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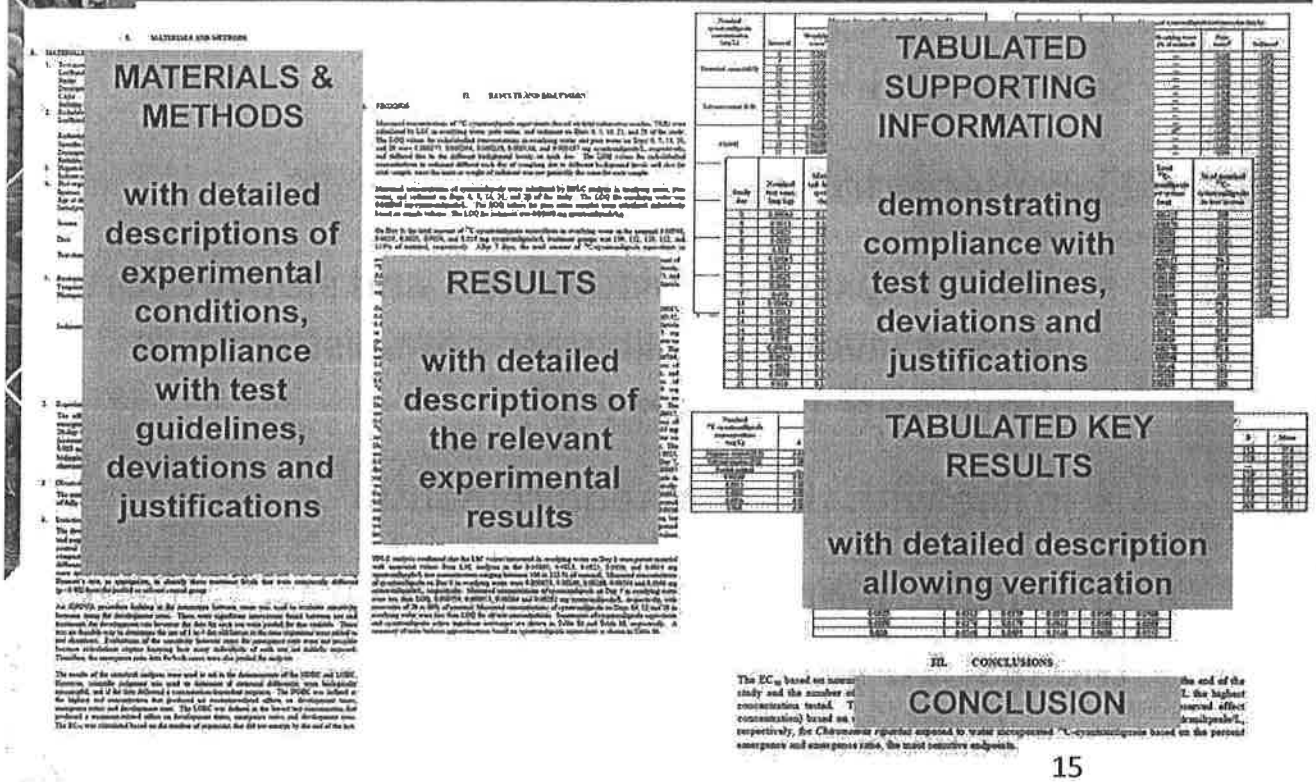
SUMMARY STUDY REPORT



