

# AMENDMENTS TO THE ARTICLE 36 LIST OF ORGANISATIONS

## SUMMARY

Commission Regulation (EC) No 2230/2004<sup>1</sup> foresees that the “*Authority’s Management Board, acting on a proposal from the Executive Director, shall draw up the list of competent organisations*” (Art.2(2)) and that “*the list shall be updated regularly, on the basis of proposals from the Authority’s Executive Director, taking account of reviews or new designation proposals from the Member States*” (Art.2(4)).

Organisations are “*designated by the Member States on the basis of criteria*”<sup>2</sup>. In accordance, new designations of competent organisations to be included on the Article 36 List, as well as substantial changes to organisations already included on the List, need to be endorsed by the Management Board.

The Management Board is presented with the updated Article 36 List, for possible adoption (Annex I), following:

- Member States’ designations of **7** new organisations for inclusion on the List.

In addition, the Management Board is informed of:

- withdrawals of **6** previously designated organisations from the Article 36 List;
- technical changes adopted by the Executive Director in his Decision dated 05/09/2016 (Annex II).

The updated Article 36 List, including all changes, is herewith presented for the adoption of the Management Board.

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<sup>1</sup> Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority’s mission (OJ L 379, 24.12.2004, p. 64–67)

<sup>2</sup> The criteria the designated organisations have to meet can be described as follows, ref. Commission Regulation (EC) No 2230/2004, Art.1(1):

- A. They must “carry out scientific and technical support tasks in the fields within the mission of the European Food Safety Authority”;
- B. They must be “legal entities pursuing public interest objectives” and be able to ensure that the “tasks entrusted to them by the Authority will be performed with independence and integrity”;
- C. They must “possess a high level of scientific or technical expertise in one or several fields within the Authority’s mission”;
- D. They must “have the capacity to operate in a network on scientific actions”.

## AMENDMENTS TO THE ARTICLE 36 LIST OF ORGANISATIONS

The Article 36 List was initially drawn up by the Decision of the Management Board of 19 December 2006, following the procedure set out in Commission Regulation (EC) No 2230/2004. The Article 36 List is regularly reviewed by the Member States for new designation proposals, deletions and changes to organisations included on the List.

### I. New designations for the Article 36 List

The Permanent Representations to the EU of Belgium, Finland, France, Norway, Portugal and the United Kingdom have officially notified EFSA of new designation proposals for inclusion in the Article 36 List of the following competent organisations:

Belgium (1):

#### **Hasselt University (Universiteit Hasselt)**

Type of organisation: University / Academic organisation

Mission of the organisation and task corresponding to EFSA's remit: Hasselt University has a pronounced regional, national and international orientation. Academic and scientific freedom, social engagement and attention for ethical standards are the basic principles of Hasselt University's research and education policy. Hasselt University was the first Flemish university to obtain the "HR Excellence in Research" label of the European Commission in 2011. In April 2016, Hasselt University's excellence in academic education and in well-defined research domains has resulted in a top 7% ranking in the second edition of U-Multirank (a new multi-dimensional, user-driven approach to international ranking of higher education institutions).

The Center for Statistics (CenStat) at Hasselt University has a long-standing expertise in biostatistics, bioinformatics and epidemiology, including the design of surveys and experimental studies; data processing and management; missing data methods; longitudinal, hierarchical and clustered data models; Bayesian models; simulation models; mathematical and statistical models for quantitative risk assessment; probabilistic models, growth models; dose response model; benchmark dose estimation; prevalence estimation, risk identification, risk factor and risk prediction models; antimicrobial, multidrug resistance; spatio-temporal modelling; disease mapping; data mining; machine learning; pattern recognition; statistical learning methods (supervised and unsupervised); classification methods; diagnostic and prognostic models; infectious disease models; transition and spread models; etc. including use and code development in software such as SAS, MatLab, R, user friendly web application interface software such as Shiny etc. Also CenStat's education and training track records are excellent, offering well-balanced, fine-tuned education with face-to-face lectures, practical work, and papers within the international master of statistics and on-site training.

Financial information: About 94% of the annual budget is covered by public funding (79% from governmental sources), less than 6% from private sources.

Finland (1):

**Natural Resources Institute Finland (Luonnonvarakeskus, Luke)**

Type of organisation: Governmental organisation

Mission of the organisation and task corresponding to EFSA's remit: Natural Resources

Institute Finland (Luke) is a governmental research institute operating under the Ministry of Agriculture and Forestry. Luke also has a role of a statistical authority referred to in the Statistics Act. Main tasks are: scientific research and development activities, produce information and expert services in support of societal decision-making and actions by public authorities, knowledge and technology transfer, produce statistics, maintain registers and to manage tasks relating to the preservation of the diversity of genetic resources and promote international cooperation. Luke is the second biggest research institute in Finland and one of the most multi-disciplinary research institutes worldwide.

