Annual report on Activities Performed by the UK NRL for GMOs in Feed and Food

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Provision of UK National Reference Laboratory Services for Genetically Modified Organisms in feed and food

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Glossary

CRM - Certified Reference Material

DNA - Deoxyribonucleic acid

EFSA - European Food Safety Authority

ENGL - European Network of GMO Laboratories

EURL - EU Reference Laboratory for GMOs in feed and food

FSA - Food Standards Agency

FVO - European Commission Food and Veterinary Office

GeMMA - genetically modified materials analysis

GMO - Genetically Modified Organism

IRMM - Institute for Reference Materials and Measurements

JRC – Joint Research Centre (Italy, Ispra)

NRL - National Reference Laboratory (nominated under Regulation (EC) 882/2004)

nrl - national reference laboratory (under Regulation (EC) 1829/2003)

OCL – Official Control Laboratory based in the UK

PA - Public Analyst

PAFF - Standing Committee on Plants, Animals, Food and Feed

PASS - Public Analyst Scientific Services

PCR - Polymerase Chain Reaction

PSP - Pre-Spotted Plate

SASA - Science and Advice for Scottish Agriculture

SC – Steering Committee

WG – Working Group

Role of the National Reference Laboratory

Commission Regulation (EU) 2017/625 (which replaced Commission Regulation (EC) 882/2004) seeks to remove variation in the way European Community legislation is implemented in different Member States. This regulation relates to official controls designed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The aim is to create an integrated and more comprehensive, risk-based, 'farm to fork' approach to official controls. The objective is to improve the consistency and effectiveness of controls across the EU and, as a consequence, raise standards of food safety and consumer protection.

The Regulation sets out the general approach that must be taken and the principles that must be adopted by the authorities in EU Member States with responsibility for monitoring and enforcing feed and food law. These include the competent authorities organising and undertaking official controls. The various central Government agencies and local authorities that are responsible for organising and undertaking official controls constitute the competent authorities and include (for food and feed) the Food Standards Agency, the Health and Safety Executive and the Department of Environment, Food and Rural Affairs (Defra).

Regulation (EU) 2017/625 also specifies requirements for certain specialised laboratories to provide the science that underpins regulation:

- Official Control Laboratories (OCLs): Central competent authorities designate official laboratories for the purposes of chemical analysis or microbiological examination of feed or food samples taken by enforcement practitioners (in the UK they are Public Analysts (PAs) and Agricultural Analysts (AAs)).
- National Reference Laboratories (NRLs): In order to provide technical and scientific support for the official control framework, the European Commission has created a network of National Reference Laboratories (NRLs) co-coordinated by European Union Reference Laboratories (EURLs).
    - EURLs are appointed by the European Commission. They provide the Commission with scientific and technical assistance. They are responsible for providing NRLs with details of analytical or diagnostic methods, including reference methods, and co-coordinating their application (in particular by organising comparative testing). They conduct training courses for NRL staff and keep them up to date in their field of expertise. They also coordinate practical arrangements needed to apply new analytical/diagnostic methods.
    - NRLs: Each Member State must designate an NRL to correspond to each EURL. NRLs must collaborate with the EURLs in their particular area of expertise and disseminate nationally information provided by the EURLs. They are responsible for co-coordinating the activities of OCLs and should, where appropriate, organise comparative tests between them. In addition, they provide scientific and technical assistance to the central competent authorities.

The responsibilities and tasks of NRLs are specified in Article 101 of Regulation (EU) 2017/625. National reference laboratories shall, in their area of competence:

a) Collaborate with the European Union reference laboratories, and participate in training courses and in inter-laboratory comparative tests organised by these laboratories;

b) Coordinate the activities of official laboratories designated in accordance with Article 37(1) with a view of harmonising and improving the methods of laboratory analysis, test or diagnosis and their use;
c) Where appropriate, organise inter-laboratory comparative testing or proficiency tests between official laboratories, ensure an appropriate follow-up of such tests and inform the competent authorities of the results of such tests and follow-up;
d) Ensure the dissemination to the competent authorities and official laboratories of information that the European Union reference laboratory supplies;
e) Provide within the scope of their mission scientific and technical assistance to the competent authorities for the implementation of MANCPs referred to in Article 109 and of coordinated control programmes adopted in accordance with Article 112;
f) Where relevant, validate the reagents and lots of reagents, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents;
g) Where necessary, conduct training courses for the staff of official laboratories designated under Article 37(1); and
h) Assist actively the Member State having designated them in the diagnosis of outbreaks of foodborne, zoonotic or animal diseases or of pests of plants and in case of non-compliance of consignments, by carrying out confirmatory diagnoses, characterisation and epizootic or taxonomic studies on pathogen isolates or pest specimens.

