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# EFSA in focus ANIMALS

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## EFSA promotes alternatives to animal testing



In a recent review of the use of experimental animals in risk assessments, EFSA's Scientific Committee outlines strategies which can reduce the number of animal studies needed and may also lead towards their replacement in some areas.

"This opinion is a thorough review of the guiding principles on the use of animals for experimental purposes. It summarises possibilities for replacement, reduction and refinement of animal testing within the different areas of EFSA's activities," said Professor Vittorio Silano, Chair of EFSA's Scientific Committee that worked on this opinion. "We hope it will help EFSA in further

developing a proactive approach to animal welfare in its risk assessment activities based on sound scientific principles."

Most of EFSA's risk assessments require experimental data. It is currently not possible to obtain all the necessary data and information required to ensure a high level of consumer protection without some animal experiments.

This opinion lists the type of internationallyrecognised alternative methods to animal testing which are available for different types of studies used in risk assessment e.g. acute toxicity, skin irritation and eye

#### EFSA advises on welfare of dairy cows

EFSA's Panel on Animal Health and Welfare (AHAW) has published five scientific opinions and a scientific report on the overall effects of the most relevant farming systems on the welfare of dairy cows and related diseases.

For more information

irritation testing – and says that these should be used in line with existing EU laws. For areas where alternative methods cannot provide all of the necessary information, such as reproductive and developmental toxicity, the opinion describes integrated testing and risk assessment strategies which can help reduce the need for animal experiments.

The opinion also proposes ways to better implement animal welfare practices within EFSA's work. For example, in line with existing EU legislation, applicants submitting dossiers to EFSA should use accepted alternative methods to animal testing whenever possible. Moreover, EFSA should fully reflect on the use of such methods when developing guidelines for applicants. In addition, EFSA, when carrying out risk assessments, should review all existing data before requesting any additional animal studies.

The opinion stresses that animal testing should be conducted in line with guidelines endorsed by the European Commission, EU agencies or other international bodies, such as the OECD. It also recommends a dialogue between EFSA and the Commission on the best ways to address the inclusion of new, validated testing methods in existing guidelines. Furthermore, it stresses the importance of good communication in this area between the different agencies dealing with chemical risk assessments.

This opinion is in line with EFSA's commitment to continue to improve animal welfare when conducting risk assessments. The Scientific Committee also recommended that EFSA should review progress on alternative methods to animal testing in three years.

For more information

## European public health agencies evaluate MRSA in livestock, pets and foods



Currently there is no evidence that eating or handling meticillin resistant Staphylococcus aureus (MRSA) contaminated food poses an increased health risk for humans, according to a recent scientific report produced by European public health agencies.

Following a request from the European Commission, EFSA and the European Centre for Disease Control and Prevention (ECDC) concluded that food-producing animals such as pigs, veal calves and broiler chickens often carry without symptoms, a specific strain of MRSA called CC398. However, while food may be contaminated by MRSA there is currently no evidence that eating or handling contaminated food can lead to an increased health risk for humans. The report also noted that people in contact with live animals that carry the CC398 strain of MRSA could be at risk of infection. This specific strain of MRSA has been associated, albeit rarely, with serious skin and soft tissue infections, pneumonia and blood poisoning in humans.

Pets can also be infected with MRSA, where the bacteria first pass from humans to pets, and then back to humans. The document noted the importance of basic hygiene measures, especially hand washing before and after contact with animals, and if possible, avoiding direct contact with nasal secretions, saliva and wounds.

The report concluded that as animal movement and contact between live animals and humans are likely to be important factors in the transmission of MRSA, the most effective control measures will be at farm level.

In a parallel review, the European Medicines Agency (EMEA) looked at the risk of colonisation or infection of livestock and pets with MRSA in the context of the authorisation and the use of antimicrobial veterinary medicines. EMEA's Committee for Medicinal Products for Veterinary Use (CVMP) found that MRSA is resistant to virtually all antibiotics from the beta-lactam group, and very often to other antimicrobials. Prudent use of antimicrobials in animals should remain a key measure. The CVMP recommended monitoring of animal consumption of antimicrobials to identify any sources of unnecessary use. The Committee also recommended that medicines of last resort for MRSA treatment in humans should be avoided in animals, so as to ensure their continued efficacy in humans.

MRSA infections are widespread in hospitals in many EU Member States and are a major cause of hospital-acquired infections, which can lead to severe illness and in some cases fatalities. In recent years, a link has also been established between MRSA in animals and human MRSA infections. Where MRSA is found amongst food-producing animals, people in contact with these animals, such as farmers, veterinarians and their families, are at risk of acquiring an MRSA infection. To raise awareness of the issue, the ECDC promotes the prudent use of antibiotics in foodproducing animals.

For more information

## Stunning and killing farmed fish: EFSA assesses fish welfare

EFSA's Panel on Animal Health and Welfare (AHAW) recently adopted scientific opinions on the welfare aspects of stunning and killing seven species of farmed fish. The species were bluefin tuna, common carp, European eel, Atlantic salmon, rainbow trout, European turbot, European seabass and gilthead seabream.

During pre-slaughter, procedures including crowding were identified as important welfare hazards for farmed tuna, seabass, seabream, trout and salmon. For eels, unloading and poor water quality in holding tanks were considered as the most importannt pre-slaughter hazard. For turbot, chilling in

ice water slurry was considered a serious welfare issue because it can cause distress due to cold shock in conscious fish. Netting was the most important pre-slaughter hazard for carp, even though 85% of carp being slaughtered are sold alive and are either killed in the retail establishments or at home. Exposure to air even if for short periods of time was also identified as a major welfare hazard for carp, seabass, seabream, trout and salmon.