Luke concentrates on new bio-based products and new business activities, productivity through digital solutions, revitalising regions through the circular economy, wellbeing from immaterial values and healthy and profitable food production. Among research priorities are Boreal Green Bio-economy, Innovative Food Chain, Blue Bio-economy and BioSociety.

Financial information: Over 94% of the annual budget is covered by public funding (71% governmental and 23% from other public sources, e.g. regional/local and EU/international), and 6% from private sources.

France (1):

**Université de Bretagne Occidentale**

Type of organisation: University / Academic institution

Mission of the organisation and task corresponding to EFSA's remit: The Université de

Bretagne Occidentale (UBO) aims to promote its research activity on the basis of academic excellence and national and international recognition by building upon scientific developments, innovating and transmitting knowledge, and emphasising the quality of education it provides. UBO is a multidisciplinary pool with national and internationally renowned research, spread between 37 research units, 16 of which are associated with major organizations, such as CNRS (Centre national de la recherche scientifique /National Centre for Scientific Research), INSERM (Institut national de la santé et de la recherche médicale / National Health and Medical Research Institute), IRD (Institut de recherche pour le développement / Research Institute for Development) and IFREMER (Institut français de recherche pour l'exploitation de la mer / French Institute for the Exploitation of the Sea).

Interdisciplinary research is structured according to four major scientific fields: i) Marine Sciences, ii) Health and Agro-environment, Materials, iii) Maths-STIC [Science and Technology for Information and Communication] and iv) Humanities and Social Sciences. UBO's research integrates within the local Breton socio-economic structure (of schools, industry and institutes) in order to develop cutting edge research in Brittany. Following main areas of expertise concerning moulds and sporulated bacteria associated with agri-food products: biodiversity (taxonomy, typing...), dynamic (follow-up of microbial population along the food process and storage), physiology (cardinal values, predictive microbiology), function (negative impact e.g. mycotoxins, off-flavours, positive impact: aromas formed by starter culture), control (impact of thermal and athermal treatments, bioprotective cultures). Fields concerning toxicology and chemical risk assessment include hazard analysis, exposure analysis and risk analysis on toxins and contaminants.

Financial information: About 89% of the annual budget is covered by public funding (77% from governmental sources) and 11% from private sources.

Norway (1):

### **Norwegian Institute of Public Health**

Type of organisation: Public Institute

Mission of the organisation and task corresponding to EFSA's remit: The Norwegian Institute of Public Health (NIPH) acts as a national competence institution for governmental authorities, the health service, the judiciary, prosecuting authorities, politicians, the media and the general public on issues related to forensic science, physical and mental health, prevention of communicable diseases and prevention of harmful environmental influences. The NIPH is a governmental institution placed directly under the Ministry of Health and Care Services. The Institute is organised in four scientific domains: i) Mental and Physical Health, ii) Infection Control and Environmental Health, iii) Health Data and Digitalisation and iv) Forensic Sciences. The secretariat of the Norwegian Scientific Committee for Food Safety (VKM) is incorporated as an independent unit in the NIPH, directly under the Director-General. VKM has nine scientific panels whose areas of responsibility largely correspond to those of the EFSA panels, and two panels within those of ECHA, as well as a Scientific Steering Committee.

Following domains mostly correspond to EFSA's mission: Mental and Physical health and Infection Control and Environmental Health. The Institute is active in preparation of draft documents, literature surveys, chemical risk assessments on nutrition, tasks requiring competence on analytic chemistry, epidemiology, surveillance, biohazards/zoonoses or microbiology.

Financial information: About 72% of the annual budget is covered by governmental sources. Less than 16% come from market activities linked to the Institute's public role towards public and private customers (e.g. more than half from sale of vaccines to the national health care system, almost 1/3 from sale of analysis). Above 12% come from project sources (mostly national public and EU funded).

Portugal (1):

### **Direção Geral de Alimentação e Veterinária**

Type of organisation: Governmental organisation

Mission of the organisation and task corresponding to EFSA's remit: Direção Geral de Alimentação e Veterinária (DGAV) is a central directorate of the Ministry of Agriculture, Forestry and Rural Development. DGAV is a regulatory, control and risk assessment and risk manager official body in the areas of Animal Health and animal welfare, Plant Health and Plant Protection Products and Biocides, veterinary medicines, food and feed. DGAV also coordinates the regulatory actions to protect Animal and Plant Genetic resources as well as Animal Breeding.

Tasks corresponding to EFSA's mission: PRA Plant health and plant health surveys and inspection; Pesticides and biocides; Pesticides residues; Veterinary medicines; Food safety; Feed safety; Animal health; Animal welfare; Animal identification; Seed and plant propagating material certification; Residues of veterinary medicines; GMO (food, feed and cultivation); Food Nutrition, including enzymes, additives and food supplements and food contact materials.

Financial information: The annual budget is entirely covered by governmental sources.

United Kingdom (2):

### **University of Hertfordshire Higher Education Corporation**

Type of organisation: University / Academic organisation

Mission of the organisation and task corresponding to EFSA's remit: The University of Hertfordshire is providing expert teaching informed by research, business and the professions.

