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# Genetically Modified Organisms in food and feed

Annual Report of the Dutch National Reference Laboratory

RIKILT Report 2012.001

I.M.J. Scholtens-Toma, B. Molenaar, S. Zaaijer, M.M.Voorhuijzen-Harink, T.W. Prins and E.J. Kok





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# Summary

This is the annual report of the Dutch National Reference Laboratory (NRL) for Genetically Modified Food and Feed (RIKILT – Institute of Food Safety). The report gives an overview of the NRL activities carried out in 2011.

In 2011 both RIKILT and the Routine Field Laboratory of the Netherlands Food and Consumer Product Safety Authority (NVWA) participated in several proficiency tests with good results.

Also RIKILT participated in two EURL/NRL meetings and the Working Group on Method Verification, the Task Force 'New Techniques' NTTF and the Working Group Unauthorized GMOs.

RIKILT has a flexible scope accreditation for real-time PCR GMO analysis in raw materials, food and feed.



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# 1 Introduction

The Dutch Ministry of Health, Welfare and Sports and the Ministry of Economic Affairs, Agriculture and Innovation are responsible for the maintenance of EU regulations in the area of GMOs, i.e. 'European Regulation (EC) 1829/2003' and 'European Regulation (EC) 1830/2003'.

Regulation (EC) 1829/2003 'European Regulation (EC) on genetically modified (GM) food and feed' states that food or feed products containing GMOs must be labelled as such. There is a 0.9% labelling threshold for the unintentional presence of GMOs that are authorized in the EU in non-GMO batches. The producer of a GMO to be authorized in the EU must supply reference material and an event-specific quantitative detection method to the EURL-GMFF. These methods are evaluated by the EURL-GMFF and subsequently validated in interlaboratory ring trials organized by the EURL-GMFF in cooperation with the European Network of GMO Laboratories (ENGL). RIKILT is a member of the ENGL.

Regulation 882/2004 stipulates which institutes within the EU member states are NRL for GMO analysis tasks. In the Netherlands RIKILT is NRL for GM Food and Feed. In the Netherlands there are two Routine Field Laboratories (RFL) that carry out GMO analysis for the Dutch government. For food this is the NVWA (Netherlands Food and Consumer Product Safety Authority). For feed this is RIKILT - Institute of Food Safety.

This report describes all NRL tasks and activities in the area of GM feed and food, as stipulated in national and EU GMO regulations and as far as they are not yet part of other national projects (e.g. in the WOT Theme 4 project on the validation and accreditation of methods for GMO detection).

## 2 NRL tasks

The NRL tasks are laid down in Directive 882/2004. There are two enforcement laboratories (Routine Field Laboratories) in the Netherlands. For the analysis of food samples this is the Dutch Food and Consumer Product Safety Authority (NVWA) and for the analysis of feed samples this is RIKILT.

The following NRL tasks have been carried out:

- Assist the EURL in interlaboratory validation studies for GMO detection methods and exchange of information on detection methods
- Participate in EURL/NRL meetings and workshops
- Participate in proficiency tests
- Perform confirmative analysis on samples of other enforcement laboratories, if requested
- Provide relevant information and advice to Routine Field Laboratories
- Check proficiency test results of Routine Field Laboratories

## 3 NRL activities 2011

### 3.1 Annual EURL/NRL workshops 2011

In 2011 two EUGL/NRL meetings were attended.

The 5th NRL workshop was integrated into the 15th ENGL Plenary Meeting (Ispra, 24-25 May 2011). Day one of this workshop was mainly dedicated to a special workshop on implementation of the 'Low Level presence' (LLP) regulation. Also GM rice detection from China and comparative testing were topics of day one. On day two an update on the different ENGL working groups was given. Other topics were: Compendium of Reference Methods for GMO Analysis and GMO Methods, two presentations on GMO Screening methods and the JRC Report on New Plant Breeding Techniques that included the work of the New Techniques Task Force (NTTF) on detection composed of 8 ENGL members. RIKILT also participated in the NTTF. More details on the 15th ENGL Plenary Meeting and the 5th NRL workshop can be found in the Meeting Report in Annex I.

The 6th NRL Workshop was integrated into the 16th ENGL Plenary Meeting (Ispra, 16-17 November 2011). This meeting was also attended by representatives of the Global GMO Network Forum Steering Committee and (partially) by representatives from the ASEAN GMF network who were participating. The most important topics were presentations and discussions on screening methods for unauthorised rice from China and detection of GM pollen in honey (5th NRL workshop). More details on the 16th ENGL Plenary Meeting and the 6th NRL workshop can be found in the Meeting Report in Annex II.