For eels, turbot and seabass/seabream there are currently no commercially available stunning methods that immediately, and without unnecessary pain or distress, induce and maintain unconsciousness until death. Electrical stunning, immediately followed by killing, was considered the preferred practically available method. For trout and salmon, percussive methods and electrical stunning were assessed to reliably cause unconsciousness in the vast majority of fish. Insufficient current/ voltage for a prolonged period during electrical stunning does not render carp immediately unconscious. The Panel, therefore, recommended further research on electrical stunning methods be carried out to ensure an immediate loss of consciousness.

For turbot, seabass and seabream, all the commercially used methods of slaughter, included a prolonged period of consciousness during which indications of poor welfare were apparent. Alternative methods to induce loss of consciousness such as the use of gas mixtures and electrical stunning have only been used experimentally. The Panel recommends the urgent development of commercial stunning methods to induce immediate (or rapid) unconsciousness.

In farmed tuna, underwater shooting caused fewer welfare problems for the slaughter of large fish compared with shooting from the surface. For smaller fish, spiking underwater gave fewer welfare problems. However, the Panel recommends the development of new slaughtering methods.



To the knowledge of the Authority's experts, depopulation for disease control has not occurred for many of the species assessed. If a disease outbreak required culling, there is no obvious method of choice for turbot, tuna, eels, seabass and seabream. Appropriate methods for emergency killing therefore need to be developed and assessed. An overdose of anaesthetics may be used for emergency killing of carp, trout and salmon.

The Panel recommended that standard operating procedures to improve the control of the slaughter process and to prevent impaired welfare should be introduced and validated for all species. Welfare indicators, which are both robust and feasible in practice, should also be developed. The Panel also recommended that a surveillance (monitoring) programme should be initiated for all the fish species so that data are available in the future to improve risk assessment, evaluate improvements over time, and to benchmark the methods used in the slaughter of farmed fish.

For more information

## EFSA assesses Cypriot study on resistance to classical scrapie in goats



EFSA's Panel on Biological Hazards has recently assessed a Cypriot study on the genetic resistance to classical scrapie (a type of transmissible spongiform encephalopathy (TSE)) in Cypriot goats. The Panel concluded that the study brings additional proof that the goats harbouring studied genotypes potentially less susceptible to classical scrapie. However,

Panel also cautioned that the study findings themselves provided insufficient evidence to support large-scale breeding to eradicate classical scrapie in Cyprus.

It has been scientifically recognised for several years that some variants of the prion protein gene, PRNP, are associated with differences in how TSEs manifests themselves in sheep (incubation period, physiopathology and clinical signs). This has led to EU breeding programmes, based on the selection of sheep known to be genetically resistant to TSE, and eradication measures in TSE-infected flocks, based on a selective elimination of genetically susceptible sheep.

In goats, it is not fully understood whether there is a similar association. However, results from a pilot project study in Cyprus indicated that there may be similar associations between variants of the PRNP gene and resistance/susceptibility to classical scrapie in goats. The European Commission asked EFSA to assess this study and the results are presented in the recently-adopted opinion.

However, the results only provided limited information. Therefore, the Panel could only conclude that the study provides encouraging information about identifying PRNP polymorphisms that could be used as part of a genetic strategy to control and eradicate TSE agents in goats. The Panel also felt that the results were insufficient to accurately and reliably evaluate whether large-scale genetic breeding to control and eradicate classical scrapie in Cyprus would be effective. The Authority recommended additional research to complement the previous study.

For more information

## EFSA's review of undesirable substances in animal feed

Most of the 30 risk assessments on undesirable substances in animal feed over the last five years have found no health risks to animals and low risks to human health. However, adverse effects could not be excluded for some animal species. EFSA's Panel on Contaminants in the Food Chain recommended reducing the presence of some substances in feed to prevent adverse human health effects.

Undesirable substances are compounds that occur naturally, or result from environmental or other contamination in the feed and food chain. The elimination of undesirable substances in feed is not always possible, but it is important to reduce their presence to avoid endangering animal or human health, or the environment.

The European Commission had asked EFSA to review the possible animal and human health risks due to the presence of undesirable substances in animal feed that are regulated under EU law. The 30 opinions published by EFSA over the last five years covered natural plant products (such as gossypol and theobromine), persistent organic pollutants (such as DDT and hexachlorobenzene), heavy metals (such as arsenic and mercury), fluorine and mycotoxins (such as aflatoxin B1).

In most cases, the Panel identified no risks to animal health resulting from feed intakes at the maximum authorised levels, provided that good animal feeding practices are followed. However, adverse animal health effects could not be excluded for some substances, such as deoxynivalenol in pigs, mercury in cats, gossypol in sheep, and theobromine in dogs and horses.

The risks of adverse human health effects due to the presence of undesirable substances in products of animal origin – such as fresh meat, eggs and milk – were generally found to be low but in some cases the Panel recommended reducing their presence, in particular for persistent organic pollutants such as camphechlor.

The need for further research was identified for several substances, and in particular regarding the extent to which the presence of these substances in feed may lead to the contamination of foods of animal origin.



These assessments allowed the Commission to update the maximum permitted EU legal limits for these substances. For example, the Panel's advice led the Commission to recommend setting out guidance values for the monitoring of mycotoxins in feed. It also led the Commission to lower the maximum levels of, for example, lead in feed, increase fluorine levels to take into account new processing techniques – for example, to improve the nutritional quality – and to introduce maximum levels for contaminants previously not covered, that are intended for animal feed, e.g. cadmium in trace elements. Some plant species have been deleted from the list of undesirable substances in feed (e.g. apricots and bitter almonds containing cyanogenic glycosides). Changes in the legislation, taking into account the most recent scientific opinions i.e. gossypol, theobromine and mercury, are currently ongoing.

For more information

## EFSA evaluates safety of ractopamine in feed



EFSA has identified weaknesses in the data underlying an international risk assessment on the safety evaluation of ractopamine. Ractopamine is a growth promoter used in animal feed in some countries outside the EU.

