European Coexistence Bureau

Summary of conclusions of the Fifth Plenary meeting of the Technical Working Group for Maize

19 - 20 June 2012,
Seville, Spain

At the Fifth Plenary Meeting of the Technical Working Group for Maize of the European Co-Existence Bureau, which took place from 19 to 20 June 2012 in Seville, Spain, the experts from the following Member States and EC services were represented:

- Austria (AT), Belgium (BE), Bulgaria (BG), Czech Republic (CZ), Denmark (DK), Germany (DE), Ireland (IE), Italy (IT), Spain (ES), Netherlands (NL), Poland (PL), Portugal (PT), Slovakia (SK) , Slovenia (SL) and United Kingdom (UK);
- Directorate General for Health and Consumers (DG SANCO);
- Directorate General for Agriculture and Rural Development (DG AGRI);
- Joint Research Centre (JRC), Institute for Prospective Technological Studies (IPTS);
- Joint Research Centre, Institute for Health and Consumer Protection (IHCP).

The main topics for discussion were:

1. **Work programme of the European Co-Existence Bureau (ECoB)** - priorities for ECoB until 2014, work programme; priorities and 2012-2013 calendar for Technical Working Group for Maize (TWG Maize); updates on staff recruitment; others (presentations by ECoB secretariat and DG SANCO)

2. **Overview of ECJ Bablok case (honey)** and situation of policy initiatives at EC level (presentations by DG SANCO and DG AGRI)

3. **Detection activities** - **research projects relevant for the honey/maize case** (briefing from JRC-IHCP)

4. **Best Practice Document (BPD) for maize of July 2010**: discussion on possible review of its content in line with honey case (overall discussion)

5. **BPD on monitoring efficiency of coexistence measures in maize crop production of February 2011:** steps to finalize the document (overall discussion)

6. **PRICE Project of FP7** for practical implementation of coexistence measures in Europe (presentation by JRC-IPTS)

1. Work programme of European Co-Existence Bureau

The work of the ECoB will continue to be based on the Administrative Arrangement between DG SANCO and the JRC, reflecting the EU policy changes which were described by ECoB secretariat. The BPD for maize of July 2010 may be reviewed in line with the European Court of Justice's (ECJ) decision on the GM pollen in honey case (C-442/091). Proposals for revisions should be finished by the end of 2012. The revision of the maize BPD for 2013 should include cross-border issues of coexistence. In addition to maize:

soybeans, potatoes and sugar beet will be a priority for the ECoB with respect to the development of future coexistence best practices. These crops were chosen because they are currently in the pipeline for authorization.

The BPD on monitoring the efficiency of coexistence measures in maize crop production of February 2011 will be reviewed in the event of new advances in sampling strategies and methods for quantification. The review will include, if necessary, a section for monitoring the efficacy of coexistence for honey production, including a state of the art of methods for detection of GM pollen in different matrices. The deadline for revising the BPD on monitoring is the end of 2012.

The multi-annual report concerning the coexistence measures of GM crops with conventional and organic farming in the EU, based on Member States' contributions, will be edited by the ECoB in 2013.

The agreed working program of ECoB till the end of 2012:

Prepare a **background document** summarizing MS' contributions and suggestions to cover the presence of GM pollen in **honey** in view of the ECJ decision in the Bablok case.	ECoB	End of September 2012
Request letter to Member States to draw up list of experts to form TWG **soybean**	ECoB/SANCO	3rd Q 2012
Send questionnaire to MS to collect data for the **Report on the coexistence of GM crops with conventional and organic farming based on MS contributions**	SANCO	3rd Q 2012
Organise a **2nd TWG maize** meeting (Seville): Discussion on background document (and comments received during the public consultation) and whether or not there is a sound base for proposals for best practice to achieve coexistence of GM maize cultivation and honey production. Discussion on technical feasibility of coexistence measures and economic consequences for MS. Discussion of final draft "Guidelines for monitoring efficiency in maize Coexistence" including considerations on honey.		4th Q 2012
Update of **Best Practice Document for Maize** and report "**Guidelines for monitoring efficiency** in maize Coexistence" sent to DG SANCO	ECoB	4th Q 2012
Report on the activities performed by the ECoB in 2012	ECoB	20 November 2012
Submission to SANCO of the draft **Report on the coexistence of GM crops with conventional and organic farming based on MS contributions**	ECoB	1st Q 2013

1st Kick off meeting **TWG Soybean**	ECoB	1st Q 2013

A new national expert, seconded to the secretariat of the ECoB, was introduced as well as the new members of the TWG for maize from Spain, Poland and the Netherlands.