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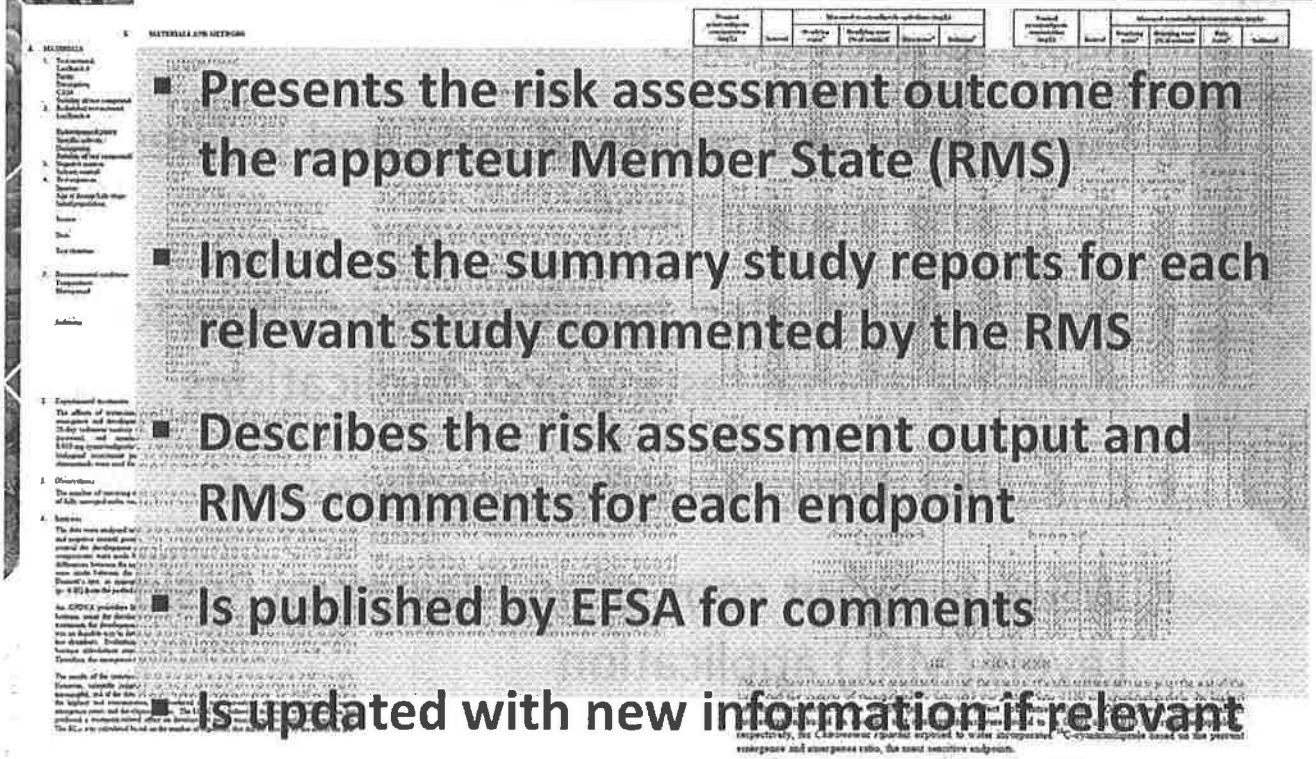
Draft Assessment Report



- Presents the risk assessment outcome from the rapporteur Member State (RMS)
- Includes the summary study reports for each relevant study commented by the RMS
- Describes the risk assessment output and RMS comments for each endpoint
- Is published by EFSA for comments
- Is updated with new information if relevant

EFSA CONCLUSION

- Output of a scientific peer review
  - Identity and Phys/Chem properties
  - Mammalian Toxicology & Workers/Bystander/residents risks
  - Residues & Consumers risks
  - Environmental Fate and Behaviour
  - Ecotoxicology & Ecosystem risks
- Conducted by EFSA scientific staff and risk assessment experts from the Member States
- The PPR Panel is not involved, except occasionally

EFSA CONCLUSIONS PUBLISHED IN 2014

Peer review of the pesticide risk assessment of:

- Sulfoxaflor 21 May 2014
- *Isaria fumosorosea* strain Apopka 97 15 May 2014
- Lambda-cyhalothrin 13 May 2014
- Human health risk assessment of the active substance chlorpyrifos 22 April 2014
- Amisulbrom 7 April 2014
- *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747 4 April 2014
- Orthosulfamuron 13 March 2014
- Gamma-cyhalothrin 11 February 2014
- Z,Z,Z,Z-7,13,16,19-doco-satetraen-1-yl isobutyrate 11 February 2014
- Metobromuron 4 February 2014
- Topramezone 3 February 2014
- Straight Chain Lepidopteran Pheromones 22 January 2014
- Ethametsulfuron-methyl 6 January 2014
- DE-126 3 January 2014
- Tebuconazole 3 January 2014

