

*Nacionalna mreža institucija i
EFSA Article 36 List*

Sadržaj prezentacije

- ❑ Pravne odrednice umrežavanja institucija unutar EU i suradnje s EFSA-om
- ❑ Vrste projektnih zadataka financiranih od EFSA-e
- ❑ Uključivanje u *EFSA Article 36 List*

Temeljni propis

- Pravna osnova za suradnju između EFSA-e i imenovanih mjerodavnih institucija zemalja članica opisana je u članku 36. Uredbe o **(EC) 178/2002** (OJ L 31, 1.2.2002, p. 1–24)

REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 28 January 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

Article 36

Networking of organisations operating in the fields within the Authority's mission

1. The Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's mission.

2. The Management Board, acting on a proposal from the Executive Director, shall draw up a list to be made public of competent organisations designated by the Member States which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.

3. The implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the procedure referred to in Article 58(2). Those rules shall specify, in particular, the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support.

4. Within one year following the entry into force of this Regulation, the Commission shall publish an inventory of Community systems existing in the fields within the mission of the Authority which make provision for Member States to carry out certain tasks in the field of scientific evaluation, in particular the examination of authorisation dossiers. The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular, for each system, any modifications or improvements which might be required to

Provedbeni propis

- o **osnivanju mreže** kao i njene **aktivnosti** definirani su **Uredbom (EC) 2230/2004**
(OJ L 379, 24.12.2004, p. 64–67)
- o **utvrđivanju detaljnih pravila** za primjenu Uredbe Europskog parlamenta i Vijeća (EZ)178/2002 s obzirom na **mrežu institucija** koje djeluju u područjima **misije** Europske agencije za sigurnost hrane (**EFSA**)

Uredba (EC) br. 2230/2004

- **Umrežavanje** na razini Europske unije mora omogućiti:
 - jačanje okvira za znanstvenu suradnju
 - razmjenu informacija i znanja
 - olakšati prikupljanje i stvaranje baza podataka o sigurnosti hrane i hrane za životinje koje su prikupila tijela/institucije unutar država članica
 - određivanje zajedničkih zadataka
 - najbolje moguće korištenje sredstava, znanstvenih i stručnih kapaciteta
 - ✓ Institucije EFSA-ine (*EFSA Article 36 List*) mreže:
 - znanstvenu i tehničku stručnost, učinkovitost i neovisnost
 - ispunjavanje zadaća s ciljem pomaganja EFSA-i u njezinoj

Zadaci koji se povjeravaju institucijama s popisa

- Širenje najbolje prakse i poboljšavanje metoda prikupljanja i analiziranja znanstvenih i tehničkih podataka
- Prikupljanje i analiziranje određenih podataka kao odgovor na pitanje zajedničkog prioriteta EU, posebno prioriteta sadržanih u programima rada EFSA-e, te u slučajevima kada je Komisiji hitno potrebna znanstvena pomoć, posebno u kontekstu općega plana upravljanja krizom
- Prikupljanje i analiziranje podataka s ciljem olakšavanja procjene rizika od strane EFSA-e, uključujući zadatke procjene u području prehrane ljudi u vezi sa zakonodavstvom EU
- Prikupljanje i/ili obrada znanstvenih podataka o bilo kojoj hrani ili hrani za životinje, organizmu, kontaminantu ili tvari koji mogu biti povezani s rizikom za zdravlje
- Prikupljanje i/ili analiza podataka o izloženosti stanovništva država članica riziku za zdravlje povezanom s hranom ili hranom za životinje

Zadaci koji se povjeravaju institucijama s popisa

- Priprema znanstvenih podataka ili radova koji pridonose zadacima procjene rizika, uključujući zadatke procjene u području prehrane ljudi u vezi sa zakonodavstvom Zajednice, za koje je EFSA odgovorna
 - Prikupljanje podataka koje mora dostaviti industrija, posebno u kontekstu postupaka odobravanja
 - Pripremanje usklađivanja metodologija procjene rizika
 - Razmjena podataka od zajedničkoga interesa, npr. uspostava baza podataka
- ✓ Svi zadaci moraju biti u skladu s točno određenim problemima identificiranim u tijeku rada EFSA-e, posebno stalnih znanstvenih panela; istraživački projekte se ne smiju duplicirati