For the 2019-2020 period, the EURL did not publish an annual work programme.

NRL duties include advising the competent authority (FSA, Defra, Chemicals Regulation Directorate and Veterinary Medicines Directorate), and OCLs on sound measurement science and appropriate sampling methods.

LGC has maintained the position for the UK National Reference Laboratory for Genetically Modified Organisms (GMOs) in feed and food since the inception of the position in 2009, following open competitive tenders in 2009, 2013 and 2017. LGC's appointment by the Food Standards Agency on behalf of the European Commission is under Regulation (EU) 2017/625, which aims to remove variation in the monitoring and enforcement of feed and food law across the European Union. As the National Reference Laboratory for GMOs, LGC conducts the following activities, as specified in the contract with the FSA:

Core Function
Objective 01 – Secretariat Service (Core Function A)
Objective 02 – Advice and Representation within the UK/EU (Core Function B)
Objective 03 – Production of Standard Operating Procedures, Codes of Practice and Guidance Documents (Core Function C)
Objective 04 – Compliance Assessment via audits and ring trials (Core Function D)
Objective 05 – Co-ordination within the UK of EURL initiatives (Core Function E)
Objective 06 – Communication of results and data use (Core Function F)

Additional Tasks
Objective 07 – Additional services and Tasks (as detailed in Annex I of the invitation to tender)

Core Function

Production of the NRL annual report

This report details the activities carried out during the 11th year of the NRL operation (April 2019-March 2020) in relation to the duties of the NRL.

OBJECTIVE 01 - SECRETARIAT SERVICES - (CORE FUNCTION A)

Tasks:

- **Disseminating information/advice supplied by the EURL and its working groups to the FSA, OCLs and other relevant laboratories in a timely and effective manner.**
- **Creating and maintaining an efficient two-way channel of communication with OCLs and relevant laboratories and the EURL, including disseminating information on analytical methods and EU Regulations to OCLs and feedback of comments from OCLs to the EURL.**
- **Providing regular updates to the FSA on NRL activities, and up-to-date information on UK OCLs and other relevant laboratories to the FSA as requested.**
- **Creation and maintenance of a dedicated website for communication of the work of the NRL including provision of advice and support to OCLs, information on methods of analyses, SOPs, latest developments and other background information.**

Example activities in relation to these Tasks:

- Compiled and submitted the NRL Annual Report 2018/2019;
- Distributed an E-mail to the FSA and all UK OCLs regarding the publication of the ENGL report on "Detection of food and feed plant products obtained by new mutagenesis techniques". The NRL fed into this report. The report reviews the state of the art of GMO analysis and outlines some of the challenges associated with detecting products arising from gene editing;
- Distributed the official EURL-GMFF report to the 36th ENGL SC meeting held in February 2019 at the JRC (Ipsra) site, to all UK OCLs and UK ENGL members;
- Wrote and distributed the LGC summary report to the 37th ENGL Steering Committee meeting held in June 2019 at the JRC (Ispra) to the FSA and all UK ENGL members;
- Distributed the official DG-SANTE guidance note (ref: SANTE/E3/AT/nn (2019) 3564027) regarding reporting of GM quantitative events to the FSA and all UK ENGL members;
- The NRL attended the 30th ENGL plenary meeting held at the JRC (Ispra) in October 2019;
- Wrote and distributed the LGC summary report to the 30th ENGL plenary meeting held in October 2019 at the JRC (Ispra) to the FSA and all UK ENGL members;
- Distributed the official EURL-GMFF report to the 30th ENGL plenary meeting held in October 2019 at the JRC (Ipsra) site, to all UK OCLs and UK ENGL members. The official report was released in January 2020.

