

## 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)). 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, following the:

- designation of **10** new organisations for inclusion on the List; and
- substantial change of **1** organisation included on the Article 36 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 29/04/2015 (Annex II).

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

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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)

## 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 of the Czech Republic, Croatia, Hungary, Italy, Slovenia, Spain and the United Kingdom have officially notified EFSA of new designation proposals for the Article 36 List for the following competent organisations:

Croatia (1)<sup>2</sup>:

- **Croatian Veterinary Institute**, a public institute. The annual budget includes 38% from non-governmental sources, i.e. 9,3% from international organizations, EU funds; 25,16% income from private entrepreneurs and companies: for services provided on the market within food safety control for food producers, market-chains and retail sale; obligatory control of Veterinary medicinal product for pharmaceutical companies - producers of drugs, and their distributors in Croatia; obligatory control of BSE for food producers, and; 3,57% from other income.

Task corresponding to EFSA`s remit: The mission of Croatian Veterinary Institute (CVI) is to enhance the conditions in the fields of animal health and welfare, human health and environment protection, through scientific research and continuous control of animal health, welfare and food and feed quality safety. Major research activities are conducted in the fields of animal health and food and feed quality and safety, development of laboratory methods, epidemiology, toxicology, welfare protection, improvement of farming process as also other public health issues, with the main goal of animal and human protection. CVI provides scientific advice and research on: Food / feed analysis, Animal health and animal welfare, Biohazards / zoonoses, Safety / risk assessment, Epidemiology / exposure, Antimicrobial Susceptibility Testing / Monitoring of Antimicrobial Resistance.

Czech Republic (1):

- **University of South Bohemia in České Budějovice**, a university / academic institution / organisation. The annual budget includes 17.79% from non-governmental sources, which consist of public non-governmental sources (subsidies from local governments, foreign grants, associations) and own resources (sales of goods and services, including counselling, courses, rent, recruitment procedures).

Task corresponding to EFSA`s remit: The Faculty of Fisheries and Protection of Waters of the University of South Bohemia (FFPW USB) is focused on fisheries, aquaculture, protection of waters and complex systems. The faculty of Agriculture is focused on the area of food a feed safety including nutrition, plant protection a plant health, animal health and animal welfare. Analytical laboratories of FFPW USB are able to carry out

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<sup>2</sup> The formal designation letter from the Permanent Representation of Croatia to the EU has not reached EFSA yet, but the Croatian Focal Point confirmed that the official letter should be received by EFSA before the MB meeting on 18 June 2015. Should this not be the case, the inclusion of the Croatian Veterinary Institute in the Art. 36 list will be tabled at the following Board meeting.

analysis of organic compounds (contaminants, additives, naturally occurring compounds) in food samples and environmental samples using state-of-the-art analytical instruments.

Hungary (1):

- **National Agricultural Research and Innovation Center (Nemzeti Agrárkutatási és Innovációs Központ)**, a Governmental organisation. The annual budget includes 45% from non-governmental sources, i.e. 6% from public non-governmental sources (national and international projects) and 39% from the use of free capacities and providing services to state-owned entities (80%) and to private costumers (20%) in: producing pathogen-free propagation materials, elaborating technological recommendations, developing analytical methods for origin protection/control, quality certification, environmental safety, food processing solutions, examinations of food products, analyses, impact assessments to assist legislation/regulation. This income is used to finance research. The Centre is independent of the private sphere.

Task corresponding to EFSA`s remit: National Agricultural Research and Innovation Center (NARIC) was established in 2014 by integrating 13 research institutes in the field of agriculture and food science and coordinating their activities. The Center is an integrated agricultural research network able to develop and perform practice-oriented research and innovation programmes. NARIC constitutes a bridge between food manufacturers and the consumers by the implementation of researches on biology, chemistry, physics and technology. NARIC provides scientific results on food safety and origin, and it takes part in development of new, healthy foodstuff and new, special technologies. Major tasks of the Centre are also assessment and classification of food raw materials and food products, development of novel, considerate technologies and preservation methods. NARIC aims to strengthen food safety procedures with new methods, setting up complex data bases and revealing contamination.

Italy (2):

- **Italian National Agency for New Technologies, Energy and Sustainable Economic Development (ENEA)**, a public institute. The annual budget includes 31% from non-governmental sources: public non-governmental sources consist of projects funded within competitive calls at international, national and regional level (96%), private non-governmental sources consist of research and service contracts awarded by SMEs or consortium (4%).