Financijske potpore u svrhu ispunjavanja zadataka

- Financijske potpore imaju oblik subvencija dodijeljenih u skladu s financijskom uredbom EFSA-e i pravilima primjene
- ❑ Projekti potpomognuti od strane EFSA-e:
 - ✓ Institucije mogu slati ponude za dotacije (*grants*) slijedom objava o pozivu za ponude (*calls for proposals*) – otvaraju se samo za kompetentne institucije sa *EFSA Article 36 List*
 - ✓ Slijedom javne objave slati ponude za pozive za tendere (*calls for tenders*) - otvoren za sve podnositelje sukladno specifikacijama u pozivu
 - ✓ Prijaviti interes za podnošenjem ponude za predstojeću nagodbenu proceduru vrijednosti 15,000.01 – 60,000 EUR (otvoren za sve podnositelje kako je navedeno u EFSA-inim smjernicama za tendere)
(*EFSA's Guidance for Tenderers*)


Primjer objave „*Call for proposals*” na EFSA-inim stranicama

Call for proposals - GP/EFSA/SCER/2014/01: Review of nonmonotonic dose-responses of substances for human risk assessment


Deadline: 28 February 2014

Call for proposals and guide for applicants  (0.6 Mb)

Annex 1 – Rules on eligibility of costs  (0.1 Mb)

Draft Grant agreement  (0.8 Mb)

Application form  (0.1 Mb)

Declaration of honour  (0.1 Mb)

Estimated budget template  (0.1 Mb)

Simplified financial statement  (0.1 Mb)

Individual Declaration of Interest Form  (0.2 Mb)

Published: 11 November 2013

Calls for proposals for grants planned under the "EFSA 2013 Work Programme for Grants and Procurement"

Parma, 20 June 2013

Please note that the information (titles, budget and timing) provided here is indicative and aims at informing potential applicants in due time. This plan reflects EFSA's scientific needs and progress in its work and is subject to adjustments and changes in the course of the year. EFSA is therefore not obliged to launch the calls indicated below.

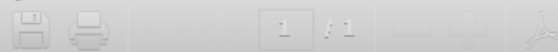
N.	Project	Estimated amount in Euros	Estimated launch period
1	Concentration data on pyrrolizidine alkaloids	€180k	2nd quarter launched in April open until 01/07
2	Relationship between seroprevalence in the main livestock species and presence of <i>Toxoplasma gondii</i> in meat	€400K	2nd quarter Launched in April open until 31/07
3	Biomarkes of exposure for mycotoxins mainly for deoxynivalenol – data collection and generation	€300K	3rd quarter
4	Genotoxicity study on deoxynivalenol (DON) and nivalenol (NIV) in vivo	€200K	3rd quarter
5	Data collection supporting the establishment of cumulative assessment groups of pesticides	€160K	3rd quarter

Open calls for tenders planned under the "EFSA 2013 Work Programme for Grants and Procurement"

Parma, 20 June 2013

Please note that the information (titles, budget and timing) provided here is indicative and aims at informing potential applicants in due time. This plan reflects EFSA's scientific needs and progress in its work and is subject to adjustments and changes in the course of the year. EFSA is therefore not obliged to launch the calls indicated below.

N.	Subject	Amount in Euros	Launch period	Type of contract
1	A decade of applications for Regulated products at EFSA – Analysis of the applicant's profile	300K	2nd quarter	Framework contract
2	Development of pest risk assessment methodologies to support EFSA Plant Health Panel scientific opinions and other EFSA scientific outputs - testing media monitoring tools to support plant health risk assessment	€200K	3rd quarter	Direct service contract
3	Transformation of non-standard data files to the standard sample description format	€200K ceiling	2nd quarter Launched in May open until 15/07	Framework contract
4	On-request recoding of the food descriptors of EFSA chemical occurrence database and food consumption database entries according to the FoodEx2 food classification and description system	€300K ceiling	2nd quarter Launched in June open until 23/07	Framework contract
5	Survey on stakeholder satisfaction	€150K	2nd quarter	Direct service contract