### 3.2 EURL working groups

RIKILT participated in the NRL/ENGL 'Working Group on Method Verification'. The final text became available on the EU-RL website in July 2011. This means that the mandate of this working group is now completed (Verification of analytical methods for GMO testing when implementing interlaboratory validated methods, Guidance document from the European Network of GMO laboratories (ENGL), prepared by the ENGL working group on 'Method Verification').

RIKILT also participated in the ENGL Task Force 'New Techniques' (NTTF). The report became available on the EU-RL website in May 2011 (New Plant Breeding Techniques and Challenges for Detection and Identification, Report from the, "New Techniques Task Force", (NTTF)). The report will be used by DG Sanco to discuss future EU regulatory decisions on New Plant Breeding Techniques with the EU countries.

### 3.3 EURL questionnaires

On request of the EURL and in relation to the Commission Regulation (EC) No 1981/2006 regarding detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council, the technical data concerning the RIKILT laboratory handled by the EURL-GMFF were checked and updated. These are technical data concerning e.g laboratory equipment, quality assurance and accreditation status.

### 3.4 Proficiency tests (GeMMA and ILC-EURL-GMFF-CT)

In a proficiency test unknown samples are analysed with a method of choice. The results are compared with other laboratories. For quantitative analyses Z-scores are calculated. A Z-score between +2 and -2 means that the result was satisfactory in comparison with other laboratories. In 2011 RIKILT participated in the GeMMA and ILC-EURL-GMFF-CT proficiency tests for DNA, food and feed matrices listed in Table 3.4.1. For NRLs it is mandatory to participate in the ILC-EURL-GMFF-CT proficiency tests. RIKILT obtained satisfactory qualitative results and Z-scores in the GeMMA 2011 tests. The official reports of the ILC-EURL-GMFF-CT proficiency tests will be issued in 2012.

Table 3.4.1. RIKILT participation in GEMMA and ILC-EURL-GMFF-CT proficiency tests.

Test	Date	Matrix	Event
GeM D29	02/2011	potato DNA	EH92-527-1 potato
GeM D29	02/2011	potato DNA	EH92-527-1 potato
GeM D29	02/2011	potato DNA	EH92-527-1 potato
ILC-CRL-GMFF-CT-01/11	04/2011	soybean powder	Roundup Ready soy
ILC-CRL-GMFF-CT-01/11	04/2011	soybean powder	Roundup Ready soy
GeM MP09	05/2011	baked product	CaMV 35S promoter
GeM MP09	05/2011	baked product	A. tumefaciens NOS terminator
GeM MP09	05/2011	baked product	Roundup Ready soy
GeM MP09	05/2011	baked product	Bt176 maize
GeM MP09	05/2011	baked product	Bt11 maize
GeM MP09	05/2011	baked product	MON810 maize
GeM MP09	05/2011	baked product	MON810 maize
GeM MP09	05/2011	baked product	GA21 maize
GeM MP09	05/2011	baked product	NK603 maize
GeM MP09	05/2011	baked product	TC1507 maize
GeM MP09	05/2011	baked product	MON863 maize
GeM MP09	05/2011	baked product	MIR604 maize
GeM MP09	05/2011	baked product	MON88017 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	MIR604 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	GA21 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	NK603 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	TC1507 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	MON810 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	MON863 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	Bt11 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	DAS59122-7 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	Bt176 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	E3272 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	MIR604 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	GA21 maize

<i>Test</i>	<i>Date</i>	<i>Matrix</i>	<i>Event</i>
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	NK603 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	TC1507 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	MON810 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	MON863 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	Bt11 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	DAS59122-7 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	Bt176 maize
ILC-EURL-GMFF-CT-02/11	11/2011	maize meal	E3272 maize

As part of the NRL tasks the Netherlands Food and Consumer Product Safety Authority was asked to report their proficiency test results to the RIKILT. The NVWA participated in two GeMMA proficiency test with good results and in the two ILC-EURL-GMFF comparative tests (reports will become available in 2012).

In December 2011 the ILC-EURL-GMFF report on the comparative testing on the detection and quantification of maize event MON810 (second ILC-EURL-GMFF proficiency test of 2010) was issued. Both RIKILT and NVWA obtained good results.

