EUROPEAN NETWORK OF GMO LABORATORIES

CONSORTIUM AGREEMENT

Between

THE EUROPEAN COMMUNITY

And

THE NATIONAL LABORATORIES RESPONSIBLE FOR

THE ENFORCEMENT OF THE EU REGULATIONS

FOR GENETICALLY MODIFIED ORGANISMS

The European Community, hereinafter referred to as "the European Community", represented by the Commission of the European Communities, hereinafter referred to as "the Commission", represented for the purpose of signing this Agreement by Dr. Roland Schenkel, Director-General of the Joint Research Centre, hereinafter referred to as “the JRC”, through two of its institutes: the Institute for Health and Consumer Protection (JRC-IHCP) and Institute for Reference Materials and Measurements (JRC-IRMM),

On one part, and

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Hereinafter all together referred to as “The European Network of Genetically Modified Organisms Laboratories” (ENGL)

On the other part.

WHEREAS:

A) Having regard to ENGL Consortium Agreement Nr. "20126-2002-11 SOSC ISP BE" of 4th December 2002 instituting the European Network of GMO Laboratories, and the requirement to adapt it in the light of the acquired experience and of the adoption of overarching European legislation[1] – such as Regulation (EC) N° 1829/03[2] and Regulation (EC) N° 882/2004[3],

B) The mission of the JRC is to provide customer-driven scientific and technical support for the conception, development, implementation and monitoring of European Union policies. As a service of the European Commission, the JRC functions as a reference centre of science and technology for the Community. Close to the policy-making process, it serves the common interest of the Member States, while being independent of special interests, whether private or national.

The mission of the Institute for Health and Consumer protection (JRC-IHCP) is to protect the interests and health of the consumer in the framework of EU legislation on chemicals, food and consumer products. It works in close partnership with other EC Directorates-General by providing scientific and technical support from scientific research and analysis in its areas of competence.

The Molecular Biology and Genomics Unit of the JRC-IHCP is the JRC reference for the provision of scientific and technical support to policy development under the EC regulatory framework for Genetically Modified Organisms (GMOs) and for the development of biotechnology expertise in areas relevant to health and consumer protection. It exercises the mandates of the Community Reference Laboratory for GM Food and Feed under Regulation (EC) N° 1829/2003 and of the Community Reference Laboratory for GMOs under Regulation (EC) N° 882/2004.

The mission of the JRC-IRMM is to promote a common and reliable European measurement system in support of EU policies. The prime objective of the IRMM is to build confidence in the comparability of measurements by the production and dissemination of internationally accepted quality assurance tools, including reference materials, validated methods, reference measurements, inter-laboratory comparisons and training.

C) The primary purpose of the ENGL is to help solving the large number of challenges that the enforcement laboratories face in the field of Genetically Modified Organisms (GMOs) in food, feed, seeds and the environment.

D) In order to significantly enhance the capabilities of the ENGL and the JRC to fulfil their responsibilities with regard to Genetically Modified Organisms, the present Consortium Agreement provides for:

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[1] As defined in Directive of the Council 2001/18 on the deliberate release in the environment and the placing on the Market of Genetically Modified Organisms, and in Regulation of the European Parliament and of the Council N° 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

[2] Regulation (EC) N° 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of genetically modified food and feed.

[3] Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

– The organization of plenary meetings for exchange of experience with the technical implementation of the Community legislation related to Genetically Modified Organisms,

– The organization of working groups on topical issues for the Genetically Modified Organisms sampling and detection,

– Co-operative research, exchange of scientists, training;

– Technology transfer;

– Exchange of scientific literature.

E) Through the ENGL, under JRC chairmanship, a European system for scientific reference has been established for the purpose of harmonization and standardization within the EU, topical research and data exchange, and thus provides an additional tool for scientific advice within the European Union.

F) Each of the Parties of the ENGL has been designated as an official enforcement laboratory either by the:

– Competent Authorities operating under Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of Genetically Modified Organisms and repealing Council Directive 90/220/EEC; or

– Competent Authorities operating under Regulation (EC) N° 1829/2003; or

– Competent Authorities operating under Regulation (EC) N° 882/2004; or

– Competent Authorities operating under EU legislation on the marketing of seed of agricultural and vegetable plant species and of forest reproductive material[4].

G) Whereas the list of ENGL members is shown in Annex 1 of this Agreement and will be updated following modifications of the membership.