OBJECTIVE 02 - ADVICE AND REPRESENTATION WITHIN THE UK/EU - (CORE FUNCTION B)

Tasks:

- **Providing impartial expert advice as requested to the FSA, OCLs and other relevant laboratories on analytical methodology in the context of Official Controls.**
- **Representing the UK at relevant EURL meetings, and its working-groups, consulting the FSA on objectives and requirements before each meeting and providing the FSA with an internal report of the meeting within two weeks of each meeting.**
- **Participating in activities organised by the EURL and contributing to the scientific input at EURL meetings and in manner which supports UK policy based on best available scientific knowledge.**
- **Advising the FSA, OCLs and other relevant laboratories on best scientific practice in testing for Official Controls and undertaking activities in consultation with the FSA that facilitate and promote their application in the UK within the policy aims of the FSA.**
- **Keeping abreast of and advising the FSA, OCLs and other relevant laboratories of developments for the sampling, testing and detection of analytes.**
- **Identifying and informing the FSA, OCLs and other relevant laboratories of emerging analytical issues or developments at a national, European or international level and recommending action to address them.**

During the April 2019 to March 2020 period, the NRL received and responded to 32 individual enquiries as part of the NRL function. This included 24 enquiries from the FSA as the Competent Authority, 4 enquiries from UK OCLs and 4 enquiries from EURL/UK stakeholders (including other UK ENGL labs and Defra). As with the previous reporting period, the duration and complexity of a number of enquires was significantly increased, mainly due to the intricacy of the enquiries related to EU exit and the likely impact upon UK science.

Example activities in relation to these Tasks:

Received and responded to 23 individual enquiries from the FSA.
Example advice provided:

- At the request of the FSA, attended and set up a number of meetings to discuss UK analytical capability post EU exit. Meetings included in-depth discussions regarding withdrawal of EURL services and lack of access to advice, technologies, reference (control) materials, pre-spotted screening plates, databases, networking and methods currently provided by the EURL. Discussions also included possible pipelines for the authorisation of new GMOs for commercial release in the UK, reviewing the current EU authorisation procedure, length of assessments, costs, and capacity/capability to conduct both intra and inter lab method validation;
- Received a query from the FSA in relation to access to EURL based services following a letter from the EC that had been distributed to Competent Authorities regarding EU exit. The NRL responded raising concerns over access to advice, technologies, reference materials, databases and emergency methods for the detection of GMOs, once services currently provided by the EURL were withdrawn;

- Communicated to the FSA a letter from DG-SANTE (ref: SANTE/E3/AT/nn (2019) 3564027) which provided guidance and clarification on reporting results from GMO analyses when two or more events may be present. The guidance addresses the quantification of results from single and stacked events. Following confirmation from the FSA the guidance was also distributed to the UK OCL network;
- The NRL attended a meeting at the FSA (Clive House, St James' Park, London) and provided in-depth advice on issues associated with the GM and Feed Additives authorisation procedure post EU exit;
- Responded to a request from the FSA in relation to UK OCL GMO analytical capability;
- Organised a teleconference with the FSA to discuss outcome of the 30th ENGL plenary meeting and attendance at forth coming UK/NRL and ENGL related meetings in view of EU exit. Further discussions were held with the FSA in relation to UK GMO analytical capability and GMO authorisation procedure in the UK post EU exit;
- Upon a request from the FSA, the UK NRL provided a list of benefits associated with continued UK participation in EURL-GMFF led Comparative Tests scheduled for the UK transition/implementation period of EU exit.

Received and responded to 4 individual enquiries from Official Control Laboratories.
Example advice provided:

- Provided advice to a UK OCL regarding testing for GM *Bacillus subtilis* in relation to production of feed additives as well as providing advice on any laboratories that offer the test;
- Received an official invitation to the 15th NRL workshop and 30th ENGL plenary meeting scheduled for the 30th September to the 2nd October 2019 inclusive. Circulated an E-mail round to all UK OCLs asking for any training requests which could be raised at the meeting;
- Received a request from a UK OCL regarding the utilisation of a Bt63 test and availability of plasmid control material suitable for use within the scope of ISO 17025 accreditation.

Received and responded to 4 individual enquiries from additional sources (e.g. other UK ENGL labs, Defra, etc.)
Example advice provided:

- Advice was provided to a UK ENGL member regarding ENGL membership in lieu of EU exit, access to EURL services and maintenance of ISO 17025 accreditation for GMO analysis;
- Provided advice to a UK ENGL member in relation to likelihood of being asked to participate in the EURL led Comparative Tests in 2020 during the UK transition/implementation period for EU exit.