### 3.5 Assistance to other laboratories

During the year 2011 information was exchanged with the NVWA, e.g. on the implications of the LLP Regulation and on several technical aspects of GM detection methods: on detection of GM pollen in honey and on SYBRGreen screening methods for unauthorised GM rice from China (Directive 2011/884/EU and EU-RL GMFF Guidance on the Application of P-35S, T-NOS and CryIAb/Ac Methods for the Detection of Genetically Modified Rice Originating from China Using Real-Time PCR).

In 2011 the NVWA laboratory moved to the RIKILT building, but still operates independently using its own equipment and under its own accreditation. In 2011 RIKILT and NVWA started comparing the validation strategies of both laboratories. The objective is to harmonize the validation approaches in the near future.

## 4 Conclusions

In 2011 RIKILT and NVWA participated in several proficiency tests with good results.

RIKILT attended two NRL Workshops in Italy and participated in the ENGL Working Groups for Method Verification and Unauthorized GMOs and in the Task Force 'New Techniques' NTTF.

## References

- Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired.
- Directive 2011/884/EU: Commission Implementing Decision of 22 December 2011 on emergency measures regarding unauthorized genetically modified rice products originating from China and repealing Decision 2008/289/EC (2001/884/EU).
- ENGL guidance document: Verification of analytical methods for GMO testing when implementing interlaboratory validated methods, Guidance document from the European Network of GMO laboratories (ENGL), Prepared by the ENGL working group on "Method Verification", EUR 24790 EN - 2011.
- ENGL guidance document: Overview on the detection, interpretation and reporting on the presence of unauthorised genetically modified materials, Prepared by the ENGL ad hoc working group on "unauthorised GMOs", December 2011.
- EU-RL GMFF Guidance on the Application of P-35S, T-NOS and CryIAb/Ac Methods for the Detection of Genetically Modified Rice Originating from China Using Real-Time PCR, 21-12-2011.
- Lusser, M, Parisi, C, Plan, D, Rodríguez-Cerezo, E, 2011, New Plant Breeding Techniques and Challenges for Detection and Identification - State-of-the-art and prospects for commercial development, Report from the "New Techniques Task Force" (NTTF) New plant breeding techniques, EUR 24760 EN - 2011.



# Annex I

## 15th ENGL Plenary Meeting Report



EUROPEAN COMMISSION  
JOINT RESEARCH CENTRE  
Institute for Health and Consumer Protection  
Molecular Biology and Genomics



Ispra, 4 July 2011

### 15th ENGL PLENARY (Ispra, 24-25 May 2011) MEETING REPORT

#### DAY 1 – 24 MAY

#### 1. Approval of the Agenda

The Chairman explained that this ENGL Plenary will have a "special" format since Day 1 will be dedicated to a workshop on "practical implementation of the LLP regulation". He added that time permitting some topics like Chinese GM rice may also be addressed at end of Day 1.

The agenda was then approved without additions.

The chairman also welcomed observers from third countries (Argentina, Brazil, Colombia, Mexico, China, India, South-Africa, Jordan and Georgia).

#### 2. Debriefing of the Chairman

The Secretariat went through the latest version of the ENGL Action List (updated further to actions decided at the 14th ENGL Plenary meeting of November 2010 and at the 20th ENGL SC meeting of February 2011).

Main pending actions include:

- Development of the upgraded ENGL website
- Publication of the UGM WG doc, which was delayed in order to be fully consistent with the final wording of the LLP regulation
- Publication of the MV WG doc which was delayed because of personnel constraints within the Secretariat – nevertheless the final text of the MV WG doc (without the official cover page) is available on ENGLNet.

### WORKSHOP ON IMPLEMENTATION OF THE LLP REGULATION

#### 1. General presentation from the EU Commission on LLP regulation

DG Sanco gave a general presentation of the LLP regulation and explained in particular:

- **Scope:** the LLP regulation will apply to GM events approved in a third country, for which an application has been pending at EFSA for at least 3 months, for which a method has been validated by the EURL and for which Certified Reference Material is available. DG Sanco will publish a list of events to which the LLP regulation applies before its entry into force ie by mid-July.
- **Compliance:** if the analytical result (in mass fraction) is higher than 0.1% + U (measurement uncertainty), the feed material will be considered as non-compliant and a RASFF notification will be required.
- The scope of the regulation, presently limited to feed material, may be extended to food at a later stage.