EFSA CONCLUSIONS OVERVIEW

- Conclusions typically cover:
  - New active substances
  - Renewals and amendments of approvals
  - Confirmatory data
  - Reviews, e.g. under Art 21
- New elements for 2014
  - First conclusions on AIR II
  - First conclusions on new actives Reg. 1107/2009

Pesticides Unit activities

Supports the Scientific Panel for pesticides PPR (Plant Protection Product and their Residues). → ➢ **Opinions** ➢ **Guidance documents** ➢ **Ad-hoc mandates**

Coordinates the Peer Review of active substances → Provides **Conclusions** for single active substances to support the EU decision-makers

Maximum Residue Levels MRLs → ➢ Reasoned Opinions ➢ Annual report

EU MRL LEGISLATION

Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels in or on food and feed of plant and animal origin

- Procedure for MRL setting
- Official control of MRLs
- Definition of responsibilities (role of Member States, European Commission, European Food Safety Authority, manufacturer of pesticides, food business operator, etc.)
- Annexes
  - Annex I: List of commodities for which MRLs are established
  - Annex II and Annex III: List of MRLs
  - Annex IV: Active substances exempted from setting MRLs
  - Annex V: specific LOQ values
  - Annex VI: processing factors

Basic regulation:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:070:0001:0016:EN:PDF

EFSA MRL REASONED OPINIONS

- About 50 RO/year reviewing MRLs for approved/non-approved active substances (Art 12 ROs)
- About 60-70 RO/year new proposals and modifications of existing MRL
- Several additional related activities

RECENT (MAY 2014) EFSA MRL REASONED OPINIONS

Art 10

- Picoxystrobin
- Ethephon
- Fluazinam
- Esfenvalerate
- Pyraclostrobin
- Triflumuron

Art 12 review

- Folpet
- Pirimicarb
- Prothioconazole
- Flutriafol
- Metaldehyde
- Dodemorph

GAP - DEFINITION

- Good Agricultural Practice (GAP) means the nationally recommended, authorised or registered safe use of a pesticide under agricultural conditions – "Label instructions"
- GAP defines the application rate, number of application/growing season, the minimum time interval before harvest (pre-harvest interval- PHI), the growth stage of the crop and the method of application
- GAP reflects the practical conditions at which the desired effect is obtained

KEY ELEMENTS

MRL assessment

✓Dossier compliant with data requirements was submitted (GAPs, field trials, …)

✓MRL proposals are based on **good agricultural practice and the lowest consumer exposure** necessary to protect vulnerable consumers;