H) Whereas the present agreement does not entitle all European GMO laboratories to become an ENGL member, in particular those laboratories that have regional responsibilities, the ENGL members as contracting party to this agreement are entitled to share the ENGL information to those GMO laboratories, either public or private, associated to them. To that end they shall compile a list of associated laboratories and ensure confidentiality rules, similar to those included in the current Agreement, are implemented. The list of these associated laboratories is shown in the annex and will be regularly updated.

[4] Council Directive 2002/54/EC on the marketing of beet seed, Council Directive 66/401/EEC on the marketing of fodder plant seed, Council Directive 66/402/EEC on the marketing of cereal seed; Council Directive 2002/56/EC on the marketing of seed potatoes, Council Directive 2002/57/EC on the marketing of seed of oil and fibre plants, Council Directive 2002/55/EC on the marketing of vegetable seed, Council Directive 1999/105/EC on the marketing of forest reproductive material

The European Community and each Member of the ENGL hereinafter referred to as the Contracting Party, have agreed as follows:

Article 1

Scope and Objective

1.1 This Agreement replaces the ENGL Agreement Nr. "20126-2002-11" of 04 December 2002, and formalises the organization of the European Network of Genetically Modified Organisms Laboratories (ENGL), under the JRC chairmanship.

1.2 The general objectives of the ENGL shall be to:

a) Provide support to the Community Reference Laboratory defined in Regulation (EC) N° 1829/03 and Regulation (EC) N° 882/2004, or by any GMO legislation that would foresee such support.

b) Consolidate and improve at European level the harmonization and standardization of scientific methods for the identification and quantification of Genetically Modified Organisms as or in products produced from Genetically Modified Organisms.

c) Act as a network of scientific excellence on the detection and traceability of Genetically Modified Organisms and the related scientific issues.

d) Provide best practice information to worldwide stakeholders through international liaisons and set up an active communication policy.

Article 2

Membership, membership withdrawal and termination

2.1 This Agreement shall enter into force on July 1st, 2009 or on the date of countersignature by the Commission, whichever is later.

2.2 New Parties designated by National Competent Authorities operating under one of the Community Acts or under corresponding equivalent Regulations and Directives of EEA, EFTA member states and Candidate Countries and Potential Candidate Countries related to Genetically Modified Organisms (GMOs), may join the ENGL. Applications must be made in writing to the ENGL President who shall refer them to the Steering Committee pursuant to Article 6.8 for decision on the admission of the new Party to the ENGL.

This Agreement may be amended at any time, subject to the prior approval by the Steering Committee of the Contracting Parties' proposed amendments.

2.3 The list of ENGL members, annexed to the present Agreement, is made publicly available and is regularly updated according to article 6.8 f. Similarly, the list of laboratories associated to ENGL members, established on the basis of article 9.3, is annexed to the present Agreement and regularly updated by the contracting parties according to article 6.8 g.

2.4 Any Contracting Party may withdraw from the present Agreement by giving a six months' written notice to the President of the ENGL Steering Committee. Such withdrawal shall not affect the conclusion of activities that are in progress and the rights and obligations ensuing from them.

2.5 Any party registered as a member of the ENGL shall withdraw from this Agreement immediately (and immediately notify the President of Steering Committee in writing of the same), if it ceases to hold an appointment by the relevant Competent Authority as set out in recital [F] above.

2.6 Notwithstanding any other provision to the contrary and in particular Article 6.6 herein, the European Community may unilaterally terminate this Agreement at any time, if it has justifiable cause. In particular, the European Community may exercise its power of termination pursuant to the present Article if research programs and/or budget allocations are no longer compatible with the continuation of the Agreement and/or the work program, or if a Party to the ENGL has breached any provisions of the Agreement, and in particular Article 9 herein.

The European Community may exercise the said power of termination after giving one month's formal notice of its intention to do so.

2.7 With a view to signing an amendment to the Original Agreement as modified by its Amendments for the admission of a new Contracting Party and/or the termination of the Agreement for a Contracting Party, the Parties to the ENGL, hereby charge the President of the Steering Committee with the power to act on their behalf and execute such amendments which shall have the sole purpose of giving effect to decisions of the Steering Committee pursuant to Article 6.8 herein relating to the admission and/or termination of a Party from the Agreement. Subject to other provisions of this Agreement, all Parties to the ENGL agree to their representation by the President of the Steering Committee for this sole purpose.