In the Q&A session, DG Sanco confirmed in particular that approval in a third country would apply to any third country and that the present limitation of scope to feed may raise some practical difficulties for implementation (this is why the scope may be extended to food at a later stage).

## **2. Presentations and discussions on "methods of analysis and expression of results"**

The first presentations from JRC-IHCP and JRC-IRMM addressed the core topic of "Measurement Uncertainty" (M.U.) and stressed in particular the following:

- The RSDr % will be confirmed and published by the EURL in the validation report (if the RSDr % is below 25% at 0.1%, the event will be eligible for the LLP list)
- The total measurement uncertainty U can be considered equal to 2 x RSDr % (see details in presentations).

So if the RSDr % is 25%, the feed material will be non-compliant if the analytical result is higher than 0.1% + (50% of 0.1%) ie is higher than 0.15% (in mass fraction).

Jana Žel and Andrej Blejec from Slovenia made a presentation on "Outlook for further harmonization of measurement uncertainty in laboratories".

In the Q&A session, the importance of availability of CRMs was stressed, in particular to calculate the M.U. in the lab. Taking into account that production of CRMs takes usually more than a year, companies should initiate contacts with CRM producers as soon as possible (and ideally well before filing their GMFF application).

Comments were also made on the need to have a harmonised way of calculating the M.U. between the different labs. Some ENGL guidance to control labs on M.U. calculation would therefore be useful.

Another presentation from JRC-IHCP addressed the topic of "Unit of Measurement" and confirmed in particular that:

- The unit of measurement to be legally used when reporting results is mass fraction and will be the one used in EURL validation reports
- In practice the following conversion factors can be used (see details in presentations):  
For heterozygous crops (eg maize): GM % in copy number = 50% of GM% in mass  
For homozygous crops (eg soya): GM% in copy number = GM% in mass
- It will be important for EURL to have access to "homogeneous" control samples (not mixtures of grains of different genetic background/zygosity) – this will be required to applicants and may later on be included in an amendment of regulation 641/2004 on implementation rules. This point will also be addressed in a Commission meeting with industry end of June.

In the Q&A session, comments were made about possible confusion on units of measurement to be used at 0.9% (GM labelling) and at 0.1% (LLP). Some ENGL guidance to control labs on units of measurement to be used and conversion factors between units of measurement would therefore be useful.

Another presentation from JRC-IHCP addressed the topic of "Stacks" and confirmed in particular that in the case of multiple stacks the EURL will verify that the individual methods work on the commercial multiple stack combination but will not run the verification on all theoretical possible sub-combinations.

## **3. Presentation and discussions on "sampling"**

R. Onori from Italy made a presentation on sampling at commodity level, based on the Italian experience with Regulation (EC) No 152/2009 on feed materials control.

It was commented that in third countries exporting to the EU, controls are in practice only done with protein-based strip tests. PCR is only used when the strip test is positive.

## **4. Presentation and discussions on "sample preparation"**

G. Berben from Belgium made a presentation focused on sample preparation at lab level, based on the discussions in the SPP WG.

At the end of all discussions on LLP, it was agreed that the Secretariat should prepare shortly a "guidance document on LLP implementation" to be circulated to ENGL members for comments/ endorsement. This ENGL guidance document should address in particular the two core topics of "measurement uncertainty" and "unit of measurement".

Time being available, the following topics were also addressed at end of Day 1:

- **GM rice detection**

DG Sanco reported that RASFF notifications on GM rice are quite regular (47 in 2010). A FVO mission was held in China early April and confirmed the presence of "other GM rice events" than Bt 63 in China. Consequently DG Sanco is preparing a revision of the emergency measure decision on Bt63 (in place since 2008) in order to broaden its scope to more events. A proposal may be presented to the Member States in July 2011 and will likely include reference to a screening method as control method.

- **Comparative Testing**

JRC-IHCP presented the (good) results of the 2<sup>nd</sup> CT round held end of 2010 and also explained that a new reporting process, more rapid, will be implemented as of the 1<sup>st</sup> CT round of 2011 : a short preliminary report will be sent quickly to participants, ie more or less 2 months after submission of results (around mid-July 2011 for CT 01/11).

It was also explained that CT 02/11 to be held in September 2011 will include not only quantitative PCR but also for the first time qualitative PCR.