✓chronic risk assessment is acceptable

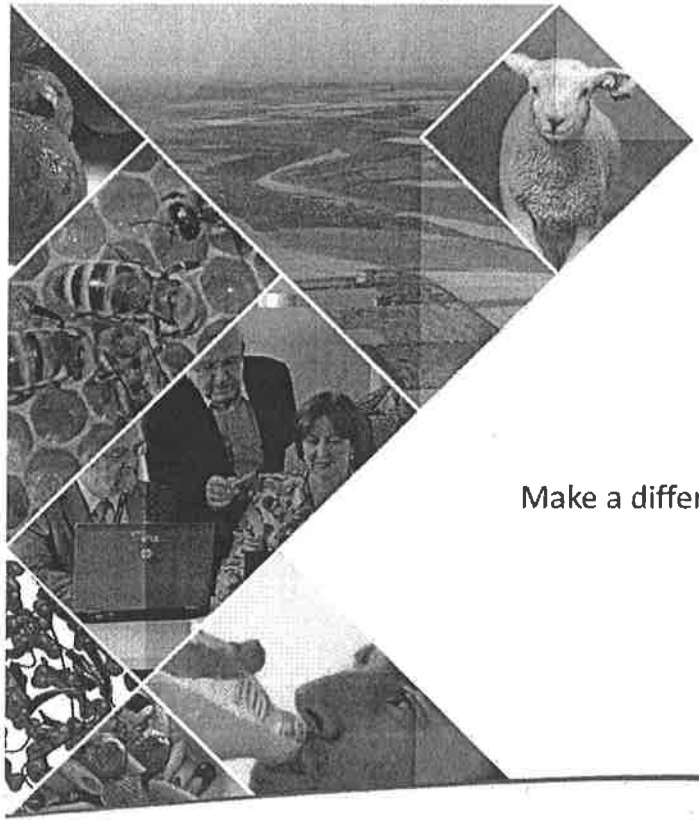
✓acute risk assessment is acceptable

ANNUAL REPORT ON PESTICIDE RESIDUES IN FOOD

REPORT for 2011 PUBLISHED IN MAY

Report for 2012 to be published in 2014

- EU-coordinated programme
- National programmes
- Dietary short-term assessment
  - Individual pesticides
  - Example of cumulative assessment for pears
- Dietary long-term assessment
- Recommendations



Thank you

Make a difference to Europe's food safety

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The role of EFSA in the BSE-related area