Task corresponding to EFSA`s remit: ENEA Technical Unit Sustainable Development and Innovation of Agro-industry System (UTAGRI) operates for the development and innovation of the national agro-industrial production system. The aim is to obtain food products using competitive, sustainable and energy-efficient processes. ENEA can develop new methods, sensors and devices for production and product monitoring; method validation; assessment of measurement uncertainty; R&DT activities on preparation and certification of Reference Materials (RMs); development and implementation of guidelines on RM selection and use, also improvement of the Quality of Chemical and Biological Measurements by diffusion/promotion of the metrological criteria and tools into the laboratory practices. ENEA has carried out, at national level, pioneer activities in Metrology for Chemical Analysis and since the '70s has been participating in international activities on Reference Materials and Methods.

- **University of Bari Aldo Moro**, a university / academic institution / organisation. The annual budget includes 1.15% from non-governmental sources.

Task corresponding to EFSA`s remit: The Department of Soil, Plant and Food (Di.S.S.P.A) developed genomic and proteomic methods to characterize bacteria involved in the production of fermented foods, food allergens and intolerances. The Department of Veterinary Medicine activities is focused on the food of animal origin safety assessment,

from animal breeding to food processing. The objectives of “Food Control and Safety” are assisting food plants and dairy products in identifying and correcting handling and processing problems affecting food quality, evaluation of hygiene monitoring for troubleshooting food shelf-life problems and quality improvement programs. The “Food Control and Safety” works with milk and dairy industries, slaughters for developing guidelines for guaranteeing health. The “Food Control and Safety” research projects include development of PCR assays for the detection of bacteria related to food such as coliformi, *Escherichia coli*, *Brucella* spp., *Mycobacteria* and *Cryptosporidium parvum*, emerging pathogens responsible for several serious outbreaks of diseases, which often may be transmitted to humans through contaminated foods. The PCR-based methods are developed as useful tools for the detection of animal species. Genomic and proteomic methods are used to characterize bacteria involved in the production of fermented foods. Research of different residues, mycotoxins, pesticides, PBCs, PAHs and drug residues. Identification of *Listeria* spp., *Vibrio* spp., *Bacillus cereus* group and *Listeria monocytogenes*, *Staphylococcus aureus* and related toxins is performed for ensuring food safety and consumer health; Identification of presence of GMO in food, and evaluation of presence of viral agents in fish and shellfish.

Slovenia (1):

- **National Laboratory of Health, Environment and Food (Nacionalni laboratorij za zdravje, okolje in hrano-NLZOH)**, a public institute. The annual budget includes 48.28% from non-governmental sources. The NLHEF (NLZOH) allocates its revenues according to the instruction issued by the Ministry of Health. The revenue delimitation is based on the executed services of the public health institutes, delimited on the basis of the branch of activity (public service, market activities). The delimitation at the NLHEF for year 2014 was: 51.72% public service and 48.28% market activities.

Task corresponding to EFSA`s remit: The NLHEF (NLZOH) operates as the National Reference Laboratory (NRL) and can provide high quality analyses for: veterinary drug residues and contaminants in food of animal origin, pesticide residues in food of animal origin and high-fat products, methods for individual residues in food of animal origin, polycyclic aromatic hydrocarbons in food of animal origin, dioxin and PCB`s in feed and food, analyses of organophosphorus compounds in honey, pesticide residues in cereals, pesticide residues in fruit and vegetables, including products with high contents of water and acid, pesticide residues, methods for individual residues, heavy metals in food, polycyclic aromatic hydrocarbons (PAH) in food, dioxin and PCB in food, mycotoxins in food of non-animal origin, for analyses of materials intended to come into contact with food, operating in the EURL-NRL network (European Union Reference Laboratory for Food Contact Materials; European Commission Joint Research Centre).

Spain (1):

- **University of Vigo (Universidade de Vigo)**, a university / academic institution / organisation. The annual budget includes 24.60% from non-governmental sources, which are distributed as follows: public prices: 39,69% (private); current transfers of non-profit organizations: 0,37% (private); current transfers of private companies: 2,42% (private); current transfers of outside: 2,15% (private); property income: 0,84% (private); capital transfers of private companies and other ones: 12,61% (private) and treasury: 41,92% (private).

Task corresponding to EFSA`s remit: The University of Vigo (UVigo) covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. In carrying out its work, UVigo also considers the possible impact of the food chain on the biodiversity of plant and animal habitats.