It was requested by TWG members that financial support should be available for their continued participation in the plenary meetings of the TWGs of the ECoB. They referred to the difficulties of some Member States to financially support their participation. The secretariat of the ECoB informed that there was no approved mechanism for financial support, but promised that this issue will be discussed with the responsible authorities in the EC.

2. Overview of Bablok case (honey)

DG SANCO and DG AGRI overviewed and summarized the main issues raised by the ECJ decision on Case C 442/09 (Bablok case).

The ECJ ruling decision categorises the pollen as an ingredient. In addition, the court ruled that honey containing GM pollen constitute foodstuffs which fall within the scope of the EU's GMO legislation in terms of authorization and labelling.

Pollen of GM maize MON810 was not originally authorized, but the authorization holder agreed to submit a new application specifically relating to pollen.

The already available opinion of European food safety authority (EFSA) stated that the pollen of GM maize MON810 is as safe as the pollen of any other maize[1].

This decision of the ECJ is difficult to align with the Codex Alimentarius, where pollen is categorized as a constituent, but not an ingredient, of honey.

The ECJ decision could not be challenged, as it is the highest legal instance of the EU. The Court's ruling relates to the legislation as it currently stands.

As a result of the ECJ decision, the requirements for beekeepers should be included in the consideration of coexistence measures. The specificity of the field trials should also be considered although it is not the main target.

The low level presence legislation is of little relevance to the present discussion: The LLP discussion is about a possible presence of not yet authorised GMOs, while the implementation of coexistence measures relates to separation of non-GM from GM crops that are authorised for cultivation in the EU.

ECoB secretariat made the additional remark that the import of honey is out of scope of coexistence activities.

Presently all these issues concerning GM maize pollen presence in honey and other bee products are under discussion in different services of the EC.

The Dutch expert presented a report for honey production which was considered as a good starting point for current discussion[2].

[1] EFSA Journal 2011; (11):2434;

[2] Ameco Environmental Services (March 2012) The possible role of honey bees in the spread of pollen from field trials, Utrecht

3. Detection activities - research projects relevant for the honey/maize case

The ongoing internal activity of the European Reference Laboratory for GM food and feed (EURLGMFF) for establishment of methods for analysis of GM maize pollen in honey where presented by JRC/IHCP.

Maize pollen makes up a very small fraction of honey, which significantly complicates isolation and detection. Quantification would be particularly difficult as a percentage of total maize pollen. GM maize pollen as a percentage of total pollen is a more realistic approach, but if stacked events are considered, it is still very challenging, even in food. Therefore the initial efforts only examined single event GMOs.

DNA extraction

The bottleneck for the analysis of GM pollen in honey is the DNA extraction. Nevertheless, there are promising extraction techniques. Honey contains DNA from a complex mixture of organisms: bees, bacteria, fungi, and many plant species. Therefore the extraction of pollen DNA from the DNA pool of honey will not allow separation from them during the next steps of analysis.

The number of pollen grains of an individual plant species present in a particular honey will determine the amount of extractable species' DNA and thus the practical limit of detection.

Detection and quantification

In general, the pollen in honey is composed of a lot of different donor species[3]. Among them, maize pollen is not very frequently found in honey. Even if it is there only a few copies of maize DNA may usually be presented. Therefore the estimation of the amount of the relevant species' DNA should be done by real-time PCR. For the detection, as a first step, it is appropriate to examine the amplification of one universal plant DNA sequence. Such a universal plant DNA sequence could be the Actin reference gene, which is already used for in-house validation[4]. However, it should be noted that the Actin assay may not detect all plant DNA equally. For example maize DNA could be detected with about 80% sensitivity in comparison to rapeseed DNA.

Another option for detection is the application of species-specific and/or event-specific methods. This approach could be especially efficient for analysis of mono-floral honey, where the plant origin is known.

The screening methods for detection should also be considered.

Calculation

The EURLGMFF validated real-time PCR detection methods quantify ratios of GM DNA to a particular plant species DNA and not the ratio of GM maize pollen DNA to overall pollen DNA, as is suggested for testing pollen in honey.