✓ Visit of Mrs. Su-San Chang (BAPIQ, Taiwan)

Pietro Stella
Scientific officer, BIOCONTAM Unit EFSA

Parma, 25 June 2014

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OUTLINE

1. BSE in the EU
2. EFSA BSE risk assessments
3. One example of use of EFSA opinions
   - BSE testing
4. Conclusion

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BSE in the EU

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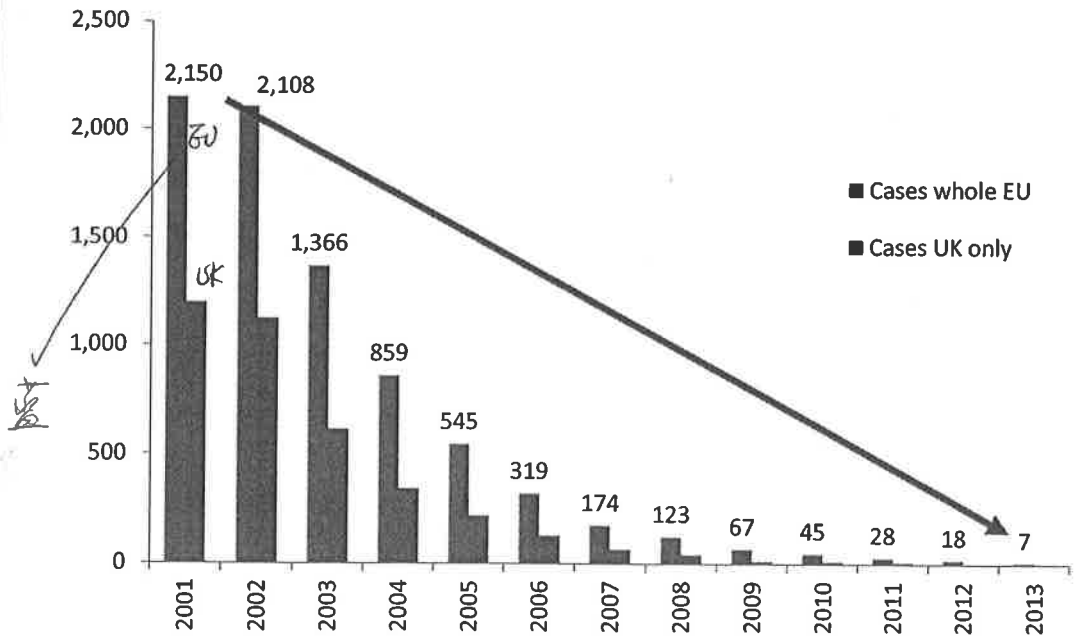
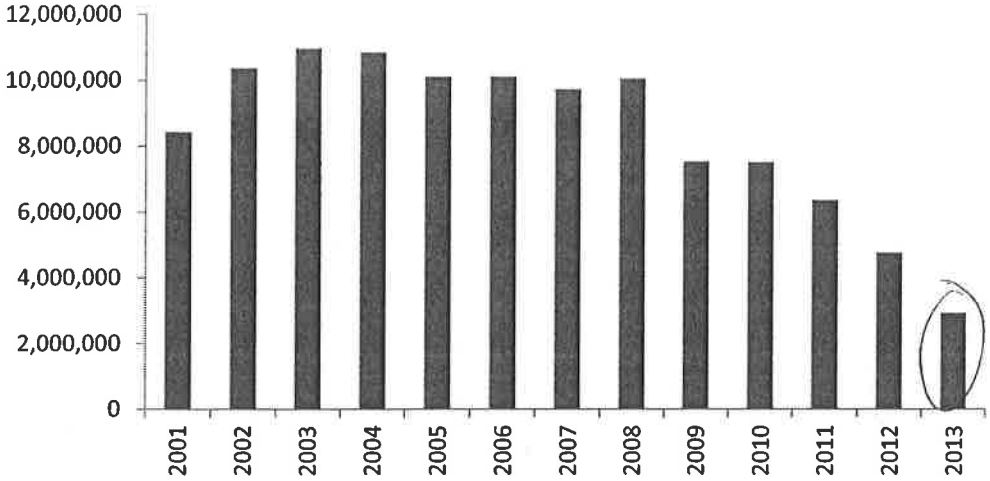
BSE cases/year in the EU