The University of Hertfordshire offers significant levels of expertise relevant to EFSA's mission. In particular this includes: i) general food and agriculture related research skills including molecular modelling, risk modelling, pollutant fate and transport, qualitative techniques, diagnostics and monitoring; ii) the collation and evaluation of scientific evidence in support of agriculture, food and environmental policy and regulatory activities; iii) science-based health and environmental risk assessments for pesticides, food, feed, chemical and emerging contaminants; iv) contaminant exposure assessments, toxicology and health; v) expertise in the areas of nutrition and dietetics including that related to healthy diets, public health, food chemistry and food contamination & toxins; vi) agricultural science including weed & pest sciences, plant pathology, pest management, entomology and mycology and vii) microbiology.

Financial information: 58% of the annual budget is covered by governmental sources and the remaining 42% from non-governmental sources (mostly from tuition fees, educational contracts and research grants and contracts).

### **Cranfield University**

Type of organisation: University / Academic organisation

Mission of the organisation and task corresponding to EFSA's remit: The Cranfield University has the following strategic priorities for 2014-19 period: i) to provide a premier learning experience that enhances the capabilities of individuals and their organisations. The university aims to provide world-class education and a UK top 10 postgraduate learning experience; ii) to be recognised for outstanding transformational research that meets the needs of business, government and wider society. The university aims to attract innovative business engaged research by having academic staff that are recognised leaders in their fields of knowledge; iii) to grow an efficient, effective and sustainable enterprise. The University will develop a Performance Enhancement Framework, coupled with enhanced organisational efficiency and the sustainable development of our estate; iv) to be renowned for our impact and influence - regionally, nationally and internationally.

In line with the EFSA's mission, the University can provide support in a number of the key 'strategic objectives': research work with the latest academic thinking and a broad experience base in terms of best practice and new thinking. This cross fertilisation of processes and methodologies can only help improve those used by the EFSA.

Financial information: About 60% of the annual budget is covered by public funding (16% governmental sources), 42.5% tuition fees, 22% research and 19.5% other funding.

EFSA has ensured that the organisations designated by the Member States comply with the criteria set out in Article 1(1) of Commission Regulation (EC) No 2230/2004. The brief abstract from the profile for each organisation provided above is based on the information submitted via the Art36-Database. Member States concluded that the organisations meet the criteria and have designated them for inclusion in the Article 36 List.

## II. Withdrawals and technical changes of organisations on the Article 36 List

### Withdrawals:

The Management Board is informed that the following organisations, being parts of the newly designated organisations, are withdrawn from the Article 36 List upon notification from the respective Permanent Representations:

Finland (1):

Entry no. 6: *MTT Agrifood Research Finland*

- merged into the *Natural Resources Institute Finland (Luonnonvarakeskus, Luke)*, newly designated for inclusion in the Article 36 List.

France (1):

Entry no. 9: *Laboratoire de Toxicologie Alimentaire, EA 3880*

- a part of the *Université de Bretagne Occidentale (UBO)*, newly designated for inclusion in the Article 36 List.

Norway (2):

Entry no. 1: *Norwegian Scientific Committee for Food Safety*

Entry no. 8: *8.1 Division of Environmental Medicine and 8.2 8.2 Division of Infectious Disease Control of the Norwegian Institute of Public Health*

- merged into the *Norwegian Institute of Public Health*, newly designated for inclusion in the Article 36 List.

Portugal (1):

Entry no. 4: *Direcção Geral de Veterinária – DSCQ*

- a part of the *Direcção Geral de Alimentação e Veterinária (DGAV)*, newly designated for inclusion in the Article 36 List.

United Kingdom (1):

Entry no. 13: *Institute of Environment and Health (as part of the Food and Environment Group) at Cranfield University*

- a part of *Cranfield University*, newly designated for inclusion in the Article 36 List.

### Technical changes:

The Management Board is also informed of the technical changes adopted by the Executive Director Decision dated 05/09/2016 (Annex II).

The technical changes to the already included competent organisations on the Article 36 List do not impact the organisations' eligibility for inclusion in the Article 36 List.

### III. Conclusion

The Management Board is presented for adoption the **updated Article 36 List** of competent organisations (Annex I).

The updated Article 36 List has **seven** newly designated organisations added by Belgium (1), Finland (1), France (1), Norway (1), Portugal (1) and the United Kingdom (2), and **six** entries deleted after withdrawals of designations by Belgium (1), Finland (1), France (1), Norway (1), Portugal (1) and the United Kingdom (1), as these entries are parts of the newly designated organisations. Details of each organisation on the Article 36 List, including specific fields of competence, are available in the Search Tool of the Article 36 Database to: all Article 36 organisations, EFSA national Focal Points, EFSA Advisory Forum members and alternates and to EFSA staff.

The updated Article 36 List will be published on the EFSA website.