Article 3

Work Program and Resources

3.1 In accordance with the objectives of this Agreement as outlined in Article 1 and on approval of its working program by the Steering Committee, Contracting Parties may undertake or participate in the following actions:

a) Where necessary, to provide advisory and/or technical support to the Community Reference Laboratory for GMOs in food and feed established by Regulation (EC) N° 1829/2003 and Regulation (EC) N° 882/2004.

b) The organization of Plenary Meetings and Working Groups;

– To initiate and maintain a dialogue on matters of Genetically Modified Organisms sampling, detection, identification and quantification, and screening for enforcement purposes;

– To explore possibilities for technical and financial co-operation for developing research projects of mutual interest;

– To design validation studies and proficiency schemes;

– To examine, discuss and interpret the results from the validation exercises and from data which may be obtained in control work;

c) The execution of on-going programs, projects and related activities that are satisfactory to the Contracting Parties, through the execution of *ad hoc* agreements to cover financial, technical, and legal matters as may be necessary.

d) The fair exchange of information and data.

3.2 Whenever possible the JRC-IHCP will provide the Contracting Parties with the full access to the available molecular data about the GMOs, their parental and taxonomically related organisms and where possible their breeding progeny.

3.3 The participation in all activities listed in Article 3.1 above, shall be on a voluntary basis according to the individual skills and functions of the Contracting Parties. Such participation shall further be subject to the availability of appropriate funds, personnel and other resources, as well as to the applicable laws and regulations, policies and programs of the Contracting Party.

3,4 The JRC shall allocate a specific budget for the costs of the organization of the ENGL and which costs shall be limited to the administrative functions of the organization. The JRC shall not be financially responsible for any direct or indirect research activities undertaken by the member laboratories. The JRC shall decide the budget allocation and the amount to be allocated for each administrative function of the ENGL on an annual basis.

Article 4

Responsibilities of the Parties

4.1 Each Contracting Party shall designate the necessary professional technical staff with the responsibility to facilitate and coordinate the various areas of collaboration agreed to by the Parties.

4.2 Each Contracting Party shall be responsible for its own personnel in the activities undertaken pursuant to this Agreement.

4.3 In the event that staff members from one or more of the Contracting Parties are required to participate for brief periods in the execution of programs, projects or activities being implemented by other Contracting Parties, such Parties shall conclude a separate agreement dealing with the secondment of staff to the concerned Parties. Such agreement shall regulate their mutual rights and obligations, as well as the conditions of co-operation to be fulfilled by the staff members and the terms under which the JRC and ENGL authorize their staff members to participate. Staff members involved in exchange programs or projects shall comply with the rules and working conditions of the host institution.

4.4 The Host Party shall assist, where possible, in meeting the personal and professional needs of the visiting staff member, including access to the institutional facilities.

Article 5

Plenary Meetings and Working groups of the contracting Parties

5.1 Plenary Meetings will be organized to discuss scientific issues, review the progress of the Work Program and evaluate the progress in the development of future programs and policies. The agenda and supporting documents for these Plenary Meetings should be distributed to the contracting Parties at least 15 days prior to the meetings.

5.2 The president of the Steering Committee shall convene the Plenary Meetings with the support of the ENGL Secretariat. Subject to approval by the Steering Committee, additional Plenary Meetings may be called, at the request of one or more ENGL Parties. These meetings shall be chaired by the President of the Steering Committee or his substitute.

5.3 The ENGL Secretariat shall distribute the minutes and resolutions of the Plenary Meetings within 10 working days. Amendments and comments to the draft will be collected from the contracting parties during the 10 working days after their distribution.

5.4 In the event of issues either requiring a further in depth discussion and analysis, or being of an urgent nature, '*ad hoc*' working groups.

Article 6

Steering Committee

6.1 The Steering Committee shall be chaired by the JRC, as Committee President. The Steering Committee is composed from one ENGL member per each Member State of the European Union or of the States to which the EEA or EFTA applies.

6.2 The Steering Committee member shall be selected by the members of the ENGL in each European Union or EEA or EFTA States by agreement between each other. One substitute per Steering Committee member shall be designated in the same manner. The selection shall be communicated in writing by the Steering Committee member to the President within 30 days from the entering into force of this Agreement.

6.3 The Steering Committee shall be appointed by the ENGL President in accordance with Article 6.

6.4. As soon as appointed, the Steering Committee shall discuss and approve the ENGL internal rules.

6.5 Supervision and co-ordination of the work undertaken by the ENGL shall be vested by the Steering Committee.

6.7 There shall be at least two meetings of the Steering Committee per year. The President of the Steering Committee shall convene the meetings.