6	Strategy support for the PMM of GMO plants	€100K	3rd quarter	Direct service contract
7	Horizontal Framework Contract on scientific services for preparatory work: a) data generation and management , b) critical analysis of information supporting, hazard/risk assessment and methodological development, c) development of quantitative & qualitative modeling and d) statistical support	€5 000K ceiling	3rd quarter	Framework contract
8	Specialised training courses on certain aspects of food safety risk assessment for EFSA Panel/Scientific Committee members, open to EFSA scientific staff	€200K	2nd quarter	Direct service contract
10	Third framework to support the preparatory work for the re-evaluation on food additives	€600K ceiling	3rd quarter	Framework contract
11	Review on low-dose effects of chemical substances for human risk assessment	€200K	3rd quarter	Direct service contract

Učesnici u procesu prijave na *EFSA Article 36. List*

- ❖ **Prijava u Article 36. Organsation Database (Art36-DB) – on line aplikacija koja podržava unos svih potrebnih informacija i kriterija propisanih provedbenim aktima**
- Kompetentna institucija koja želi ući na EFSA Article 36. List
- Imenovani nacionalni predstavnik EFSA Focal Point/Član EFSA Advisory Forum
- Stalno predstavništvo/Misija RH u EU
- EFSA
 - Izvršni direktor (EFSA's Executive Director)
 - EFSA Upravni odbor (EFSA's Management Board)

Kompetentna institucija (putem kontakt osobe)

- Ima mogućnost imenovanja jedne ili više kontakt osobe (navesti u upitniku)
- Popunjava upitnik i dostavlja sve neophodne dokumente
- Obavještava FP o popunjavanju online upitnika
- Ažurira upitnik u slučaju bilo kakvih promjena u instituciji
 - uključujući i tehničke promjene koje nemaju utjecaj na formalne kriterije koje institucija mora ispuniti (npr. ime kontakt osobe ili kontakt detalja, manje promjene u području nadležnosti i sl.)
 - značajnije promjene (one koje imaju potencijalnu implikaciju na formalne kriterije (npr. promjene u strukturi, načinu financiranja ili nadležnosti institucije)
- Obavještava EFSA-u i FP o promjenama
- Obavještava sve relevantne znanstvenike i stručnjake institucije (ili prijavljenog dijela) o svakom novom javnom pozivu ili natječaju EFSA-e kao i svakoj informaciji proslijeđenoj od EFSA-e

Imenovani predstavnik – nacionalni Focal Point/ EFSA Advisory Forum

- Prepoznaje i kontaktira nove potencijalne kompetentne institucije
- Pomaže pri ispunjavanju online upitnika
- Vršiti provjeru dokumenata i informacija koji su propisani formalnim kriterijima Uredbe (EC) No 2230/2004
- Šalje tiskanu kopiju potrebne dokumentacije Stalnom predstavništvu/Misiji RH u Bruxellesu
- U suradnji sa kompetentnom institucijom osigurava ažuriranje upitnika

Stalno predstavništvo/Misija RH u Bruxellesu

- Dostavlja EFSA-i i Europskoj komisiji dokaze o udovoljavanju kriterija za uključivanje na *EFSA Article 36 List* slanjem tiskanih upitnika i ostale neophodne dokumentacije
- Formalno informira EFSA-u i Europsku komisiju o promjenama u profilu institucije koja je već nominirana
- Formalno opoziva imenovanu instituciju i zahtjeva uklanjanje sa *EFSA Article 36 List*
- Provjera i revidiranje liste se vrši najmanje svake tri godine