**DAY 2 – 25 MAY morning**

**ENGL COMMON SESSION, 1829/2003 AND 882/2004 SESSIONS**

**1. Update on ENGL Working Groups**

- **Unauthorised GMOs – WG-UGM**

The WG chairman (A. Holst-Jensen) explained the amendments that were made to the UGM WG document in order to be fully consistent with the final LLP regulation text. He presented in particular the latest version of the decision tree and added that this decision tree still required some minor amendments (incl. addition of footnotes).

Subject to these additional minor amendments, the ENGL endorsed the document, which should therefore be published shortly.

- **Method Verification - WG-MV**

The WG chairwoman (L. Hougs) explained that the first version of the WG document is a guideline for verification/implementation at the lab level of a validated method without any change (a second version of the doc may be prepared later to take into account some changes to the validated method). The final text of MV WG doc is ready since April and already available in ENGLNet. Because of administrative delays hard-copies are not yet available but publication should now take place soon.

- **Method Performance Requirements - WG-MPR**

The WG co-Chairman (U. Marchesi) recalled the key objectives set in the MPR WG kick-off meeting of November 2010 and the priorities set in the 2<sup>nd</sup> meeting of February 2011 (incl. qualitative methods as first priority and then taxon-specific and screening methods). The third meeting will be held after this Plenary but it already looks the WG will need more time than expected to complete its tasks.

- Sample Preparation Procedure – WG-SPP

The WG chairman (G. Berben) updated the ENGL on the recently launched SPP WG (two meetings so far). He added that an existing CEN document from TC 327 on sample preparation for animal feedingstuffs will be very useful for the SPP WG.

## **2. Compendium of Reference Methods for GMO Analysis and GMO Methods Database**

The Secretariat explained that V1 of the Compendium (November 2010) was slightly revised in a V2 of the compendium in April 2011 (only minor and editorial corrections were included).

This V2 of the compendium is available on-line on the EURL website and was the basis for developing the new GMOMETHOD database which is also on-line on the EURL website since early May. A short demonstration of this new database was made.

The ENGL members welcomed the new GMOMETHOD database as a useful and user-friendly tool and asked questions about the updating of the database.

The chairman confirmed that the database will be updated regularly (and that date of the latest update should appear clearly on the website). He added that the list of EURL validated methods will remain as presently under 'status of dossiers' on the EURL website, in parallel with the new database.

## **3. Screening Methods**

S. Pecoraro from Germany made a presentation on the GMO Finder screening tool. It includes in particular information on the source/quality of data used in the database. More detailed information is available upon request.

D. Morrisset from Slovenia and I. Huber from Germany made two presentations on the GMOseek project (general overview and specific topics like multiplex screening method)

## **4. New Plant Breeding Techniques**

The Secretariat explained that a JRC report on New Plant Breeding Techniques (including the work of the New Techniques Task Force on detection composed of 8 ENGL members) was published early May and is available on the JRC website.

This JRC report will now be used by DG Sanco (together with other information like for instance an upcoming EFSA opinion on safety of New Techniques) to further discuss with the Member States future EU regulatory decisions on New Plant Breeding Techniques (eg to fall or not under EU legislation on GMOs).

## **5. International Harmonisation**

- Codex

M. Lema (Argentina) updated the ENGL on the CCMAS WG on GMO detection which he chaired and which concluded its activities in 2010. He explained that the final document now approved by Codex is quite general and has a broader scope than GMO detection per se. No revision of the document is foreseen but if need be specific Annexes to the document (eg on PCR detection) could be proposed.

- Biosafety Protocol

The Secretariat updated the ENGL on three recent Biosafety Protocol meetings in which, further to the COP-MOP5 meeting decisions of October 2010, the topic of GMO detection was addressed:

- IAC-BCH meeting (Montreal 29 March-1 April): agreement to integrate/link the upcoming JRC database on GMO Methods to the global BCH database
- Biosafety Training workshop on GMO detection for customs officials from Central and Eastern Europe region (Ljubljana 11-13 April): JRC presentation on ENGL experience on GMO analysis and achievements in harmonisation and ENGL members presentations on sampling and PCR
- EU BCH workshop (Berlin 12-13 May): JRC presentation on role of JRC as EU BCH national focal point and agreement that JRC and ENGL should discuss "EU input" on GMO detection to the global BCH (which information to be notified by whom?)

It was agreed to discuss the topic "submission of EU information on GMO detection to the global BCH" at the next ENGL SC meeting.