OBJECTIVE 03 - PRODUCTION OF STANDARD OPERATING PROCEDURES, CODES OF PRACTICE AND GUIDANCE DOCUMENTS - (CORE FUNCTION C)

Task:

- **Contributing to the development of standardised operating procedures, relevant codes of practice and guidance documents for use by OCLs and other relevant laboratories, as requested by the FSA.**

Activities in relation to these Tasks:

- The UK NRL contributed as a recognised author on the published European Commission guidance document entitled "Overview and recommendations for the application of digital PCR" (ISBN 978-92-76-00180-5; ISSN 1831-9424; doi:10.2760/192883). This technical report, published by the Joint Research Centre, provides guidance and recommendations for establishing dPCR capability in an analytical testing environment, with a focus on quantitative analysis of GMOs. Link: http://publications.jrc.ec.europa.eu/repository/bitstream/JRC115736/overview_applicationdpcr_engl_online.pdf
- The UK NRL is a task leader within the ENGL Working Group on DNA extraction. The Working Group aims to provide a guidance document on the selection of DNA extraction methods and their scope for specific food and feed matrices in the frame of official controls. LGC is responsible for leading on the task associated with webspace development, including drafting a searchable online table of experiences associated with DNA extraction from experts, as well as drafting guidance for the maintenance and curation of the table, a guide on how to use it and to identify any trends;
- Attended the ENGL Working Group meeting for DNA extraction at the JRC (Ispra) to further formulate guidance on DNA extraction from difficult matrices. Invited as a Task Leader to provide an update on progress of the Working Group at the ENGL meeting;
- The UK NRL has continued input into the revision of the EU publication "Guidance document on Measurement Uncertainty for GMO Testing Laboratories" as a recognised author. The publication is due out later this year.

OBJECTIVE 04: COMPLIANCE ASSESSMENT VIA AUDITS AND RING TRIALS - (CORE FUNCTION D)

Tasks:

- **Ensuring consistency and quality of testing approaches applied by UK OCLs and other relevant laboratories, including advising on corrective action following adverse reports on OCLs from UKAS**
- **Co-ordinating training exercises to promote best laboratory practice in respect of analysis**
- **Participating in proficiency tests and method validation studies organised by the EURL, informing the FSA of the results and implementing any corrective measures required**

Example activities in relation to these Tasks:

- Participated in and submitted results for the 19th EURL Comparative Test (ILC_EURL_GMFF_CT_01_19). Received Z-scores of -0.3 and 0.0 for the two maize events of Maize NK603 and Maize DP4114 respectively, which were both successfully detected and quantified in the samples. This round represented the first reporting round the Applied Biosystems™ QuantStudio™ 7 Flex Real-Time PCR System under ISO 17025 accreditation. Results were communicated to the FSA;
- Participated in and submitted results for the 20th EURL Comparative Test (ILC_EURL_GMFF_CT_02_19). Received Z-scores of 0.3, 0.6, 1.9 and 0.3 for the events of Soya 40-3-2, Soya MON87708, Cotton GHB119 and Soya DAS-44406 respectively, which were all successfully detected and quantified in the samples. Results were communicated to the FSA. This was a completely blind sample, reflecting the increased complexity of EURL Comparative Tests, and the first time a GM cotton event had been included (whereupon only 22 out of 70 participant labs reported a result for this event).

OBJECTIVE 05 - CO-ORDINATION WITHIN THE UK OF EURL INITIATIVES - (CORE FUNCTION E)

Task:

- **Archiving of Standard materials (Control Materials) provided by the EURL**

Example activities in relation to these Tasks:

- The NRL continues to maintain a dedicated physical and electronic register for control materials held in a secure cold room.
- Received, registered and archived the following new ENGL control plasmids:
    - Cotton DSA 81910-7
    - Cotton GHB811
    - Maize MON87419-8
    - Soya GMB151
- A full list of the registered ENGL plasmid control materials is provided in Annex 2.