6.8 The Steering Committee shall:

a) Manage the strategic operations of the ENGL;

b) Define and approve the annual working plan, install the appropriate working groups and set the deliverables and monitor the execution;

c) Take decisions in accordance with the responsibilities and duties established in the work program;

d) Ensure quality control;

e) Inform the Contracting Parties of all decisions taken during the meetings;

f) Make public the list of ENGL members defined in Article 2.3 and the updates thereof. To that purpose the Steering Committee shall have the power to add a party to the ENGL in accordance with Article 2.3 and 2.4 or to require a Party to withdraw pursuant to Article 2.5;

g) Approve the updates of the list of laboratories established on basis of article 9.3

h) Approve the agenda of the Plenary Meetings;

i) Approve the participation of non ENGL members [e.g. observers, speakers, etc.] to the ENGL meetings;

j) Approve the classification of the ENGL deliverables and documents.

6.9 The Steering Committee will make all efforts to agree by unanimity. If unanimity cannot be reached within a reasonable period of time, a Steering Committee Member or the President has the right to request a formal vote on a written proposal. In such an event, the President submits the written proposal to the members of the Steering Committee from the European Union Member states, EEA and EFTA countries, requesting their votes within 10 working days, one vote per said Steering Committee member. In exceptional cases, the President of the Steering Committee reserves the right to stipulate a shorter voting period. A decision is reached through a simple majority of the vote cast. In case of ballot, the President shall have a casting vote. Members either abstaining or voting against the proposal reserve the right to express their comments. These comments shall then form part of the report on the vote.

6.10 The ENGL Secretariat shall make available the minutes and agreed resolutions of the Steering Committee Meetings within 10 working days. Amendments and comments to the draft will be collected from Steering Committee members during 15 working days from their distribution.

6.11 The competencies of the Steering Committee are without prejudice to the JRC's powers under this Agreement, including, but not limited to terminating the Agreement for reasons of non-performance and to determine the consequences of such a termination.

6.12 Any changes to the membership done in accordance with Article 2 shall be communicated without delay to the President.

Article 7

ENGL Secretariat

7.1 The JRC shall act as Secretariat.

7.2 On behalf of, and in good agreement with the Steering Committee, the ENGL secretariat shall:

a) Handle the day-to-day management of the ENGL;

b) Receive and select the proposed items to be included in the agenda of the Plenary Meetings, the Steering Committee Meetings and of eventual break- out working groups;

c) Convoke the Steering Committee Meetings;

d) Produce minutes of the Steering Committee meetings;

e) Schedule and inform the Contracting Parties of the dates of the Plenary Meetings and any changes in the composition of the Steering Committee;

f) Be the channel for submitting all documents, for general liaison between the ENGL Parties and the Genetically Modified Organisms producing and/or distributing Companies;

g) Register all the information flows between the ENGL Parties and the JRC, in order to quantify performance based evaluations; and

h) On behalf of the Steering Committee, and in conjunction with the Contracting Parties where necessary, exchange information with national or international organizations performing work similar to that of the ENGL.

Article 8

Reports

The Steering Committee shall prepare reports on the activity of the Contracting Parties – constituted by the Minutes of the Meetings (Plenary, Steering Committee, *ad hoc*) and by a collection of the handouts – without prejudice to the preparation of more structured documents on a case-by-case basis.

Article 9

Confidentiality and Intellectual Property Rights

9.1 Unless otherwise specified according to Article 6.8-i, the data, information and material exchanged in the frame of the present Agreement, as well as the information resulting from the activities under this Agreement, shall be confidential by default.

9.2 In order to be able to receive information classified as confidential each Contracting Party shall implement the necessary measures to guarantee the confidential nature of the data information and/or material circulated, according to national regulations or national laws.

9.3 The Contracting Party may share all information distributed within ENGL with other GMO laboratories of their countries that have similar obligations as those stipulated in the current Agreement but that are not or cannot be nominated as a formal ENGL Member. The Contracting Party shall, prior to the signature of this Agreement, provide the list of associated public or private GMO laboratories and ascertain to safeguard the confidentiality obligations stipulated under the current Agreement. The lists shall be collated into a single list and annexed to the Agreement. It shall be regularly updated according to article 6.8 g.

For the purpose of updating the said Annex, each Contracting Party shall forward an updated list to the Steering Committee President identifying any additions or deletions of laboratories to which it may be linked by confidentiality obligations. Such list shall be provided to the Steering Committee immediately after a laboratory is deleted or added to its list.

9.4 In the event that a Contracting Party wishes to communicate sensitive information resulting from the activities under this Agreement through publication and/or public forums during the performance of this Agreement and for one year following the termination of the Agreement, it shall do so by formal request to the Steering Committee. The Steering Committee shall decide upon the method of communication within two months from the date of the request. The collaboration of the other Parties shall be acknowledged in any publication or public forum.

