the plenary meeting.

The draft agenda (see attached document) was approved.

1. General issues: Information by DG SANCO – new policy on coexistence

Mrs. Alice Stengel representing DG SANCO informed TWG Members about the transfer of competences in coexistence from DG AGRI to DG SANCO. DG SANCO and the JRC will be responsible for developing the future ECoB work programme. DG AGRI will continue to participate in this work. Previously the stakeholder consultations of ECoB documents were conducted by DG AGRI via their advisory groups. They will now be managed by DG SANCO, probably via the SANCO advisory group, with the possibility to create an ad hoc group. This will be discussed soon.

DG SANCO will also manage the COEX-NET meetings. The next meeting of COEX-NET will probably take place at the beginning of 2011.

DG SANCO will also prepare the next coexistence report (published every 3 years). The next report is expected in 2012.

Mrs. Stengel informed TWG Members about

- 1) The new approach proposed by the Commission on GMO cultivation (in general terms)
- 2) The new Recommendation on coexistence (in details)

She explained that the new approach responds to a clear request by 13 Member States at the environment Council in June 2009 and follows the guidelines given by President Barroso for the new Commission.

Commissioner Dalli announced in March 2010 that he would present a new approach to GMO cultivation by the summer of 2010. This more flexible approach, which is in line with the demands of several Member States and stakeholders, maintains the harmonised EU authorisation system based on science, whilst giving Member States more freedom to decide if they want to cultivate GMOs or not.

The Commission adopted a package in July 2010 with

- 1) A new Recommendation on coexistence,
- 2) A limited legislative proposal,
- 3) A communication presenting the overall new approach.

The aim of the legislative proposal is to revise the Directive 2001/18/EC to secure the legal certainty for Member States to restrict or prohibit the cultivation of GMOs on their territory on other than scientific grounds, without recourse to the safeguard measure. The text is currently under discussion with Council and Parliament (co-decision procedure).

The new Recommendation (of 13 July 2010) is replacing the previous Recommendation on coexistence of 2003. This new Recommendation has the following aims:

- to better reflect the possibility of the legislation (Article 26a of Directive 2001/18) for Member States to adopt measures to avoid unintended presence of GMOs in other products;
- to take into consideration the extreme diversity of European farming systems, natural conditions and economic conditions and the experience gained over recent years regarding coexistence;
- to recognize that the potential loss of income linked to GMO presence is not necessarily limited to exceeding the 0,9% threshold of the legislation;
- to clarify that under certain climatic and/or agronomic conditions Member States may exclude GMO cultivation from large areas if other measures are not sufficient.

During the AGRI Council on 27 October, Commissioner Dalli presented the new approach and explained the content of the new Recommendation, which better reflects the possibility for Member States to establish coexistence measures to avoid the unintended presence of GMOs in conventional and organic crops and their need for sufficient flexibility to take into account their regional and national specificities. Commissioner Dalli also announced the publication of the first ECoB's Best Practice Document dealing with maize crop production and explained that the practices suggested in the document are applicable within the framework of the Commission's new approach to coexistence and GMO cultivation. This document details a set of non-binding practices, which aim to assist Member States develop and/or refine their national or regional approaches to coexistence.

Following the introduction by Ms. Stengel, JRC and DG SANCO explained that the publication of this Recommendation overlapped in time with the publication of the Best Practice Document which, in this situation, required an update and this was done by ECoB. TWG Members agreed with the necessity of amendment but stressed that the changes should have been put to the TWG members for quick consultation, even taking into account the urgency.

The ECoB Secretariat provided assurance that in similar situations a quick e-mail consultation will be organised. Also, the possibility to use a preface-style addendum was considered as an alternative solution for similar situations.

The ECoB Secretariat informed that a possibility of reimbursement of travel costs of members attending TWG meetings will be discussed with DG SANCO. The ECoB Secretariat declared the JRC (Action AGRITECH) is willing to temporarily cover those costs for the next plenary meeting, planned for June 2011.

2. Discussion on TWG contributions to the Best Practice Document on efficiency of coexistence measures for maize:

- overview of contributions

Data collection was conducted in June 2010. TWG Members were provided with the indicative list of issues to be addressed in the Best Practice Document agreed during the third plenary meeting in May 2010.