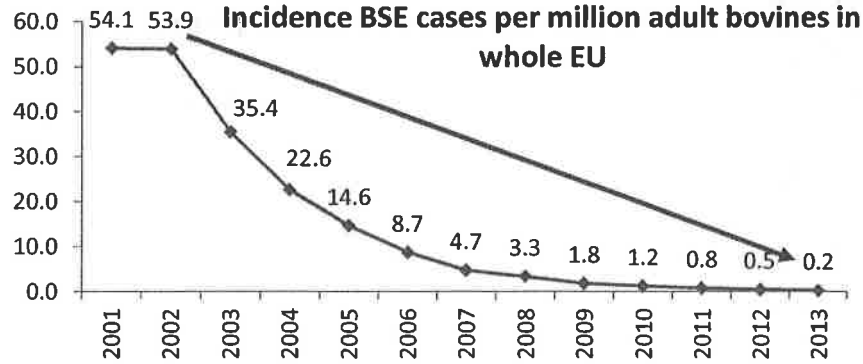
- Constant decrease

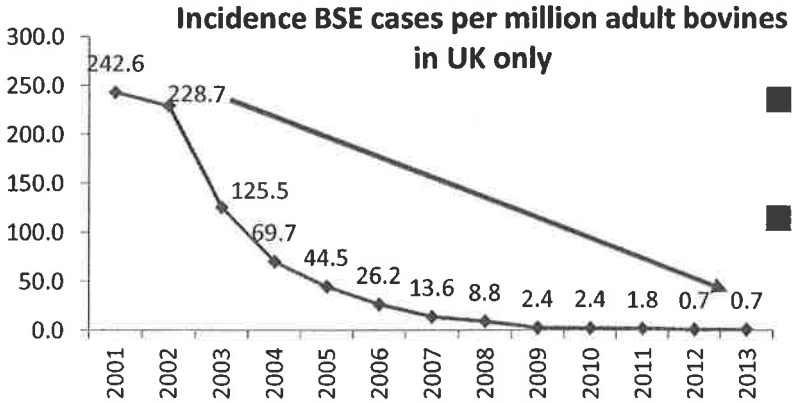
N° BSE tests/year in the EU



- Several millions/year
- We will see later reason for drop in recent years

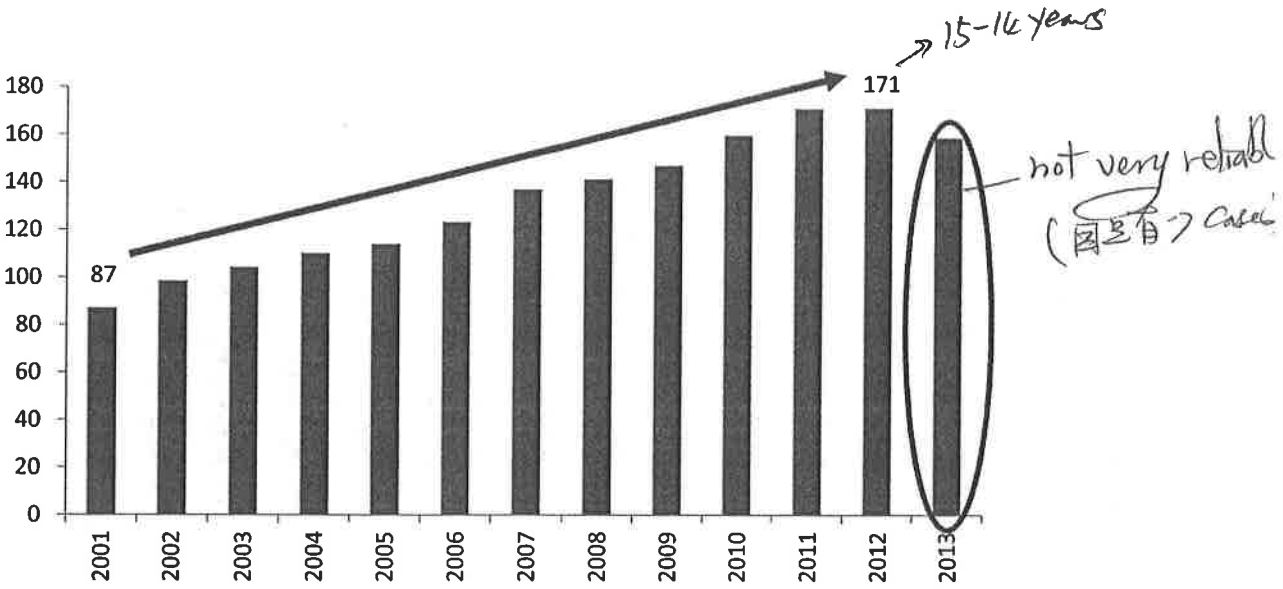
Incidence/year BSE in the EU





- Constant decrease
- UK ≈ whole EU

Average age (months)/year BSE cases in the EU



- Constant increase
- 2013 not reliable: too few cases (7)!

Considerations on BSE decline in the EU

Main EU measures to control **BSE spread**

- Jul 1994: feed ban mammalian MBM to ruminants
- Jan 1995: pressure cooking of ruminant waste, reinforced later
- Oct 2000: removal of Specified Risk Materials
- Jan 2001: EU wide total feed ban for food producing animals
- May 2003 : ABP Regulation and controls on animal feed

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Considerations on BSE decline in the EU

GBR categorisation: assessment stability BSE cattle system => a stable system eliminates BSE over time

Country	System stable since
....	....
France	1997
Ireland	1997
Italy	1999 (neutrally stable)
The Netherlands	1998
Germany	Stability foreseen by mid 2000
Poland	Very unstable still in 2000
UK	1996

Assessments issued in 2000/2001 by EU SSC on the basis of risk management measures implementation at country level

Source: Scientific Steering Committee (former MDSC) - Outcome of discussions
http://ec.europa.eu/food/fs/sc/ssc/outcome_en.html

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Current BSE risk categorisation

REGULATION (EC) No 999/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 May 2001

laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

(OJ L 147, 31.5.2001, p. 1)

The BSE status of countries or regions may be determined only on the basis of the criteria set out in Annex II, Chapter A. These criteria shall include the outcome of a risk analysis on the basis of all the potential factors for the appearance of bovine spongiform encephalopathy as defined in Annex II, Chapter B, and their development over time, as well as comprehensive active and passive surveillance measures taking into account the risk category of the country or region.