Ractopamine is a drug, prohibited from use in food-producing animals in the EU, except for therapeutic purposes. In certain countries outside the EU its regular use is allowed in feed for pigs and cattle, to accelerate weight gain, improve feed efficiency and increase the leanness of carcasses. The EU ban on the substance applies to meat produced in the EU and imported from third countries.

The international body charged with recommending maximum residues of veterinary drugs in foods – the Committee for Residues of Veterinary Drugs in Foods of the FAO/WHO's Codex Alimentarius Commission – has proposed maximum residue

levels based on a risk assessment carried out by the Joint FAO/ WHO Expert Committee on Food Additives (JECFA).

The European Commission, which represents the EU in international organisations, asked EFSA to review this and other scientific information regarding the safety of ractopamine. EFSA also considered other relevant issues, particularly safety for target species and product quality.

EFSA found weaknesses in the data underlying the JECFA assessment. This would undermine any proposal for a maximum residue level for ractopamine. The Authority found that the study

on cardiovascular effects in humans cannot be taken as a basis for deriving an Acceptable Daily Intake (ADI) of 0-1 micrograms per kilogramme of body weight per day, as proposed by JECFA.

EFSA's risk assessment included the results of its consultation with the EU's Reference Laboratory responsible for drugs, such as ractopamine, and the European Medicines Agency (EMEA). EMEA fully supported the Authority's safety evaluation of ractopamine.

For more information

## Ensuring transparency in risk assessments

EFSA's Scientific Committee has adopted recommendations on ensuring transparency in risk assessment to guide the future scientific work of EFSA. They are contained in two opinions, covering the scientific and procedural aspects of risk assessments.

The opinion on the scientific aspects deals with the overarching principles applicable to all of EFSA's scientific outputs. These include general aspects, such as ensuring that risk assessments are understandable and reproducible, and that standardised procedures and terminology are used in the assessments. The opinion also covers documenting the scope and objectives of the work, describing the data and data sources used, encompassing what data are included/excluded, explaining and justifying the assumptions and the assessment process. In addition, other general principles dealt with include considering opinions issued by bodies/committees other than EFSA. Moreover, opinion conclusions should address the terms of reference, should reflect the opinion's scope and objectives, and characterise the risk under consideration.

The opinion covering procedural aspects looks at a range of issues. These include: handling requests for scientific opinions; selecting qualified independent scientists for the assessment; involving stakeholders; confidentiality; procedures for adopting

opinions; and revising and updating scientific opinions that are already adopted.

These two opinions form part of EFSA's overall framework of supporting good risk assessment practice.



For more information

## Assess food nanotechnology case-by-case, advises EFSA

EFSA has concluded that the use of nanoscience and nanotechnologies in food and feed should be assessed caseby-case. This is one of the conclusions of its scientific opinion adopted by the Scientific Committee in March.

The opinion focused on the use of nanotechnologies, particularly engineered nano materials, in the food and feed chain. It looked at approaches and methodologies available for risk assessment of these very small particles but does not address any specific applications of particular materials. As a result, the Scientific Committee concluded that established international approaches to risk assessment can also be applied to engineered nano materials. The Scientific Committee also found that the current data limitations and lack of validated test methodologies could make risk assessment of specific nano products very difficult and subject to a high degree of uncertainty.

To address this, the Scientific Committee recommends additional research and investigation.

"EFSA's opinion will help the EC [European Commission] to explore appropriate measures, assess existing legislation and determine the scope of possible further requests for scientific opinions from EFSA in this field," said Prof Vittorio Silano, chair of EFSA's Scientific Committee that developed the opinion. "EFSA has already received a small number of such requests and is adopting the case-by-case approach."

"This issue will remain a priority for EFSA's Scientific Committee," he continued. "We are establishing a working group of experts to be kept informed of any emerging scientific and other data that will help us deliver the best possible scientific opinions based on the most up-to-date evidence available. EFSA will take a cautious caseby-case approach and looks forward to further data and research becoming available to help inform future scientific opinions."

For more information

## **Meeting reports**

## Meeting Advisory Forum animal health representatives



12 May 2009 - Vilnius, Lithuania

Following a successful first meeting in 2008, the second meeting of Advisory Forum representatives on animal health took place in Vilnius on 12 May, 2009, hosted by the Lithuanian State Food and Veterinary Service. The aim of this meeting was to further enhance the exchange of information between EFSA and Member States, and strengthen cooperation on animal health and welfare.

The participants received an overview of EFSA's scientific cooperation and assistance tools and projects which could be relevant for this network, such as EFSA's expert database and Focal Points network. Examples of the importance of data collection and analysis were also given during the discussions. EFSA's work with Member States on bee mortality, and the stunning and killing of farmed fish was highlighted.

EFSA provided an overview of its activities in the area of harmonisation of risk assessment methodologies and data collection. EFSA also updated the experts on the last year's activities and scientific opinions published by the Animal Health and Welfare panel (AHAW) as well as relevant documents produced by the Scientific Committee, such as scientific opinions on animal cloning, alternatives to animal testing, and transparency in risk assessment.

Among the key topics of the meeting was the presentation of a report on the organisation, approach and risk assessment procedures applied in the Member States in the area of animal health and welfare. This report is based on the results of a questionnaire developed last year, which gathered information on the organisation of the relevant national bodies currently performing risk assessment in these areas. The report includes information on how animal health and welfare risk assessments are structured in the various countries – responsibilities, tasks, expert involvement and transparency in the risk assessment work. It also presents ongoing national activities related to risk assessment procedures and outlines possibilities for future cooperation with EFSA. This report will be published on EFSA's website shortly.