The majority of submissions dealt with the issue of sampling and testing.

The issues connected with analysis of monitoring results and possible follow-up and communication and exchange of data between countries were not addressed by TWG Members during data collection.

Regarding those issues a two-step approach was decided on. The TWG will address them once the indicators and methods of monitoring of efficiency of coexistence measures in maize crop production are identified.

- requests from TWG Members

TWG Members have proposed the following additional issues to be addressed in the Best Practice Document:

- The pollen flow from non-GM towards GM-fields

The issue of pollen mediated gene flow from non-GM to GM fields (referred to as "reverse coexistence" by some authors) was discussed in the context of possible future approval for cultivation of GM varieties with quality traits. The market price of such harvests would likely be dependent on the content of a specific product and/or its purity so the outcrossing with non-GM varieties may have a negative influence on that.

The TWG decided to address this problem in the Best Practice Document. At present there is no indication that different coexistence measures should be used in that case; however there might be a need to identify different indicators of their efficiency for both cases of gene flow.

- Measurement uncertainty and its implications

The issue of measurement uncertainty was discussed and considered necessary to be addressed in the Best Practice Document. The measurement uncertainty shall be known to decide if the analytical result confirms compliance with targeted GM contents. This issue was already addressed by JRC-IHCP and the network of European GMO laboratories. The Best Practice Document will refer to this data.

- Possible use of technologies

The issue of use of certain technologies (i.e. GPS for identification of sampling points in the field) was discussed by TWG Members. As the availability to use such techniques in standard controls may be limited in certain Member States the document should be flexible enough to provide alternative, less technologically demanding practices.

- Inclusion of alpha and beta risks or methods of their estimation.

The TWG agreed, that the information about the risk of taking an incorrect decision to reject the sample complying with set standards (alpha risk or type 1 error) and the beta risk (or type 2 error) resulting in a failure to reject a false hypothesis of sample compliance should be discussed in the case of every recommended best practice (subject to sufficient data availability).

- European and national legislation regarding monitoring of coexistence
- Information (recommendation?) on plan of the monitoring, inspection and laboratory control and ability to enforce this plan
- Methods of GMO detection – validation, harmonization, standardization
- Information (recommendation?) on sampling methods, strategy and management

The list of issues to be addressed in the Best Practice Document submitted by the Slovak Republic was not accompanied by any explanation or justification. TWG Members have analysed the proposals and decided that the majority of them are already planned to be addressed in the document. The TWG will also not give recommendations regarding validation and harmonization of GMO detection methods as those methods are validated at EU level before the approval of placing on the market of any GM product. The information about the existing system of validation etc. of detection methods will be included in the Best Practice Document.

The information about existing legislation/practices regarding monitoring of efficiency of coexistence measures will be included in the document. TWG Members will provide the respective data, including the information not only about enforced practices but also planned ones, if they are developed.

- The issue of local varieties

According to the proposal the monitoring of efficiency of coexistence measures should include the monitoring of GM content in local (open pollinated varieties). The issue was discussed and the TWG concluded that, as no specific coexistence measures were recommended in case of those varieties (existing measures aimed at protection of such

varieties from any pollen-mediated gene flow, also from modern conventional varieties, were considered sufficient), the issue will not be addressed in Best Practice Document.

3. Discussion on scope, structure and content of Best Practice Document

- **Scope of the Best Practice Document**

The TWG discussed the scope of the best practice document. As the aim of the coexistence measures recommended in case of maize crop production was to comply with targeted GM content on the farm gate the current document should not go beyond this point. The issue of effectiveness of coexistence measures (in practice expressed as proportions of fields/harvests complying with coexistence rules) vs. the efficiency which contains as well the assessment of costs of coexistence practices and possibly, the assessment of applicability of coexistence measures was discussed. It was agreed that the BPD should deal with the efficiency of the coexistence measures and will not be restricted to effectiveness only.