[3] Laube I, Hird H, Brodmann P, Ullmann S, Schone-Michling M, Chrisholm J, Broll H (2010) Development of primer and probe sets for the detection of plant species in honey. FoodChem 118:979–986

[4] Waiblinger HU, Ohmenhaeuser M, Meissner S, Schillinger M, Pietsch K, Goerlich O, Mankertz J, Lieske K, Broll H (2012) In-house and interlaboratory validation of a method for the extraction of DNA from pollen in honey, Journal of Consumer Protection and Food Safety, 7(3):243-254

Honey can carry pollen grains from at least 50 plant families, wind pollinated as well as insect pollinated species[2]. The number of pollen grains per gram of honey can vary from less than 1,000 to 28,000. The weight of pollen grains among different plant species varies significantly: from 13.4 µg per grain for oilseed rape to 250-350 µg per grain for maize[5]. The pollen content in one gram of honey is in the range of 43 µg to 670 µg[6].

In view of all these figures the quantification of GM pollen as % w/w or % GM genomes could significantly differ, even though pollen grains are effectively haploid segregants of the paternal plant genotype. In terms of % GM DNA, they are therefore 0% or 100% - unlike maize grains which may contain more complex proportions of GM and non-GM genomes.

4. Discussion on possible review of the Best Practice Document (BPD) for maize of July 2010

Member States' experiences

The Czech Republic and Spain, the main GM maize producers, reported that based on their risk analysis and control samples the risk of adventitious presence of GM maize pollen in honey seems to be so low that it does not require any changes to the coexistence regulations which are already in place. The Czech Republic reported 13 control samples of honey collected near GM maize fields with no presence of GM maize pollen in them. Germany, however, gave evidence that the honey collected near field trials with GMOs contained traces of GM pollen. Spain specified that the main region for honey production is its West part where there is no cultivation of GM maize, but also mentioned that honey production in Spain is spread all over the country. Spain is the biggest producer of honey in the EU. It was concluded that the information and evidence in that respect are still limited and are not conclusive.

German traders require honey to be certified as being free of GM pollen. Samples are taken for analysis before import to Germany and only in the case of negative results for GM pollen presence is, its importation accepted.

Poland stated that, based on literature data and their practical observations and experience, bees are not attracted to maize during the nectar collection period.

Backgrounds for BPD

Belgian expert stated that the flowering window for maize is quite short, only 2-3 weeks. Therefore suitable preventive measures could be proposed such as the brushing of bees before entering the beehive as is done for pollen collection.

Considering the gaps in information and experience it is necessary to make an overview of existing data in a background paper. After collection of background information and flagging the knowledge gaps, analysis will allow the ECoB to propose the best practices.

[5] Fonseca, A.E., M.E. Westgate, L. Grass and D. Dornbos Jr. (2003). Tassel morphology as an indicator of potential pollen production in Maize. Crop Management. DOI: 10.1094/CM-2003-0804-01-RS. Available online at: www.plantmanagementnetwork.org/pub/cm/research/2003/tassel/. Accessed January 2012.

[6] Van der Ham, R.W.J.M., J.P. Kaas, J.D. Kerkvliet and A. Neve (1999). Pollenanalyse. Stuifmeelonderzoek van honing voor imkers, scholen en laboratoria. Stichting Landelijk Proefbedrijf voor Insectenbestuiving en Bijenhouderij Ambrosiushoeve

The final step will be the analysis of the technical and economical feasibility of the proposed coexistence measures.

The region-specific approach could be important because climate conditions in some areas of EU maize cultivation are more limited and honey contamination with GM maize pollen will be not an issue.

The probability of adventitious presence of GM maize pollen will be determined by attractiveness of different plant species during the flowering period for bees and determination in that respect of the flying distances. Its management can be based on isolation distances utilization. The honey production before maize flowering is no considered as an option.

Summary of framework conclusions for coexistence measure proposal

1. The starting point and the reference is the TWG maize document on maize coexistence of July 2010;

2. Products to cover are honey and other derived products such as pollen sold in the market.

3. Working hypothesis is that adventitious presence of GM maize pollen is calculated as % of GM maize pollen in total pollen found in the sample;

4. The thresholds for coexistence should be between the limit of quantification and legal limit for labelling (which is 0.9%). It is in line with the Commission Recommendation of 13 July 2010 in which freedom is given to the Member States to set it accordingly for coexistence purposes.

5. The coexistence measures should be addressed to the GM maize producers. They could also be advised for beekeepers as well in order to provide coexistence measures in both production streams. In that respect a mutual agreement between them is welcome as well as national coexistence measures. All these measures should be technically and economically consistent. Region-specificity of the discussed coexistence measures should be evaluated additionally.

6. The review covers only coexistence between EU maize crop production and honey and other honey bee products produced in the EU.

7. The review considers, as in the BPD of July 2010, maize with a single transformation event.

8. The review will include, if necessary, a section on how to monitor the efficacy of coexistence for honey production, including a state of the art of methods for detection of GM pollen in different matrices.