The meeting was concluded by a discussion on past and future cooperation between EFSA and Member States on animal health and welfare. The participants reiterated that these special meetings are very useful and suggested they take place more

This network of Advisory Forum animal health representatives was launched, in accordance with EFSA's strategy for cooperation and networking with Member States. Norway, Iceland, Switzerland and the European Commission were invited to participate as observers. This thematic platform for cooperation and networking on scientific advice and risk assessment is based on a dynamic exchange of information among all participants. It provides all partners an extra resource to strengthen and coordinate their efforts both at national and European levels. The Forum has a collaborative approach in working with the Member States. EFSA and Member States can join forces addressing European risk assessment and risk communications issues, scientific matters and the early response to emerging risk issues in the specific areas of animal health and welfare.

For more information

## > Working together

## Update on EFSA's Scientific Cooperation projects

A key priority for EFSA is mobilising scientific resources throughout Europe. To help drive joint EFSA Member State collaboration, the Authority has established working groups for scientific cooperation (ESCOs) in a number of areas. Participants in ESCO projects include national experts nominated by Member States through the Advisory Forum, members of the Scientific Panels or Scientific Committee, and EFSA's scientific staff.

One of the working groups, covering emerging risks, has built on EFSA's achievements to date to identify and communicate emerging risks. The working group recommended that EFSA complete and validate its overall approach to emerging risks, particularly in relation to data sources and indicators. This included ensuring that EFSA can learn from non-food safety sectors. The Authority should also develop an approach to communicate emerging risks responsibly and establish a fully-functioning network to share data and results with other specialist bodies. In addition, overall awareness of this area should be increased including further research into ways to identify emerging risks.

Another working group looked at fostering harmonised risk assessment approaches in Member States. It recommended in its final report that EFSA and Member States develop so-called 'country profiles' for a better understanding of how risk assessment is organised in different countries. In addition, risk assessment outputs of national organisations should be made publicly available. With this in mind EFSA developed an Information Exchange Platform to share scientific information between EFSA and Member States. Efforts are also needed to implement quality management tools in the risk assessment process. Within specific scientific areas, they also recommended that risk assessment approaches need to be further harmonised.

Meanwhile, an ESCO working group was created to characterise the potential hazards or benefits of isoflavones from soy or red clover in food and food supplements, following a German request for advice. Isoflavones are natural plant substances. Products containing isoflavones – e.g. soya-based products – are growing in popularity in Europe. However, although they are considered to be part of a healthy diet, there are questions

surrounding their health impact. The work of this group should help EFSA decide whether a full risk assessment is required.

For more information.



## > Events

## Inaugural plenary meetings of the renewed Scientific Committee and Panel members

Membership of EFSA's Scientific Committee and Panels is re-established every three years. As the mandates of EFSA's Scientific Committee and some Panels were due to expire in summer 2009, EFSA launched a call to renew members. The re-established Scientific Committee and Panels began meeting in summer 2009.

**Scientific Committee** 

Parma, 21-22 July 2009 List of members

Animal Health & Welfare (AHAW)

Parma, 2-3 July 2009 List of members

Contaminants in the food chain (CONTAM)

Parma, 1-3 July 2009

**List of members** 

Additives and products or substances used in animal feed (FEEDAP)

Parma, 16-17 June 2009

List of members

**Biological Hazards (BIOHAZ)** Parma, 10-11 June 2009

List of members

## > **Publications**

## 2007 report on foodborne outbreaks in the EU now available

The recently-published 2007 report on foodborne outbreaks in the EU reveals that Salmonella was, as in previous years, the most commonly reported cause of outbreaks. Eggs and egg products were the most common source of outbreaks.

Foodborne outbreaks are infections or intoxications in humans caused by the consumption of contaminated food. In total, in 2007, 5,609 foodborne outbreaks were reported by Member States, a slight fall compared to 2006. Of these outbreaks, 36% were verified by laboratory detection of the pathogen or by epidemiological evidence showing a link between human infection and the food source. These verified outbreaks affected almost 40,000 people resulting in 3,291 hospitalisations and 19 deaths.

Salmonella was again the most commonly reported cause of foodborne outbreaks in the EU. S. enteritidis was the most common serovar involved and eggs or egg products were the most frequently involved in these outbreaks. Foodborne viruses, mainly calicivirus (including norovirus), were reported as the second most common known cause of outbreaks, most frequently from crustaceans, shellfish, molluscs and buffet meals. Campylobacter also remained a common cause of outbreaks.

The majority of foodborne outbreaks in 2007 were outbreaks affecting more than one household. The contaminated foodstuffs were most commonly consumed in homes or in restaurants, cafés, hotels or other caterers. Other places where outbreaks occurred included schools, canteens, and hospitals or medical care facilities.

Member States varied considerably in the numbers and proportions of verified outbreaks reported. However, this may be due to differences in the sensitivity and efficiency of the national systems for investigating and reporting outbreaks.

The report was based on information submitted by 22 Member States, as well as Norway and Switzerland. The report was jointly published by EFSA and the European Centre for Disease Prevention and Control (ECDC).

For more information.

# Controlling *Campylobacter* in the food chain: scientific colloquium report available



The latest in EFSA's series of scientific colloquium reports has been published. It assesses the health benefits of controlling *Campylobacter* in the food chain.

The colloquium was organised to discuss openly the current issues and future challenges concerning the risk assessment of *Campylobacter* in the EU food chain. In particular, the debate focused on the best approaches for data collection and quantitative risk assessment to determine the human health impact, fluoroquinolone resistance, and what are the most effective control measures.

Even though *Campylobacter* is recognised as the leading cause of acute bacterial enteritis in Europe, the true incidence of campylobacteriosis is considerably higher than reported, and underestimation is likely to vary considerably between countries. Therefore, at the meeting, colloquia delegates recommended that public health surveillance systems be further strengthened. Also experts should increase their collaboration to improve and standardise data collection so as to provide baseline informa-

tion on campylobacteriosis, and to monitor the effectiveness of interventions. In addition, given contaminated poultry meat is a major source of human exposure, relevant quantitative risk assessment models need to be further developed to support EUwide risk management strategies.