On international harmonisation, the Chairman added:

- A short update on two networking workshops on GMO analysis that were held in Mexico in March 2011 and will be held in Singapore in June 2011.
- A confirmation that the 2<sup>nd</sup> Global Conference on GMO analysis will not be held in 2012.

Finally M. Lema from Argentina made an announcement on the first international workshop on GM animals that will be held in Buenos Aires Argentina on 5-9 September 2011 (the last day will include discussions on various topics, including detection, and ENGL is invited to attend) – see details at <http://www.agrobiotecnologia.gov.ar/gmanimal2011/>.

The meeting was concluded by a presentation from the Secretariat on the Action List agreed upon in this 15<sup>th</sup> ENGL Plenary. Date of the next ENGL Plenary was also confirmed on 16-17 November 2011.

Finally the Chairman warmly thanked S. Tomasina, who has provided secretarial support for the organisation and logistics of the ENGL meetings for 3 years and who is now leaving the JRC.

# Annex II

## 16th ENGL Plenary Meeting Report



EUROPEAN COMMISSION  
JOINT RESEARCH CENTRE  
Institute for Health and Consumer Protection  
Molecular Biology and Genomics



Ispra, 30<sup>th</sup> November 2011

### 16th ENGL PLENARY (Ispra, 16-17 November 2011)

#### MEETING REPORT

#### DAY 1 - Wednesday 16 November AM

##### 1. Approval of the Agenda

The Chairman introduced the speakers and guests invited to participate to this 16<sup>th</sup> ENGL Plenary, including in particular members of the Global GMO Network Forum Steering Committee (N. Al Hmoud (Middle East), N. Campos Reales (Latin America), C. Viljoen (Africa)) and 8 representatives from the ASEAN GMF network who were participating to a Study Tour at JRC and attending partly the ENGL.

Apologies were received in particular from D. Zhang from China and from a research team from INRA France who had been invited to talk about GM rice and about cloned animals respectively.

The agenda was approved without addition.

##### 2. Debriefing of the Chairman

The Chairman first announced that beginning of 2012 he will take over a new position as "GMO Policy Adviser" and will relocate to the JRC in Geel, Belgium. However in practice this will have no impact on the chairmanship and functioning of the ENGL.

D. Plan reviewed the latest version of the ENGL Action List following the 15<sup>th</sup> ENGL Plenary meeting of May 2011 and the 21<sup>st</sup> ENGL SC meeting of October 2011.

The two main actions which are delayed are the upgrading of the ENGL website and the completion of the mandate of the Method Performance Requirements WG.

Regarding the ENGL website, the Chairman commented that the ENGL SC decided to establish an ad hoc task-force on this issue (composed of a few JRC staff and ENGL members) in order to get the upgraded ENGL website running by mid-2012. A call for interest to join this ad hoc Task Force will be circulated soon. The Chairman also commented that the preferred option would be to have an integrated EU-RL/ENGL website which would then be a "one-stop shop" website for GMO detection information.

The Secretariat also presented the ENGL 2012 Annual Work Programme (as discussed and approved by the ENGL SC) – see document on ENGLNet.

##### 3. ENGL Common Session

###### 3.1 Update on ENGL Working Groups

###### - Unauthorised GMOs – WG-UGM

The final text of the WG-UGM document is available on the EU-RL website since September 2011. The mandate of the WG-UGM is therefore completed. However formatting and publication of the document as a JRC report are still pending.

###### - Method Verification - WG-MV

The final text of the WG-MV document is available on the EU-RL website since July 2011. The mandate of the WG-MV is therefore completed. Publication of the document as a JRC is also completed (and hard-copies of the report were distributed at the ENGL Plenary)

- Method Performance Requirements - WG-MPR

The two co-chairmen of the WG-MPR (M. Mazzara and U. Marchesi) presented an update of the activities of the WG. The WG has been facing significant delays and completion of the mandate (initially foreseen in 2011) will be postponed to 2012. A 4<sup>th</sup> WG meeting could not yet be arranged.

The ENGL chairman invited the WG-MPR to organise its 4<sup>th</sup> WG meeting asap. If need be, this could be a two full days meeting in order to catch up with the work programme. This could possibly be done on 6-7 February (just before the next ENGL SC meeting).

- Sample Preparation Procedure – WG-SPP

The WG-SPP chairman (G. Berben) updated the ENGL on progress achieved by the WG-SPP following the latest meeting held in Ispra on 15<sup>th</sup> November. The WG is operating smoothly and further work will now continue electronically. A last meeting of the WG-SPP will be necessary early 2012 to finalise a document that could then be presented to the ENGL SC for approval (submission may therefore ideally take place at the next ENGL SC meeting in February 2012).