Working procedure for the review

The experts of TWG for maize are asked to submit scientific and technical information (including data on best practice) related to the topic, such as data on maize pollen presence in honey, critical steps during maize/honey production, monitoring methods, etc, with emphasis in flagging knowledge gaps;

The ECoB secretariat will receive contributions until 3rd of September 2012 to the mailbox of ECoB - JRC-IPTS-ECoB@ec.europa.eu

The ECoB secretariat will prepare and submit a draft document summarizing the different proposals and the background information to DG SANCO by the end of September 2012.

DG SANCO will be responsible for stakeholder consultations and feedback to ECoB.

Based on the above will be submitted proposals for amendment or no of coexistence practices for maize cultivation.

ECoB will organize the 6th Plenary Meeting of the TWG for maize in November 2012 in which a proposal for a consensus document will be discussed.

Cross-border issues

The cross-border coexistence document is requested by DG SANCO in order to facilitate discussion with Member States. In that respect the experience of Member States producing GMOs or performing field trials on a large scale (Spain, Czech Republic, Portugal, Romania, France, Germany and UK) will be essential. The main difficulties for the establishment of common coexistence measures for border areas come from differences in national and regional policy and are not at the technical level.

The efficient approach for progress in this area will be the mapping and examining of cross-border coexistence measures. Germany and Denmark already took the first step to trans-border agreement making. In that point it is clear that cross-border coexistence is more of an administrative and legislative issue than a technical one. For that reason it is mostly out of the scope of the ECoB. The target for the ECoB will be the examination of technical measures to be adopted and the possibility of their harmonization among the Member States. A possible example could be the existing technical agreement between Spain and Portugal for border farms for utilization of common coexistence measures.

Analysis of differences of cross-border coexistence measures between Member States and third countries could be part of the background document, but it is impossible to advise improvement in the BPD for maize according to the relevant EU legislation.

5. Discussion on finalization of BPD on monitoring efficiency of coexistence measures in maize crop production (latest draft of February 2011)

The first draft of BPD on monitoring efficiency of coexistence measures in maize crop production was sent by ECoB secretariat in February 2011. During the first round of consultations for the background part of the document contributions from 7 Member States: AT, DE, F, NL, PL, PT and UK were received. The Best practices part of document was commented and contributed by 4 Member States: DE, F, PL and NL.

It was agreed that the ECoB secretariat will send a reminder to all members of the TWG and the deadline for the contributions will be extended to the 1st October.

The members of the TWG for maize are asked to submit contributions both on the background document as well as proposals for best practices on monitoring the efficiency of coexistence measures in maize crop production. The members who have already submitted this information are free to upgrade their contributions.

The requested information should cover the following topics:

1. Scientific/technical information for the recent advancement of sampling strategies and methods for quantification;

2. Experience of the Member States for monitoring the efficiency of coexistence measures in maize crop production and the necessity for monitoring the efficacy of coexistence for honey production, including a state of the art of methods for the detection of GM pollen in different matrices, with emphasis on flagging knowledge gaps;

3. Best practice questionnaire.

The detailed templates for the background document consultation and contributions to the BPD on monitoring the efficiency of coexistence measures in maize crop production will be submitted by the secretariat of the ECoB.

6. PRICE Project of FP7

The PRICE project (Dec 2011 - Dec 2014) will investigate the cost of coexistence practices in a number of Member States including the innovative solutions chosen by farmers to reduce coexistence compliance costs. A software module based on models resulting from previous projects (Co-Extra, SIGMEA) will be further developed with the aim of combining the natural science-based knowledge of cross pollination, including biological containment methods at farm and regional level, with solutions based on farmers' knowledge and experience with coexistence measures. The software module will be tested in the field, used to systematically analyze different strategies for achieving coexistence, and developed into a user-friendly decision-support tool for stakeholders (e.g. farmers, grain handlers). Implications for traceability and labelling at farm and regional level will also be assessed. The risk of adventitious presence of GM events in GMO-free commodities is also important within international supply chains of agricultural commodities. PRICE outlines several scenarios relating to the evolution of the global market of GMO-free commodities taking into account a number of important parameters (e.g. prices, compliance costs) supported by two detailed case studies. A wide range of stakeholders participate from the start of the project via an interactive stakeholder platform for securing the practical relevance of PRICE activities and the link with similar activities in the EU and worldwide.

JRC-IHCP reported data of measurement of pollen flow, collected by a two trap system and followed by real time PCR detection.