Concerning fluoroquinolone resistance, delegates recommended monitoring the use of antimicrobials overall in animals, in particular, when planning any intervention. However, experts noted that it is unlikely that there will be a single effective measure applicable across all Member States, since current interventions show limited effectiveness or are difficult to sustain. Therefore, among the recommendations made were running well-designed field trials, informed by quantitative risk assessments, to test the most promising strategies. Novel control strategies are also required but will need advanced planning to evaluate their efficacy and safety.

The report contains the presentations given at EFSA's 12<sup>th</sup> scientific colloquium, which took place in Rome, Italy, on 4 December 2008. It also contains reports from discussion groups, as well as an overall summary and full recommendations.

For more information

## Strategic Plan 2009-2013 published as a glossy report

EFSA has published a print version of its Strategic Plan for 2009-2013. The plan, adopted by the Management Board in December 2008, sets out EFSA's medium to long-term strategic direction.

Six key, high-level objectives have been identified in the Plan to help the Authority set priorities over the coming five years as its

work continues to evolve driven by regulatory, environmental, scientific, technological and other global factors.

For the full document.

# Scientific cooperation expands and output doubles, shows EFSA's 2008 Annual Report

EFSA's recently-published 2008 Annual Report, underlines how the Authority has matured and continued to grow. The report shows that among EFSA's achievements in 2008: the Authority doubled its scientific output; significantly expanded scientific cooperation with Member States, and beyond; and launched its 5-year Strategic Plan.

In 2008, EFSA finalised 489 scientific outputs. These included scientific opinions, reports, guidance documents and statements. Two new scientific panels were also created.

Scientific cooperation was further strengthened. Networks grew to include 1,200 experts, 30 national food safety bodies and almost 400 scientific organisations. EFSA Focal Points were established in all 27 EU Member States, and cooperation agreements were signed with the European Centre for Disease Prevention and Control, and the European Commission's Joint Research Centre.

In its Strategic Plan for 2009-2013 EFSA has mapped out its future direction, priorities and organisation to best prepare for the challenges ahead in the medium- and long-term, such as emerging risks, global warming and globalisation. For the first time, the Annual Report will also be made available in all EU official languages in the autumn.



## Calls

## Call for data for further advice on animal cloning

EFSA published a call for new scientific evidence following the European Commission's request for further advice on the implications on animal cloning. This call follows EFSA's previous opinion on animal cloning, published in July 2008.

Specifically EFSA sought information which has become available since January 2008. Such data could include new scientific publications, as well as scientific information which was not as yet published.

EFSA was particularly interested in the health and welfare of animal clones throughout their life, and information on the causes of pathologies and mortality in clones. EFSA also sought information on the cloning of sheep, goats and chicken, especially concerning the:

- > Health and welfare of the surrogate mother and clone;
- > Extent epigenetic dysregulation occurring in clones is transmitted to their offspring;
- > Genetic make-up of animal clones;
- > Comparative physiology of clones and conventional animals, including their reproductive capacity;
- > Safety of consuming animal clones and their products (meat, milk products, eggs).

The call closed on 30 April 2009.

For more information.

### Article 36 calls

Article 36 of EFSA's Founding Regulation allows the Authority to financially support projects and activities that contribute to EFSA's mission. This financial support is exclusively given to a list of competent organisations capable of assisting EFSA in its work. The list was drawn up on the basis of nominations made by Member States in an EFSA Management Board decision.

#### **Article 36 calls awarded**

#### CFP/EFSA/FEEDAP/2009/01

Review of mycotoxin detoxifying agents used as feed additives: mode of action, efficacy and feed/ food safety

Agence Française de la Sécurité Sanitaire des Aliments (AFSSA), (FR)

#### CFP/EFSA/CONTAM/2008/02

Survey on use of veterinary medicinal products in third countries

Central Science Laboratory, (UK)

For all calls awarded.

## Latest mandates received

## Mandates received per unit: February-May 09

Information on all other on-going requests is available in EFSA's register of questions.

#### **Assessment Methodology (AMU)**

Hazard characterization of use of dietary isoflavones and isolated isoflavones from soy or red clover in food and food supplements.

Requestor: **EFSA** 

06-Mar-2009 Reception date: Deadline: 31-Dec-09

Ouestion number: EFSA-Q-2009-00457

Review of the efficacy under field conditions of notified biocides, compared to sodium hydroxide and sodium carbonate

Requestor: **EFSA** 

Reception date: 27-Mar-09 Deadline: 15-Apr-08

Question number: EFSA-Q-2009-00492

#### **Animal Health and Welfare (AHAW)**

#### Ticks as vectors of Crimean-Congo Hemorrhagic Fever

Requestor:

Reception date: 14-May-09 Deadline: 30-Sep-10

EFSA-Q-2009-00595 Question number:

Ticks as vectors of African Swine Fever

**EFSA** Requestor:

Reception date: 14-May-09

Deadline: 31-Mar-10

31-Mar-10

EFSA-Q-2009-00594 Question number:

The risk of introduction of African swine fever into the EU, especially from the Caucasus or Eastern Europe

Deadline:

Requestor: **European Commission** 

Reception date: 24-Mar-09

Question number: EFSA-Q-2009-00506

The welfare aspects of the management and housing of grand-parent and parent stocks raised and kept for breeding purposes

Requestor: **European Commission** 

Reception date: 24-Mar-09

EFSA-Q-2009-00505 Question number:

Deadline: 30-Jun-10

The influence of genetic parameters on the welfare and the resistance to stress of commercial broilers

Requestor: **European Commission** 

Reception date: 24-Mar-09

Question number: EFSA-Q-2009-00504 Deadline: 30-Jun-10

**Epizootic Hemorrhagic disease** 

Requestor: **European Commission** 

Reception date: 24-Mar-09

Question number: EFSA-Q-2009-00503 Deadline: 31-Dec-09

31-Dec-09

Good practice in conducting scientific assessments in animal health using modelling

Requestor:

09-Feb-09 Reception date:

EFSA-Q-2009-00408 Question number:

**Biological Hazards (BIOHAZ)** 

Deadline:

Risk of transmission of TSEs via semen and embryos in small ruminants (sheep and goats)

Requestor: **European Commission** 

Reception date: 29-May-09

Question number: EFSA-Q-2009-00620 Deadline: 1-Nov-09

**Parasites in fishery products** 

Requestor: **European Commission** 

Reception date: 30-Mar-09 Deadline: 31-Dec-09

Question number: EFSA-Q-2009-00516

**Contaminants in the food chain (CONTAM)** 

Request for an urgent scientific opinion on the risks for public health due to the presence of nicotine in wild mushrooms

Requestor: **European Commission** 

Deadline: Reception date: 27-Apr-09 07-May-09

Ouestion number: EFSA-O-2009-00528

**Feed Additives (FEEDAP)** 

Red carotenoid-rich bacterium Paracoccus carotinifaciens

Requestor: **European Commission** 

29-May-09 Deadline: Reception date: **Under consideration** 

Question number: EFSA-Q-2009-00629

Natuphos (3-phytase) for minor species (quails, pheasants, partridges, guinea fowl, geese, pigeons, ostriches, peacocks, flamingos) ornamental birds

Requestor: **European Commission** 

Reception date: 18-May-09 Deadline: **Under consideration** 

Question number: EFSA-Q-2009-00603

Endofeed® DC (endo-1,3(4)-beta-glucanase and endo-1-4-beta-xylanase) for chickens for fattening, laying hens, pigs for fattening, minor avian and porcine species

**European Commission** Requestor:

11-May-09 Deadline: Reception date: Under consideration

Question number: EFSA-Q-2009-00585

6-phytase for sows

Requestor: **European Commission** 

Reception date: 27-Apr-09 Deadline: **Under consideration** EFSA-Q-2009-00536 Question number:

6-phytase for salmonids

Requestor: **European Commission** 

Reception date: Deadline: Under consideration 27-Apr-09

EFSA-Q-2009-00535 Question number:

alfa-galactosidase and 1,4-beta-glucanase for chickens for fattening

**European Commission** Requestor:

Reception date: 27-Apr-09 Deadline: **Under consideration** 

Question number: EFSA-Q-2009-00534

**Bacillus subtilis for weaned piglets** 

Requestor: **European Commission** 

Reception date: 27-Apr-09 Deadline: **Under consideration** 

EFSA-Q-2009-00533 Question number:

Bacillus subtilis GR-101 and Aspergillus oryzae GB-107 for piglets, chickens for fattening, calves for fattening and for rearing, fish (salmonidea and other fish), lambs and goats for rearing and fattening, dogs

Requestor: **European Commission** 

Reception date: 20-Apr-09 Deadline: Under consideration

EFSA-Q-2009-00525 Question number:

Selenomethionine for all species

Requestor: **European Commission** 

Reception date: 15-Apr-09 Deadline: **Under consideration** 

Question number: EFSA-Q-2009-00524

Monteban (Narasin) for chickens for fattening

Requestor: **European Commission** 

Reception date: 08-Apr-09 Deadline: 06-Jan-10

Question number: EFSA-Q-2009-00502

Mintrex® Mn (Manganese chelate of hydroxy analogue of methionine) for chickens for fattening

Requestor: **European Commission** 

Reception date: 30-Mar-09 Deadline: 30-Sep-09 Question number: EFSA-Q-2009-00489

Canthaxanthin for chickens for fattening; chickens reared for laying; laying hens; salmon and trout; other poultry, other fish, petfood and other non-food producing animals

Requestor: **European Commission** 

Reception date: 25-Mar-09 Deadline: **Under consideration** 

Question number: EFSA-Q-2009-00486

Endo-1-4-beta-xylanase, subtilisin and alpha-amylase for laying hens

**European Commission** Requestor:

Reception date: 12-Mar-09 Deadline: **Under consideration** 

Question number: EFSA-Q-2009-00470

L-isoleucine for all animal species

Requestor: **European Commission** 

Reception date: 09-Mar-09 Deadline: Additional data requested

Question number: EFSA-Q-2009-00456 Sodium benzoate for piglets

Requestor: European Commission

Reception date: 27-Feb-09 Deadline: Additional data requested

Question number: EFSA-Q-2009-00446

Paromomycin sulphate for turkeys for fattening and turkeys reared for breeding

Requestor: European Commission

Reception date: 23-Feb-09 Deadline: 30-Jun-09

Question number: EFSA-Q-2009-00445

**Scientific Committee & Advisory Forum (SC&AF)** 

European Commission request for further advice on the implications of animal cloning (SCNT)

Requestor: European Commission

Reception date: 06-Mar-09 Deadline: 30-Jun-09

Question number: EFSA-Q-2009-00449

**Zoonoses (Data Collection)** 

Community Summary Report on foodborne outbreaks in 2007 in the EU

Requestor: **EFSA** 

Reception date: 03-Apr-09 Deadline: 30-Apr-09

Question number: EFSA-Q-2009-00514

Availability of molecular typing methods of foodborne pathogens in the EU Member States

Requestor: **EFSA** 

Reception date: 03-Apr-09 Deadline: 30-Apr-09

Question number: EFSA-Q-2009-00513

Issuing guidance on harmonised survey methods for foodborne pathogens in foods in the EU

Requestor: **EFSA** 

Reception date: 03-Apr-09 Deadline: 31-Jul-11

Question number: EFSA-Q-2009-00512

Rabies and Q fever in the EU - harmonisation of monitoring and reporting

Requestor: **EFSA** 

Reception date: 03-Apr-09 Deadline: 31-Jul-11

Question number: EFSA-Q-2009-00511

Certain zoonotic parasites in the EU - harmonisation of monitoring and reporting

Requestor: **EFSA** 

Reception date: 03-Apr-09 Deadline: 31-Dec-10

Question number: EFSA-Q-2009-00510

Revision of the Zoonoses reporting web-application and running the Zoonoses support help-desk

Requestor: **EFSA** 

Reception date: 03-Apr-09 Deadline: 31-Jul-09

Question number: EFSA-Q-2009-00509

**Opinions and other documents** 

List of adopted opinions and other documents per unit: Feb-May 2009

Disclaimer: This is not the full list of all EFSA opinions but only those considered relevant to this newsletter. For full list.