- **The structure and content of the Best Practice Document**

The TWG discussed and agreed the structure of the Best Practice Document based on an indicative list of issues discussed during the previous TWG meeting and on the proposals submitted by TWG Members. The ECoB Secretariat will elaborate the first draft of the Best Practice Document based on this structure.

The opinions of TWG Members on the following issues were collected during the meeting:

- Indicators for efficiency of coexistence measures

The TWG has provisionally identified the following indicators of efficiency of coexistence measures: GM content in the harvest from the neighbouring non-GM fields, the costs of respective coexistence measures applied, and the applicability of the measure from the farmer's point of view.

No conclusion could be reached so far concerning the precise definition of "costs of coexistence measures". Several TWG members were of the opinion that assessment of such costs should be based on a cost-benefit analysis of GM maize cultivation.

- Coverage (for example percentage of concerned market players which should be monitored in each year).

The TWG will not recommend minimal numbers of farms to be monitored. That should be decided by individual Member States based on available budget and monitoring capacity.

- Monitoring strategy – random choice of sampling points vs. stratified method (i.e. probes taken from areas likely to cause problems).

If possible the monitoring activities should be targeted at those fields/farms which may be problematic or are located in the areas where coexistence may be difficult to achieve.

- Possible need for development of monitoring-aid tools (i.e. tools which would allow the identification of the problematic areas or fields).

TWG Members decided that there is no need for development of new monitoring-aid tools. The existing ones should be however tested and possibly adapted to different climatic/agronomic conditions in different Member States.

4. Study visit to Portugal

TWG Members visited two maize growing farms with different profiles: a dairy farm and a farm producing grain maize for feed production.

In the case of the dairy farm the main production is silage maize which is mostly used on-farm for animal feeding. The main reason for adoption of GM Bt maize was the ease of crop management (no need for monitoring of pest infestation), the quality of harvest (mycotoxins) and the reduction of insecticide use that was applied previously with the irrigation water. As the main farm profile is milk production the time which can be spent on managing corn borers in maize is limited.

The farmer mentioned similar costs of growing Bt and conventional maize – the cost of Bt seeds is around 50 EUR/ha higher and is compensated by a lower pesticide cost (normally the conventional fields are sprayed twice during the season, each application cost is approximately 25 EUR/ha).

In the event of high pest pressure the quality of conventional harvest and the yield decreases. It is not likely that the farmer would adopt herbicide tolerant maize varieties in the case of their being available, as the weeds are not the main problem on his farm.

TWG Members were able to compare the GM and non-GM maize fields, as approximately 20% of maize grown on the farm is conventional to ensure the compliance with refuge requirements present in Portuguese law. Despite the pesticide treatment (1 spraying) the infestation of non-GM maize by corn-borer was significant (approximately 1 pest per plant).

In the case of the farm producing grain maize reduced tillage practices have been used on the farm since 2005. The change of farming system caused yield reduction in the first two years after the change, but currently the harvests are comparable with the ones obtained by neighbouring farmers using tillage practices. The harvest is sold for feed production. The Bt maize was adopted on the farm to avoid problems caused by corn borers, which however is not the main problem in the farm. The increased soil fertility caused the appearance of fertile soil weeds species, which are difficult to eradicate. Therefore the farmer would be willing to adopt herbicide tolerant varieties.

The field visit was followed by presentations of Portuguese coexistence rules, control and monitoring activities.

In the case of Portugal every year 50% of farms/areas on which GM maize is grown is controlled in terms of compliance with legal requirements. The monitoring of effectiveness of coexistence measures is also foreseen by Portuguese law. Each year about 20 samples are tested to check the GM content in the non-GM field neighbouring the Bt maize field. The sampling points are evenly distributed across the field. The monitoring is targeted at the fields more likely to cause coexistence problems.

The following presentations were focused on the farmer's point of view on GM maize cultivation and on the presentation of development of GM cultivation zone in the Mondego valley. Creation of such zones is an example of a practical solution for the areas where coexistence may be difficult to achieve due to small field sizes. Farmers inside the production zone are not obliged to apply coexistence measures and harvests from the entire area are labelled as containing GM. Only the farmers on the borders of the production zones must observe the requirements for segregation of two production systems.