### **3.2 New ENGL Advisory Group on "Consideration and Selection for Validation of Detection Methods (Method Selection for Validation MSV)**

The Chairman introduced the mandate of this new "Advisory Group", which was proposed by A. Holst-Jensen and endorsed by the ENGL SC (the full mandate is included in the ENGL 2012 AWP. In short this AG will address validation of "other methods" than event-specific methods).

The Chairman added that the concept behind an "Advisory Group" was to have a more rapid and efficient operational structure than a standard ENGL WG.

He confirmed that a call for interest to join this Advisory Group will be circulated soon so that the group can start working asap (mainly through e-mails and phone calls).

### **3.3 FP 7 research project calls – discussions on possible ENGL proposals**

The Chairman explained that in the last years few projects related to ENGL activities could receive FP7 funding. However with new activities (related for instance to GM animals or New Plant Breeding Techniques) some funding may be available for the next round of FP7 projects (July 2012 publication). However any ENGL proposal would need to be submitted to DG RTD asap (by end November 2011).

He added that so far one proposal was received (from J. Zel and A. Holst-Jensen). This was distributed as "room document" and commented by various ENGL members.

During discussions, reference was made to further research needed on allergen detection (incl. possibly the need to have an EU-RL on allergens) and for which the ENGL experience would be useful. At this opportunity the chairman mentioned that mid-December he will attend a DG Sanco meeting involving all EU-RLs.

It was agreed to submit to DG RTD the proposal as commented by ENGL, as well as additional ideas like the ones related to allergen detection.

### **3.4 Compendium of Reference Methods and Methods Database – update from JRC**

The Chairman confirmed that work was on-going to update the Compendium and the Database presently available at <http://gmo-crl.jrc.ec.europa.eu/gmomethods/> and should be completed by end 2011.

The Chairman also presented an iPad version of the GMOMethods Database that was recently developed. iPad applications will also be developed for other existing EU-RL information tools (eg the EU-RL table on status of validation dossiers).

## DAY 1 - Wednesday 16 November PM

### 4. Session 1829/2003

#### 4.1 EU regulatory discussions (Chinese GM rice testing)

The Chairman announced that, further to various discussions between the Commission and the Member States, a new emergency measure on Chinese GM rice was finally adopted on Monday 14<sup>th</sup> November. This new Decision should be published around mid-December and will enter into force 20 days later (revision may take place after 6 months).

The key objective of this new Decision is to broaden the scope of the EU Decision to include detection of various GM rice events in addition to Bt63. The EU Decision accordingly refers to various detection methods (based either on TaqMan or on SyberGreen) with a broad scope of detection.

Three presentations on GM rice testing were made by Dr Maede from Germany, the JRC and Dr Piednoir from Belgium.

Dr Maede proposed in particular to create an ad hoc rice WG to keep collecting information on Chinese GM rice events. Some questions were also raised about the SyberGreen methodology since ENGL members are not familiar with it. A technical meeting would be welcome on this methodology.

After discussions, it was decided:

- to collect ENGL comments and to finalise asap (by 1<sup>st</sup> December) a new EU-RL guidance document on implementation of the new EU Decision on Chinese GM rice.
- to explore the possibility to organise a technical meeting for NRLs dedicated to the SyberGreen methodology and GM rice testing
- to establish a EU-RL WG on GM rice that will keep collecting info on Chinese GM rice, in particular ahead of a possible revision of the EU Decision in 6 months-time.

#### 4.2 International Harmonisation

The Chairman welcomed and introduced the 8 representatives from ASEAN who were participating to a Study Tour at the JRC and were joining the ENGL Plenary (Dr Lorn from Cambodia, Dr Namtini from Indonesia, Dr Kaur from Malaysia, Dr Eusebio from Philippines, Dr Phua and Dr Wang from Singapore, Dr Nittaya from Thailand, Dr Ham from VietNam)

Dr Wang from Singapore then made a presentation on the ASEAN GM Food Testing network (which is in place since 2004 and is coordinated by Singapore). Dr Wang highlighted the excellent collaboration ongoing between the ASEAN Network and the JRC (cooperation which may be formalised soon through the signature of a Memorandum of Understanding).