**Animal Health & Welfare (AHAW)** 

Species-specific welfare aspects of the main systems of stunning and killing of farmed tuna

Question number: EFSA-Q-2008-443 Adopted: 30-Apr-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902516857.htm

Species-specific welfare aspects of the main systems of stunning and killing of farmed turbot

Question number: EFSA-Q-2008-442 Adopted: 30-Apr-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902524256.htm

#### Species-specific welfare aspects of the main systems of stunning and killing of farmed sea bass/bream

Question number: EFSA-Q-2008-441 Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902441174.htm

#### Species-specific welfare aspects of the main systems of stunning and killing of farmed eels (Anguilla anguilla)

Question number: EFSA-Q-2008-440 Adopted: 20-Mar-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902441076.htm

#### Species-specific welfare aspects of the main systems of stunning and killing of farmed carp

Question number: EFSA-Q-2008-439 20-Mar-09 Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902496686.htm

#### Species-specific welfare aspects of the main systems of stunning and killing of farmed rainbow trout

EFSA-Q-2008-438 Question number: Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902441012.htm

#### Species-specific welfare aspects of the main systems of stunning and killing of farmed Atlantic salmon

Ouestion number: EFSA-O-2008-437 20-Mar-09 Adopted: http://www.efsa.europa.eu/EFSA/efsa locale-1178620753812 1211902440910.htm

#### **Assessment Methodology (AMU)**

Request for a scientific opinion on cadmium in food - Toxicokinetic modelling - meta-analysis of dose-effect relationships and the related benchmark dose, heavy metals / cadmium

EFSA-Q-2009-00472

#### Defining output-based standards to achieve and maintain tuberculosis freedom in farmed deer, with reference to member states of the European Union

Aricle in Elsevier Preventive Veterinary Medicine

Authors: Simon J. More a,\*, Angus R. Cameron b, Matthias Greiner c, Richard S. Clifton-Hadley d, Sandra Correia Rodeia e, Douwe Bakker f, Mo D. Salman q, J. Michael Sharp h, Fabrizio De Massis e, Alicia Aranaz i, M. Beatrice Boniotti j, Alessandra Gaffuri k, Per Have e, Didier Verloo e, Michael Woodford I, Martin Wierupm

15-Jul-08 Accepted 26-Mar-09 Received

#### **Biological Hazards (BIOHAZ)**

#### Updated risk for human and animal health related to the revision of the BSE monitoring regime in some Member States (EU15, Slovenia and Cyprus)

Question numbers: EFSA-Q-2008-753, EFSA-Q-2008-712 Adopted: 22-Apr-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902502788.htm

#### The use and mode of action of bacteriophages in food production

EFSA-Q-2008-400 Question number: Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902525399.htm

#### Mandate for a consolidated opinion on use of antibiotic resistant marker genes (ARM) used as marker genes in genetically modified plants

EFSA-Q-2008-706 Question number: Adopted: 26-Mar-09

#### Quantitative estimation of setting a new target for the reduction of Salmonella in breeding hens of Gallus gallus

EFSA-Q-2008-291 26-Mar-09 Question number: Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902440821.htm

#### **Genetic TSE resistance in goats**

EFSA-Q-2008-774 05-Mar-09 Ouestion number: Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902400699.htm

#### Assessment of the public health significance of meticillin resistant *Staphylococcus aureus* (MRSA) in animals and foods

Question number: EFSA-Q-2008-300 05-Mar-09 Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902408708.htm

#### Contaminants in the food chain (CONTAM)

#### Pectenotoxins in shellfish

Question number: EFSA-Q-2006-065C Adopted: 27-May-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902599809.htm

#### Review of the criteria for acceptable previous cargoes for edible fats and oils

EFSA-O-2009-00236 Adopted: **Question number:** 26-May-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902553518.htm

#### Request for an urgent scientific opinion on the risks for public health due to the presence of nicotine in wild mushrooms

Question number: EFSA-Q-2009-00528 Adopted: 07-May-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902603897.htm

#### Influence of processing on the levels of lipophilic marine biotoxins in bivalve molluscs

EFSA-Q-2009-00203 Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902424332.htm

#### Uranium in foodstuffs, in particular in mineral water

Question number: EFSA-Q-2007-135 Adopted: 25-Mar-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902498761.htm

#### Marine biotoxins in shellfish – Saxitoxin group

Question number: EFSA-Q-2006-065E Adopted: 25-Mar-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902452476.htm

#### Nitrites as undesirable substance in animal feed

EFSA-O-2005-287 Question number: Adopted: 25-Mar-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902444119.htm

#### Feed Additives (FEEDAP)

### Safety and efficacy of the product Ronozyme® NP (6-phytase) for use as feed additive for poultry, weaned piglets and pigs for fattening

Question number: EFSA-Q-2008-430 Adopted: 14-May-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902553801.htm

#### 035/GalliPro (Bacillus subtilis) for chickens for fattening

Ouestion number: EFSA-O-2008-331 Adopted: 14-May-09

#### Preliminary evaluation of the safety and efficacy of paromomycin sulphate for turkeys for fattening and turkeys reared for breeding

Question number: EFSA-Q-2009-00445 Adopted: 13-May-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902556384.htm

#### Safety and efficacy of AveMix® XG 10 (endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase) for use as feed additive for chickens for fattening

Question number: EFSA-Q-2008-308 13-May-09 Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902553011.htm