5. Information of the GMCC-11 conference in Vancouver, Canada.

Mr. Rodriguez Cerezo informed TWG Members that the GMCC-11 conference will take place in Vancouver in October next year. The first announcements will be circulated soon.

6. Next steps: update of calendar

October 2010- January 2011	Data collection: - enforced/planned monitoring strategies in Member States - issues to be discussed: (indicators of efficiency, level of monitoring, coverage, monitoring strategy, monitoring-aid tools) Preparation of the first draft of "guidelines for the monitoring of efficiency in maize coexistence" (ECoB secretariat)
February 2011	Consultations of the First Draft (TWG and stakeholders)
March –April 2011	Redrafting of document, implementation of comments – Second Draft (EcoB secretariat)
May 2011	Consultations of Second Draft (TWG and stakeholders)
End June 2011	Plenary TWG meeting (discussion of stakeholders' consultations and final decisions on remaining issues)
July 2011	Redrafting of document (EcoB Secretariat)
September – October 2011	Proofreading, quality check, consultations of the document with DG SANCO. Formatting for printing.
End October 2011	Approval of the final formatted text by TWG

**European Coexistence Bureau (ECoB)
Technical Working Group for Maize (TWG-Maize)
Fourth Plenary meeting**

6 & 7 October 2010

**European Commission (EC), Joint Research Centre (JRC)
Institute for Prospective Technological Studies (IPTS)
Venue: calle Inca Garcilaso 3, Edificio Expo, 1st floor, Room A30, 41092 Seville, Spain**

Organisers

Day 1: Marta Czarnak-Klos, Emilio Rodríguez-Cerezo

Day 2: Paula Cruz de Carvalho, Marta Czarnak-Klos

DRAFT AGENDA

Wednesday 6 October 2010 – Meeting in Seville

- | | |
|-------------|--|
| 09:00-09:30 | Welcome, meeting overview (accept agenda, logistics) |
| 09:30-10:00 | Presentation by DG SANCO – new policy on coexistence; the role of ECoB |
| 10:00-11:00 | Discussion on TWG contributions to the Best Practice Document on efficiency of coexistence measures for maize:
- overview of contributions
- requests from TWG Members |
| 11:00-11:30 | <i>Coffee</i> |
| 11:30-13:30 | Continuation of discussion - requests from TWG Members |
| 13:30-14:30 | <i>Lunch</i> |
| 14:30-16:00 | Discussion on scope, structure and content of Best Practice Document
Identification of knowledge gaps |
| 16:00-16:30 | <i>Coffee</i> |
| 16:30-17:30 | Continuation of discussion if needed, conclusions of the meeting and next steps.
Information of the GMCC-11 conference in Vancouver, Canada |
| 17:30 | End of meeting day 1 |

Thursday 7 October 2010 – Meeting and fields visit in Elvas (Portugal)

- 08:15-11:30 Travel Seville-Elvas
Meeting point: main entrance IPTS building
- 11:30-13:45 Field visit to farms in the Caia- Elvas region and meeting with farmers and official
Local time: inspectors:
10.30-12.45 Farmers: Mr Gisbert Van Hal; Mrs Maria do Amparo Barbas, Mrs Gabriela Cruz
Official inspectors: Mr Rui Rosado, Mr Fernando Carranca
- 13.45 -15.00 *Lunch*
- Local time:*
12.45-14.00
- 15.00-17.00 Meeting in INRB/L-INIA* building
- Local time:*
14.00- 16.00 14.00-14.30 GM cultivation and monitoring activities in Portugal
Mrs Paula Cruz de Carvalho, General Directorate for Agriculture and
Rural Development
- 14.30-14.45 GM cultivation and monitoring program: a farmer point of view
Mrs Gabriela Cruz, farmer
- 14.45-15.00 GM production zones and monitoring program: the seed industry point
of view
Mr Carlos Teixeira, Portuguese Seed Producers and Seed Trade
Association (ANSEME)
- 15.00- 16.00 Discussion
- 17.00-20.00 Travel Elvas - Seville
- 20.00 End of meeting day 2

* National Institute for Agriculture Research