OBJECTIVE 06 - COMMUNICATION OF RESULTS AND DATA USE - (CORE FUNCTION F)

Tasks:

- **The Contractor shall ensure that the FSA receives regular updates of any developments related to the core functions of the NRL.**
- **The Contractor shall notify the FSA immediately by email of any deviations which may affect the cost, specifications and timing of the annual work programme.**
- **The Contractor shall notify the FSA immediately by email of any unusual occurrences resulting from any of the core functions of the NRL.**
- **The Contractor shall provide interim reports during the annual work programme.**
- **Provide an internal report of meetings with other organisations (such as Official Control Laboratories, the EU-RL and ENGL) within 10 working days.**
- **Any results or reports arising from the work of the NRL will not be communicated to any external parties without the written permission of the FSA.**
- **The use of the data for presentations and / or papers will not be permitted unless written permission has been sought and given by the FSA.**
- **The Contractor will maintain records for a period of 3 years from the end of the contract.**
- **In other work related to the core functions of the NRL the specified deadlines agreed between the FSA and the Contractor should be met.**
- **If necessary, at the end of the Contract all information and data gained from, and required for, NRL function over the course of the Contract will be handed over to the FSA. This will include assisting with transfer of archived reference materials.**
- **The Contractor will keep the NRL website up to date on developments, relevant information (especially to the OCLs) and the work of the NRL.**

Example activities in relation to these Tasks:

- The UK NRL is in constant contact with the FSA by E-mail and phone in relation to queries, updates, developments and deliverables;
- The UK NRL is available for provision of advice on GMO analysis to all UK OCLs by E-mail, phone and face-to-face meetings where appropriate;
- Summaries on all ENGL plenary meetings that the UK NRL attends are supplied to all UK OCLs and the NRL is fully contactable in order to provide further details on each meeting as is necessary;
- Full meeting reports for the ENGL plenary and NRL annual meetings and summaries of the ENGL SC meetings are provided to the FSA;
- The NRL routinely organises, hosts and chairs the annual National Reference Laboratory Liaison Meeting with the FSA.

ADDITIONAL TASKS

OBJECTIVE 07:- ADDITIONAL SERVICES AND TASKS (as detailed in Annex I of the invitation to tender)

Tasks:

- **If required, assist the EURL in testing and validating the methods of detection for GMOs, when necessary.**
- **Participate and contribute to the scientific input at meetings, e.g. the European Network of GMO Laboratories (ENGL) meetings, and working groups in a manner which supports UK policy on GMOs based on best available scientific knowledge.**

Example activities in relation to these Tasks:

- The NRL hosted the annual FSA-NRL liaison meeting for the GMO and Feed Additive positions at LGC in July 2019;
- The NRL hosted an additional FSA-NRL liaison meeting for the GMO and Feed Additive positions at LGC in January 2020;
- The UK NRL attended a two day workshop on dPCR accreditation for GMO analysis and use of conversion factors from copy number/copy number to mass/mass reporting units, at the JRC (Geel). The UK NRL was one of the expert participants invited to give a presentation on the subject area in addition to participating in the workshop;
- The NRL represented the UK at the 37th European Network of GMO Laboratories (ENGL) Steering Committee meeting, held at the JRC (Ispra) in June 2019;
- The NRL attended the 30th ENGL plenary meeting held at the JRC (Ispra) in October 2019.

Annex 1: Additional links to NRL annual reports and Newsletters

Copies of previous GMO NRL annual reports and Newsletters are freely available to download from the UK GMO-NRL webpages at: https://www.lgcgroup.com/what-we-do/national-laboratory-and-government-roles/national-laboratory-roles/national-reference-laboratories/ .