9.5 Unless otherwise stated by a specific written agreement established under this Agreement, the ownership of inventions, whether or not patentable, made or conceived whilst performing any activity under this Agreement shall belong to the Party employer of the Inventor. Where inventions are made or conceived by more than one Inventor having different employers, the invention shall be owned in common by the said Parties. Where inventions are patentable, the

patentee is the Owner by right. If the Owner waives its right to a Patent, the Owner must inform the other Party which shall be entitled to the rights derived from the application for a patent and from the patent itself.

9.6 The provisions of this Article shall survive the expiry of this Agreement for as long as a patent protects the inventions.

9.7 Contracting parties shall be subject to their statutory obligations under national law when acting under Article 9.

Article 10

Liabilities of the Contracting Parties

10.1 Any loss, damage or injury of non-nuclear origin suffered by one Contracting Party as a result of its own default – by its personnel or its agents in connection with the performance of this Agreement – shall be borne by such Party.

10.2 Each Contracting Party shall be liable for any loss, damage or injury of non-nuclear origin caused by itself, its personnel or its agents to third parties in their facilities arising out of the performance of the Agreement.

10.3 Each Party shall be solely responsible for any damages resulting from any fault, negligent acts, omissions or any other conduct by itself, its personnel or its agents giving rise to claims for damages by another Contracting Party and/or third parties arising out of the performance of this Agreement, and shall hereby indemnify each of the other Parties in respect of same.

10.4 Notification shall be given to each Contracting Party of any claim against the Community for which the a Contracting Party is, or may be, liable and such Contracting Party shall be given the opportunity to assume responsibility for its defence.

Article 11

No Partnership or Agency

Nothing in this Agreement shall be deemed to create a partnership or agency between the Contracting Parties. Each Contracting Party shall act on its own behalf and be solely responsible with regard to its personnel suppliers and subcontractors.

Article 12

Applicable Law

The present Agreement shall be regulated by the Belgian law.

Article 13

Competent Court

13.1 In case of dispute or difference between the Contracting Parties arising out of or in connection with this Agreement, the Parties shall first endeavour to settle the dispute amicably. Such effort shall be deemed to have failed when one of the Contracting Parties so notifies the other Party in writing.

13.2 The Court of First Instance of the European Communities, and in the case of appeal, the Court of Justice of the European Communities, shall have exclusive jurisdiction in any dispute between the JRC and the Parties to the ENGL concerning the validity, application and interpretation of this Agreement.

Article 14

Administrative Provisions

All correspondence concerning the performance of this Agreement shall be addressed as follows:

For administrative matters:

EUROPEAN COMMISSION - Joint Research Centre

Institute for Health and Consumer Protection

Management Support Unit

To the attention of the Head of Unit

I-21027 Ispra (VA) - Italy

For technical matters and for the Secretariat:

EUROPEAN COMMISSION - Joint Research Centre

Institute for Health and Consumer Protection

Molecular Biology and Genomics Unit– TP 331

To the attention of the ENGL Secretariat

Via Fermi, 1

I-21027 Ispra (VA) Italy

Article 15

Language of the Contract

This contract is drafted in one copy in the English language, which shall be the only authentic language of the contract.

Article 16

Signature of the Contract

EUROPEAN NETWORK OF GMO LABORATORIES

CONSORTIUM AGREEMENT

Between

THE EUROPEAN COMMUNITY

And

THE NATIONAL LABORATORIES RESPONSIBLE FOR THE ENFORCEMENT OF THE EU REGULATIONSFOR GENETICALLY MODIFIED ORGANISMS

For the European Commission, Signature

Done in Brussels on:.....
Dr. Roland Schenkel
Director General of the Joint Research Centre
European Commission

For the contracting Institution[5], Signature

Done in……on……..……

[5] *Institution, Address, Country, Represented for the purpose of signing this Agreement by(Title) Forename, Name, and function, Stamp of Institution if any*

Annex to be inserted to the Consortium Agreement of July, 1st, 2009 of the European Network of GMO Laboratories.

Article 1

In accordance to article 2.3 and 6.8 f) of the Consortium Agreement, the ENGL Steering Committee makes public and update the following list of member institutions of the European Network of GMO Laboratories.

(Here comes the list)

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(Here comes the list)

Article 2

In accordance to Articles 2.3, 6.8 g. and 9.3 of the Consortium Agreement, The ENGL Steering committee updates the following list of laboratories associated to ENGL member institutions.

(Here comes the list)