European Food Safety Authority - EFSA

- Provjerava podatke unesene u online upitnik Art36DB
- Obavještava kompetentnu instituciju dali su unesene informacije potpune, dali su potrebne dodatna objašnjenja ili informacije (shodno tome obavještava FP)
- Provodi procjenu kompetentne institucije sukladno formalnim kriterijima (putem Article 36 Committee)
- Ako je došlo do promjena unutar kompetentne institucije obavještava kompetentnu instituciju (+FP) jesu li one značajne te jeli potrebno promjene predočiti Stalnom predstavništvu/Misiji RH u Bruxellesu
- Organizira procedure za usvajanje ili promjene (opoziv) *EFSA Article 36 List* od strane EFSA Executive Director i EFSA Management Board
- Ažurira *EFSA Article 36 List* na web stranici sukladno odlukama EFSA Executive Director i Management Board
- Obavještava Stalno predstavništvo/Misiju u Bruxellesu, predstavnika EFSA Advisory Forum, FP kao i kompetentnu instituciju o odluci EFSA

EFSA Executive Director

- Usvaja i donosi odluku o prihvaćanju institucije na *EFSA Article 36 List*
(usvaja tehničke promjene institucija koje se već nalaze na listi)
- Priprema prijedlog o ažuriranju *EFSA Article 36 List*
(imenovanju kompetentne institucije, promjenama ili uklanjanju sa liste)

EFSA Management Board

- Usvaja odluku o ažuriranju *EFSA Article 36 List* (imenovanju kompetentne institucije, promjenama ili uklanjanju sa liste)



Art. 36 of Regulation EC 178/2002 and Art. 1 of Regulation EC 2230/2004

LIST OF COMPETENT ORGANISATIONS DESIGNATED BY THE MEMBER STATES WHICH MAY ASSIST THE AUTHORITY WITH ITS MISSION

MEMBER STATE	COMPETENT ORGANISATIONS ¹
AUSTRIA	1. Agentur für Gesundheit und Ernährungssicherheit GmbH (AGES - Austrian Agency for Health and Food Safety)
	2. Umweltbundesamt GmbH (Austrian Federal Environment Agency Ltd)
BELGIUM	1. Belgian Federal Agency for the Safety of the Food Chain (FASFC) and Scientific Committee of the Federal Agency for the Safety of the Food Chain (Sci Com-FASFC)
	2. Belgian Superior Health Council
	3. Belgian Biosafety Advisory Council
	4. Commission for Advice on Plant preparations
	5. Scientific Institute of Public Health

Postupak za uključivanje institucija u *EFSA Article 36. List*

1. Predstavnik EFSA Advisory Forum/Focal Point (FP) mogu identificirati institucije u svojoj zemlji kao kompetentnu za *EFSA Article 36. List*
 - institucija može sama iskazati interes FP predstavniku ili izravno EFSA-i (EFSA će instituciju uputiti na FP - može pružiti pomoć i savjete u procesu imenovanja organizacije kandidata u svojoj zemlji)
2. Institucija se registrira putem online aplikacije u *Article 36. Organisation Database* (Art36-DB) kao gost korisnik „*Guest User*” (samo pri prvoj prijavi)

Article 36 Organisations Database

Registration

First name

Last name

Email

Organisation name

Country

For IT issues please contact the EFSA Service Desk.
Telephone: +39 0521 036123 Email: servicedesk@efsa.europa.eu

*e-mail:
URL i ID*

Article 36 Organisations Database



Login

Application Id:

For IT issues please contact the EFSA Service Desk.
Telephone: +39 0521 036123 Email: servicedesk@efsa.europa.eu

The **Introduction** page opens.

Article 36 Organisations Database

APPLICATION ID: [LOGOUT](#) [TERMS OF USE](#)  [USER GUIDE](#) 

The application session time limit is 90 (ninety) minutes

INTRODUCTION CONTACTS GENERAL INFORMATION SCIENTIFIC COMPETENCE FIELDS OF COMPETENCE APPLICATION STATUS

Introduction

The aim of EFSA's Database of Article 36 Organisations (Art36-DATABASE) is to assist EFSA and the Member States in the management (maintenance and updating) of the list of competent organisations in the context of Article 36 of Regulation (EC) No. 178/2002 (hereby called the "List"). The Art36-DATABASE is set up on the EFSA server and is accessible by password only. Please note the Art36-DATABASE may be subject to improvements in the future. The Terms of Use may therefore need to be updated accordingly.