Annex 2: List of ENGL Control materials housed by the NRL

GM	Species	ENGL plasmid no.
Event 558 (GMM)	Bacillus Subtilis	pENGL-00-EM-01/18-01
281-24-236	Cotton	pENGL-00-14/05-01
3006-210-23	Cotton	pENGL-00-14/05-01-B
COT102	Cotton	pENGL-00-05/16-01
DAS 81910-7	Cotton	pENGL-00-06/16-01
GHB119	Cotton	pENGL-00-04/11-01
GHB614	Cotton	pENGL-00-14/07-01
GHB811	Cotton	pENGL-00-04/18-01
LL25	Cotton	pENGL-00-13/04-01
MON1445	Cotton	pENGL-00-15/04-01
MON15985	Cotton	pENGL-00-24/04-01
MON531	Cotton	pENGL-00-16/04-01
MON88701	Cotton	pENGL-00-01/13-01
MON88913	Cotton	pENGL-00-05/07-01
T304-40	Cotton	pENGL-00-05/11-01
GM Strain AG3139	E.coli	pENGL-00-04/08-01
GM Strain 19E	E.coli K-12	pENGL-00-06/08-01
3272	Maize	pENGL-00-03/06-01
5307	Maize	pENGL-00-07/11-01
59122	Maize	pENGL-00-03/05-01
Bt11	Maize	pENGL-00-10/07-01
Bt11	Maize	pENGL-00-12/05-01
BT176	Maize	pENGL-00-18/04-01
DAS-40278	Maize	pENGL-00-10/10-01
DP-4114	Maize	pENGL-00-02/14-01
GA21	Maize	pENGL-00-15/05-01
GA21	Maize	pENGL-00-29/04-01
LY038	Maize	pENGL-00-01/06-01
MIR162	Maize	pENGL-00-08/08-01
MIR604	Maize	pENGL-00-04/05-01
MON810	Maize	pENGL-00-25/04-01
MON863	Maize	pENGL-00-01/04-01
MON87403	Maize	pENGL-00-02/15-01
MON87411	Maize	pENGL-00-01/15-01
MON87419-8	Maize	pENGL-00-02/17-01
MON87427	Maize	pENGL-00-03/12-01 MON87427
MON88017	Maize	pENGL-00-16/05-01
MON89034	Maize	pENGL-00-06/06-01
MZHG0JG	Maize	pENGL-00-04/16-01
MZIR098	Maize	pENGL-00-04/17-01

GM	Species	ENGL plasmid no.
NK603	Maize	pENGL-00-27/04-01
T25	Maize	pENGL-00-08/04-01
T25	Maize	pENGL-00-08/04-01
TC1507	Maize	pENGL-00-02/04-01
VCO	Maize	pENGL-00-07/12-01
DP73496	Oilseed rape	pENGL-00-02/12-01
MON88302	Oilseed rape	pENGL-00-09/11-01
Ms1	Oilseed rape	pENGL-00-11/04-01
Ms11	Oilseed rape	pENGL-00-03/16-01
Ms8	Oilseed rape	pENGL-00-06/04-01
Oxy-235 genomic DNA	Oilseed rape	Oxy-235 oilseed rape
Rf1	Oilseed rape	pENGL-00-09/04-01
Rf2	Oilseed rape	pENGL-00-10/04-01
Rf3	Oilseed rape	pENGL-00-07/04-01
RT73	Oilseed rape	pENGL-00-26/04-01
T45	Oilseed rape	pENGL-00-14/04-01
Topas 19/2	Oilseed rape	pENGL-00-12/04-01
EH92-527-1	Potato	pENGL-00-09/05-01
Bt63	Rice	pENGL-00-EM02/06/01
40-3-2	Soybean	pENGL-00-08/05-01
A2704-12	Soybean	pENGL-00-13/05-01
A5547-127	Soybean	pENGL-00-01/08-01
CV127	Soybean	pENGL-00-01/09-01
DAS44406-6	Soybean	pENGL-00-01/12-01 DAS44406-6
DAS-68416-4	Soybean	pENGL-00-11/10-01
DAS81419-2	Soybean	pENGL-00-03/13-01 DAS81419-2
DP-305423-1	Soybean	pENGL-00-07/07-01
DP-356043-5	Soybean	pENGL-00-04/07-01
FG72	Soybean	pENGL-00-04/10-01
GMB151	Soybean	pENGL-00-01/18-01
MON87460	Soybean	pENGL-00-04/09-01
MON87701	Soybean	pENGL-00-05/09-01
MON87705	Soybean	pENGL-00-01/10-01
MON87708	Soybean	pENGL-00-02/11-01
MON87751	Soybean	pENGL-00-03/14-01
MON87769	Soybean	pENGL-00-07/09-01
MON89788	Soybean	pENGL-00-05/06-01
SYHT0H2	Soybean	pENGL-00-04/12-01
H7-1	Sugar beet	pENGL-00-28/04-01
MON71200	Wheat	pENGL-00-EM-02/18-01