M. Mazzara updated the ENGL on the meeting of the ISO SC 16 that was held in Washington in October. Several ISO standards related to "methods for molecular biomarker analysis" will be either revised or developed in the next 2-3 years. By April 2012 a guidance document on 'preparation of DNA for specific applications' will also be prepared by the US and the EU (represented the JRC, ENGL input will therefore be collected in the coming weeks).

D. Plan updated the ENGL on the Biosafety Protocol. The latest actions have been to link the EU GMOMethods database with the Biosafety Protocol BCH and to register the EU-RL to the future BCH e-network of GMO labs.

Finally the Chairman updated the ENGL on the Global GMO Network Forum (GGNF) event that will be held in September-October 2012 in Brussels and will gather around 100 participants. Organisation of this important event will be further discussed in a meeting of the GGNF SC on Friday 18<sup>th</sup> November.

In the meantime regional networking workshops are planned in South Africa, Colombia and the Philippines in the first-half of 2012.

The Chairman also mentioned a training course on GMO detection that will be held in Cyprus in September 2012, in the frame of the Cyprus Presidency of the EU.

## DAY 2 - Thursday 17 November AM

### 4.3 GM animals

The Chairman introduced Dr Salamone from Argentina who participated to the first international workshop on GM animals that was held in September 2011 in Buenos Aires. Dr Salamone presented an overview on various techniques that are being used to develop GM animals (out of which cloning appears to be so far the most appropriate). Applications of GM animals would include molecular pharming, xenotransplantation, metabolism efficiency. However these techniques need to be improved and all regulatory approvals need to be obtained before commercial applications can take place.

The chairman concluded that next ENGL actions related to GM animals will be discussed at the next ENGL SC meeting.

## 5. Session 882/2004 (5<sup>th</sup> NRL workshop)

### 5.1 Detection of GM pollen in honey

Dr Waiblinger from Germany made a presentation on activities on-going in Germany regarding validation of a DNA extraction method from honey (a multi-lab ring trial will be organised in December). He highlighted that DNA extraction was a crucial step for DNA analysis from "difficult" matrices like honey. He added that quantification of GM pollen in total pollen was presently not possible and that, further to the recent European Court of Justice Judgement on honey, the German government will host a workshop on the topic in Berlin on 13-14 December 2011.

Various technical questions were asked to Dr Waiblinger. The DG Sanco representative added that the EU-RL was asked to work on the issue of detection of GM pollen in honey and that the regulatory implications of the European Court of Justice Judgement on honey still need to be confirmed.

The Chairman concluded that activities related to pollen detection on-going in Germany and at the EU-RL will need to be coordinated.

### 5.2 Quality

S. Trapmann from the JRC IRMM updated the ENGL on the activities of the Accreditation Task Force. A meeting with the European Accreditation body will take place in December. The Accreditation Task Force document should be finalised shortly afterwards and therefore should hopefully be ready for presentation to the ENGL SC in its February meeting.

Regarding Proficiency Testing, the EU-RL confirmed that reports on the latest CT rounds (which have been delayed) will be circulated asap.

D. Plan referred to the two NRL training sessions on "ISO 17025 accreditation" that were held in Ispra in March 2011 and in Bulgaria in September 2011. Since both courses were successful, similar trainings will be held in 2012. ENGL members willing to host such training sessions should inform the Secretariat.

He also referred to the upcoming EURL customers' satisfaction survey that will be run by end 2011. ENGL members are welcome to answer the (short) electronic questionnaire they will receive.

## 6. Conclusions

D. Plan presented the latest version of the ENGL Action list based on the 16<sup>th</sup> ENGL Plenary discussions.

On behalf of the ENGL (and ahead of his relocation to the JRC in Belgium), A. Burns from the UK thanked G. Van den Eede for his chairmanship of the ENGL over the years he was based in the JRC in Italy.

The Chairman confirmed that irrespective of his relocation he will be chairing the next ENGL Plenary (which is likely to be held in June 2012 in Ispra, but the final date still needs to be confirmed).





RIKILT - Institute of Food Safety is part of the international knowledge organisation Wageningen UR (University & Research centre). RIKILT conducts independent research into the safety and quality of food. The institute is specialised in detecting and identifying substances in food and animal feed and determining the functionality and effect of those substances.

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The research institute in Wageningen is the National Reference Laboratory (NRL) for milk, genetically modified organisms, and nearly all chemical substances, and is also the European Union Reference Laboratory (EU-RL) for substances with hormonal effects.

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