Member States, and third countries wishing to be retained on the list of third countries approved for the export to the Community of the live animals or of the products covered by this Regulation, shall submit to the Commission an application for their BSE status to be determined, accompanied by the relevant information on the criteria set out in Annex II, Chapter A, and on the potential risk factors specified in Annex II, Chapter B, and their development over time.

CHAPTER II

DETERMINATION OF BSE STATUS

Article 5

Classification

1. The BSE status of Member States or third countries or regions thereof (hereinafter referred to as 'countries or regions') shall be determined by classification into one of the following three categories:

— negligible BSE risk as defined in Annex II,

— controlled BSE risk as defined in Annex II,

— undetermined BSE risk as defined in Annex II.

After the International Office of Epizootic Diseases (OIE) has established a procedure for the classification of countries by category and if it has placed the applicant country in one of those categories, a re-assessment of the Community categorisation of the country concerned in accordance with the first subparagraph of this paragraph may be decided, if appropriate, in accordance with the procedure referred to in Article 24(2).

ANNEX II

DETERMINATION OF BSE STATUS

CHAPTER A

Criteria

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Current BSE risk categorisation

►B

COMMISSION DECISION

of 29 June 2007

establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk

(notified under document number C(2007) 3114)

(Text with EEA relevance)

A. Countries or regions with a negligible BSE risk

Member States

B. Countries or regions with a controlled BSE risk

Member States

— Belgium, Bulgaria, the Czech Republic, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, the United Kingdom

EFTA countries

— Switzerland

— Liechtenstein

Third countries

— Brazil

— Canada

— Chile

— Taiwan

— Mexico

— United States

EU Risk managers
决定其监测[illegible]
BSE
MC 022 标準高

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Current BSE risk categorisation

OIE's 82nd General Session May 2014:

- Negligible BSE risk
  - 36 countries and 1 zone, including 18 EU MSs
- Controlled BSE risk
  - 17 countries, including 10 EU MSs
- Undetermined BSE risk

Current BSE risk categorisation

ANNEX V

SPECIFIED RISK MATERIAL

1. **Definition of specified risk material**

The following tissues shall be designated as specified risk material if they come from animals whose origin is in a Member State or third country or of one of their region with a controlled or undetermined BSE risk:

(a) as regards bovine animals:

(i) the skull excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months;

(ii) the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, of animals aged over 30 months; and

(iii) the tonsils, the intestines from the duodenum to the rectum and the mesentery of animals of all ages.

2. **Derogation for Member States**

By way of derogation from point 1, tissues listed in that point whose origin is in Member States with a negligible BSE risk shall continue to be considered as specified risk material.

EFSA BSE risk assessments

FIELDS OF ACTIVITY 2012-2014

- Scientific Opinion on BSE risk in bovine intestines and mesentery
  http://www.efsa.europa.eu/en/efsajournal/pub/3554.htm
- Updated revision of the Norwegian annual monitoring programme for BSE
  http://www.efsa.europa.eu/en/efsajournal/pub/3380.htm
- Revision of the Norwegian annual monitoring programme for BSE
  http://www.efsa.europa.eu/en/efsajournal/pub/3119.htm
- Scientific Opinion on the risk of transmission of classical scrapie via in vivo derived embryo transfer in ovine animals
  http://www.efsa.europa.eu/en/efsajournal/pub/3080.htm