Competent organisations in the context of Article 36 of Regulation (EC) No. 178/2002 should all fulfil the legal requirements of Article 36 paragraph 3 of Regulation (EC) No. 178/2002 and Article 1 and 3 of Commission Regulation (EC) No. 2230/2004. To facilitate the designation of competent organisations in the EU Member States EFSA has developed a questionnaire to assist Member States with the selection of appropriate candidates and facilitate EFSA's processing of the information to be used in the preparation for the list of competent organisation to be submitted to EFSA's Management Board. Member States are requested to complete the questionnaire for all nominated competent organizations and return it to EFSA through their Permanent Representations to the EU¹.

The Art36-DATABASE is an electronic, online version of the abovementioned questionnaires.

The specific objectives of the Art36-DATABASE are the following:

Facilitating the maintenance and updating of information concerning approved organisations on the List. Contact persons of each organisation can request updates to EFSA by modifying the organisation's profile and making a new submission (of the modified profile). These submissions will be subsequently evaluated by EFSA and processed accordingly. EFSA will appropriately notify the contact persons on the outcomes of these evaluations and in case further actions are needed by the organisation (e.g. updates to the

Article 36 Organisations Database

APPLICATION ID:

[LOGOUT](#) [TERMS OF USE](#) [USER GUIDE](#)

To save your data use the save button on each page/tab or be aware that when changing tabs your data is automatically saved.
The application session time limit is 90 (ninety) minutes

[INTRODUCTION](#) **[CONTACTS](#)** [GENERAL INFORMATION](#) [SCIENTIFIC COMPETENCE](#) [FIELDS OF COMPETENCE](#) [APPLICATION STATUS](#)

CP ID: 0101

Title First name Last name Email
Fax Email 2 Phone Phone 2 Email notify enabled¹

¹If you check "Email notify enabled", the related contact person will receive emails from EFSA on published calls for proposals and other relevant notifications. We recommend that at least one contact person be enabled for notifications.

For IT questions please contact [SERVICEDesk](#) and for other questions please contact [Cooperation.Article36](#)

ADD CONTACT

SAVE

- Nakon ispunjavanja profila institucije administrator EFSA Art36 online baze dodjeljuje korisničko ime na kontakt osobu (jednu ili više) koja će u budućnost jedina imati pristup bazi u svrhu eventualnih izmjena

2.1 GENERAL INFORMATION

Organisation name¹

Organisation city

Street

Postal code

Click on the Add button to add at least one Legal entity name, Legal authorised representative and Title of legally authorised representative

Is the organisation fully or partially dependent on NGO's with a specific interest in EFSA's mission? Yes No

If not fully or partially dependent on funding from private sector or NGO's does the organisation accept grants from the private sector or NGO's in the areas of work where EFSA needs their contributions? Yes No

If so, please provide examples.

Name of legal entity^{2,3} Name of legally authorised representative^{1,3} Title (position) of legally authorised representative³

ADD

GENERAL INFORMATION

SCIENTIFIC COMPETENCE

FIELDS OF COMPETENCE

 Yes NoURL Country

Does the organisation have procedures and/or measures in place ensuring that any tasks entrusted to them by EFSA can be performed with independence and integrity? Yes No

2.2 DESCRIPTION OF THE ORGANISATION

Status (private, governmental) and function of the organisation

- University / Academic institution / organisation
- Governmental organisation
- Public Institute
- Foundation
- Private organisation
- Part of a network / consortium
- Other

If yes, please provide any documentation as appropriate.

Other measures to ensure independence and integrity?

Organisation status other (please specify)

WORKING PROCEDURES

Are the working procedures defined in writing and periodically evaluated? Yes No

If yes, could they be made available to EFSA if requested? Yes No

Are working procedures accredited or quality certified? Yes No

If yes, what type and by whom? (e.g. ISO, OECD/GLP, national accreditation board)

Mission of the organisation
Please provide a brief description (e.g. mission statements, max. 200 words). In case the organisation is not a fully State controlled body, please provide evidence that it carries out activities of public interest. In case the organisation operates as part of a network, please provide a description of the network and its operating conditions.