### UK (3):

- **Glasgow City Council**, a public institute. The annual budget includes 10% from non-governmental sources.

Task corresponding to EFSA`s remit: Glasgow City Council is the lead authority for Glasgow Scientific Services. Glasgow Scientific Services is a European Food and Feed enforcement laboratory providing the Public Analyst, Agricultural Analyst and Food Examiner services to 16 Local Authorities throughout Scotland, as well as providing the analytical services required to support this role. The results of Glasgow Scientific Services analysis can be used to enforce UK and EU food law. The laboratory also participates in EU funded validation exercises and work in partnership with The Laboratory of the Government Chemist, The Food Standards Agency, Health Protection Agency, The Drinking Water Inspectorate and SEPA.

- **Public Health Wales NHS Trust**, a Governmental organisation. The annual budget includes 22.30% from non-governmental sources, i.e. capital charges income (3.2%), microbiology test income (13.4%), grant / programme income (3.1%) and other income (2.6%).

Task corresponding to EFSA`s remit: Through its national reference units in Toxoplasma, Cryptosporidium and Antimicrobial Chemotherapy, Public Health Wales can provide expert input and advice on matters relating to microbiological safety of food. These specialist facilities each have a major research programme aimed at improving public health. PHW's Centre for Disease Surveillance and Control routinely collects data on a range of foodborne illnesses and, together with the public health teams working within the community, offer strong opportunities both for strengthening the existing evidence-base and also horizon-scanning through enhanced surveillance for potentially emerging threats to human health. All of these facilities and capabilities can be delivered from within a governance framework that shares the same core values of scientific excellence, independence, openness, transparency and responsiveness shared with EFSA.

- **University of Leeds**, a university / academic institution. The annual budget includes 74.75% from non-governmental sources, i.e. 58.70% from public (mainly tuition fees and NHS Teaching contracts) and 16.05% from private (mainly cash and short-term investments) sources.

Task corresponding to EFSA`s remit: Risk assessment and scientific assistance in the areas of contaminants, plant health, nutrition, food ingredients and packaging, GMO and pesticides.

EFSA has screened the new designation proposals to ensure that they comply with the criteria set out in Article 1(1) of Commission Regulation (EC) No 2230/2004<sup>3</sup>. The designated organisations were found to meet the criteria and are therefore considered eligible for inclusion in the Article 36 List.

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<sup>3</sup> The criteria the designated organisations have to meet can be described as follows:

- 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".

## **II. Substantial changes to organisations on the Article 36 List**

The following organisation on the Article 36 List has changed substantially:

UK (1):

- Entry no. 27: Department for Environment, Food and Rural Affairs (Defra), including:
  - Animal and Plant Health Agency (APHA)
  - Centre for Environment, Fisheries and Aquaculture Science (Cefas)since 1<sup>st</sup> of April 2015, the Food and Environment Research Agency (Fera) ceased to exist as an executive agency of Defra.

The Permanent Representation of the UK has officially notified EFSA of the changes.

EFSA has screened the entity's profile to ensure that it complies with the criteria set out in Article 1(1) of Commission Regulation (EC) No 2230/2004. The organisation was found to meet the criteria and is therefore considered eligible for inclusion in the Article 36 List.

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

The Management Board is informed that the organisations listed below were predecessors to or parts of the newly designated organisations, and are withdrawn from the Article 36 List upon notification from the respective Permanent Representations:

Hungary (4):

- Entry no. 4: Central Food Research Institute (CFRI)
- Entry no. 8: Corvinus University of Budapest Research Institute for Viticulture & Enology
- Entry no. 9: Hungarian Meat Research Institute (Public Benefit Company) /OHKI KHT
- Entry no. 11: Research Institute for Fisheries, Aquaculture and Irrigation

Slovenia (1):

- Entry no. 12: Public Health Institute of Maribor

UK (1):

- Entry no. 3: Glasgow Scientific Services

The Management Board is also informed of the technical changes adopted by the Executive Director in his Decision dated 29/04/2015 (Annex II).

### III. Conclusion

The Management Board is presented for possible adoption, the updated Article 36 List of competent organisations (Annex I) after adding the newly designated organisations from the Czech Republic, Croatia, Hungary, Italy, Slovenia, Spain and the United Kingdom, updating the entries with notified changes and deleting those entries for which designation has been withdrawn.

#### Document history

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