#### Assessment of the safety of all carotenoids authorised in 70/254

Question number: EFSA-Q-2003-060c Adopted: 12-May-09

#### Safety evaluation of ractopamine

Question number: EFSA-Q-2008-433 Adopted: 02-Apr-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902436747.htm

#### Safety of Mintrex®Zn (Zinc chelate of hydroxy analogue of methionine) as feed additive for chickens for fattening

Question number: EFSA-Q-2008-424 Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902496432.htm

#### Safety and efficacy of Miya-Gold<sup>®</sup>S (Clostridium butyricum) as feed additive for chickens for fattening

Ouestion number: EFSA-Q-2008-303 Adopted: 02-Apr-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902496474.htm

#### Efficacy of the product Levucell SC20/Levucell SC10ME (Saccharomyces cerevisiae) as feed additive for leisure horses

Question number: **EFSA-Q-2008-472** Adopted: 01-Apr-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902498295.htm

#### Safety and efficacy of Bactocell PA (Pediococcus acidilactici) as feed additive for shrimp

Question number: EFSA-Q-2008-421 Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902499067.htm

#### Safety and efficacy of Bactocell PA (Pediococcus acidilactici) as feed additive for fish

Question number: EFSA-Q-2007-205 Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902498541.htm

#### Safety and efficacy of chromium methionine (Availa®Cr) as feed additive for all species

Question number: EFSA-Q-2006-066 Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902504594.htm

#### Safety and efficacy of SELSAF (Selenium enriched yeast from Saccharomyces cerevisiae CNCM I-3399) as feed additive for all species

Question number: EFSA-Q-2008-381 Adopted: 05-Mar-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902428860.htm

#### Safety and efficacy of Yea-Sacc1026® (Saccharomyces cerevisiae) as feed additive for horses

Question number: EFSA-Q-2008-009 Adopted: 04-Mar-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902394568.htm

#### Safety and efficacy of Bonvital (Enterococcus faecium) as feed additive for chickens for fattening

Question number: EFSA-Q-2008-289 Adopted: 03-Mar-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902390754.htm

#### Safety and efficacy of guanidinoacetic acid as feed additive for chickens for fattening

EFSA-Q-2007-050 Question number: Adopted: 03-Mar-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902403006.htm

#### Safety and efficacy of the product ColiCure (Escherichia coli) as a feed additive for horses

Question number: EFSA-Q-2005-167 Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902391773.htm

#### Safety and efficacy of 25-hydroxycholecalciferol as a feed additive for poultry and pigs

Question number: EFSA-Q-2008-014 Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902343650.htm

#### Safety and efficacy of Biosprint® (Saccharomyces cerevisiae) as a feed additive for sows

Question number: EFSA-Q-2008-302 Adopted: http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902338514.htm

#### Scientific Committee & Advisory Forum (SC&AF)

#### ESCO Working Group on "Botanicals and Botanical Preparations"

Question numbers: EFSA-Q-2008-388a, EFSA-Q-2008-388b Adopted: 30-Apr-09

#### Animal welfare - implementation of a pro-active policy on the welfare of animals in the context of EFSA's mission and tasks as stated in Regulation 178/2002

Ouestion number: EFSA-Q-2005-231 Adopted: 08-Apr-09

### Transparency in Risk Assessment, development of comprehensive guidance

Question numbers: EFSA-Q-2005-00298, EFSA-Q-2005-00299, EFSA-Q-2005-050Ba, EFSA-Q-2005-050Bb Adopted: 07-Apr-09

#### The potential risks arising from nanoscience and nanotechnologies on food and feed safety

EFSA-Q-2007-124b Question number: Adopted: 10-Feb-09

#### Risks arising from nanoscience and nanotechnologies on food and feed safety and the environment

Question number: EFSA-Q-2007-124a Adopted: 10-Feb-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902361968.htm

#### **Opinions and other documents**

Risks arising from nanoscience and nanotechnologies on food and feed safety and the environment

Question number: EFSA-Q-2007-00228 Adopted: 10-Feb-09

Use of benchmark dose approach in risk assessment – Guidance of the Scientific Committee

Ouestion number: EFSA-O-2005-232 Adopted: 26-May-09

**Zoonoses (Data Collection)** 

Community Summary Report on foodborne outbreaks in 2007 in the EU

EFSA-Q-2009-00514 Question number: Adopted: 30-Apr-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902515341.htm

Report on the availability of molecular typing methods for Salmonella, Campylobacter, verotoxigenic Escherichia coli, Listeria monocytogenes and Staphylococcus aureus isolates from food, animals and feedingstuffs in European Union Member States (and in some other reporting countries)

Question number: EFSA-Q-2009-00513 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902507851.htm

Reporting manual for the zoonoses web based reporting application for year 2009

Question number: EFSA-Q-2009-00476 Adopted:

Guidance Document of the Task Force on Zoonoses Data Collection - Manual for reporting of foodborne outbreaks in the framework of Directive 2003/99/EC

Question number: EFSA-Q-2009-00475 Adopted: 31-Mar-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902438533.htm

Report on statistical analysis of temporal and spatial trends of zoonotic agents in animals and food Part I: Critical review of the statistical analysis carried out on the Community Summary Report 2006 data

Ouestion number: EFSA-O-2008-264 Adopted: 31-Mar-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902520585.htm

Manual for reporting on Zoonoses, Zoonotic Agents and Antimicrobial Resistance in the framework of Directive 2003/99/EC and of some other pathogenic microbiological agents for information derived from the reporting year 2008

EFSA-Q-2008-671 Question number: Adopted: 18-Mar-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902432152.htm

Report on the proposed technical specifications for a survey on *Listeria monocytogenes* in selected categories of ready-to-eat food at retail in the EU

Question number: EFSA-Q-2008-415 Adopted: 22-May-09 http://www.efsa.europa.eu/EFSA/efsa\_locale-1178620753812\_1211902556892.htm