Does the organisation accept external assessments concerning the fulfillment of the requirements? Yes No

CONFIDENTIALITY

Are there specific legal obligations for the organisation's staff and / or experts to maintain confidentiality of information and documents? Yes No

Postupak za uključivanje institucija u *EFSA Article 36. List*

3. EFSA vrši provjeru online upitnika
4. U slučaju nedostatka traženih informacija ili potrebe dodatnog pojašnjenja- EFSA šalje zahtjev direktno kontakt osobi institucije (o tome obavještava FP)
5. Kada je podnošenje zahtjeva završeno EFSA o tome informira instituciju i FP
6. Zemlja članica (član EFSA Advisory Forum/FP/tijelo uspostavljeno posebno u tu svrhu) - provjerava informacije o instituciji sukladno kriterijima uspostavljenim u Commission Regulation (EC) No 2230/2004 (važno zbog jezičnih različitosti i važećeg nacionalnog zakonodavstva)
7. Ako je ishod provjere pozitivan – FP šalje tiskani primjerak online upitnika zajedno sa svim popratnim dokumentima Stalnom predstavništvu/Misiji RH u Bruxellesu

Postupak za uključivanje institucija u *EFSA Article 36. List*

8. Stalno predstavništvo/Misija službeno imenuje instituciju za uključivanje u *EFSA Article 36. List* dostavljanjem upitnika i svih ostalih dokumenata EFSA-i (poštom/dostavom), primjerak Europskoj komisiji (naznačava da li kompetentna institucije ima mogućnosti i kapacitete za rad u mreži i/ili obavljaju zadatke koje mogu biti povjerene od EFSA-e)
9. EFSA provodi dvostruku provjeru institucije prema kriterijima uspostavljenim u Commission Regulation (EC) No 2230/2004 i priprema prijedlog EFSA Upravnom Odboru (*EFSA Management Board*) o uključivanju institucije u *EFSA Article 36. List*
10. EFSA Upravni Odbor odlučuje o uključivanju institucije u *EFSA Article 36. List*
11. EFSA obavještava Stalno predstavništvo/Misiju, FP kao i instituciju o rezultatima odluke EFSA Upravnog Odbora, objavljuje ažuriranu *EFSA Article 36. List* na svojim stranicama

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Planirane daljnje aktivnosti HAH-a

- ❑ Radionica o pristupu i praktičnoj primjeni

Article 36. Organsation Database (Art36-DB)

- ❑ Krajem siječnja 2014. godine

- ❑ Radionicu će voditi predstavnik AFSCO Advisory Forum and Scientific Cooperation Unit

Poziv za upisnik u EFSA:
(EFSA's Scientific Committee and Panel members)

Sign up
as an **Expert**

- Your profile >
- User guide >

ONLINE APPLICATION FORM

[Send cancellation email](#) | [Servicedesk](#) | [Print](#)

WARNING: Your application was last submitted about one year ago (last update:2013-01-07) Please re-submit after performing any necessary updates.

General Expert Information**Institutional Information****Fields Of Competence****Additional Expert Information****Data Protection Notice**

Fields marked with * are mandatory

NAME:

Surname/Last Name*

MILOS

Forename(s)/First Name(s)*

Sanja

Title

 Dr Mr Mrs Ms Other Prof**ADDRESS FOR CORRESPONDENCE:**

Street name and number*

Porečka 29

Postal code*

31 000

Town/City*

Osijek

Country*

CROATIA

Telephone number

++385 31 227 670

Mobile phone number

++385 91 323 5545

Fax number

++385 31 214 901

Email address*

smilos@hah.hr

Modify

Alternative email address

smilos@hah.hr

(The Authority should be informed of any address change)

PROFESSIONAL SITUATION:

Professional Situation*

 Employed Retired Self-employed Unemployed**GENDER:**

Gender*

 M F**NATIONALITY:**

Nationality*

CROATIA

Hvala na pažnji!

- Hrvatska agencija za hranu
- I. Gundulića 36b/III
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