FIELDS OF ACTIVITY 2012-2014

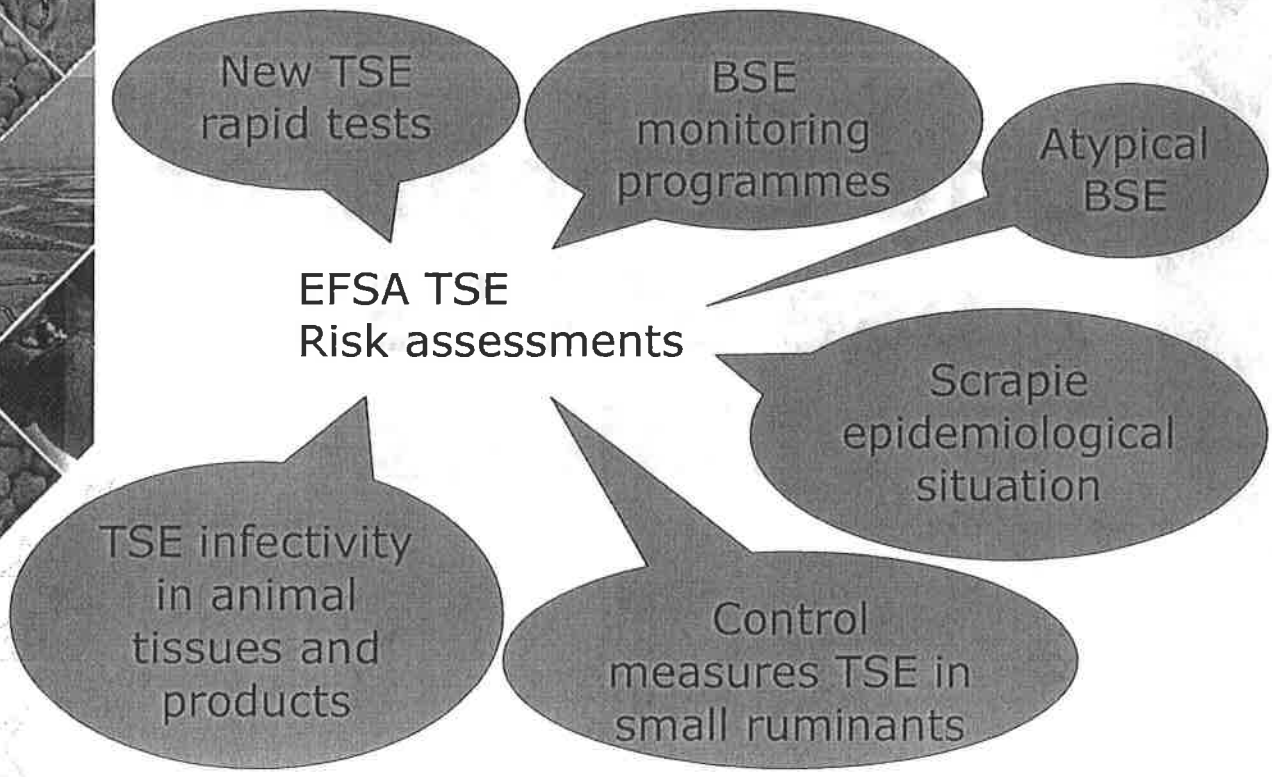
- Scientific and technical assistance on the provisional results of the study on genetic resistance to Classical scrapie in goats in Cyprus
  http://www.efsa.europa.eu/en/efsajournal/pub/2972.htm
- Scientific and technical assistance on the minimum sample size to test should an annual BSE statistical testing regime be authorised in healthy slaughtered cattle
  http://www.efsa.europa.eu/en/efsajournal/pub/2913.htm
- Scientific Opinion on the evaluation of new TSE rapid tests submitted in the framework of the Commission Call for expression of interest 2007/S204-247339
  http://www.efsa.europa.eu/en/efsajournal/pub/2660.htm

FIELDS OF ACTIVITY 2012-2014

ONGOING:

- Scientific Opinion on the scrapie situation in the EU after 10 years of monitoring and control in sheep and goats
  Finalisation expected: July 2014
- Scientific Report of EFSA on a protocol for further laboratory investigations into the distribution of infectivity of Atypical BSE
  Finalisation expected: July 2014

Fields of activity 2012-2014



EUROPEAN COMMISSION: EU TSE ROADMAPS

http://ec.europa.eu/food/food/biosafety/tse_bse/docs/roadmap_2_en.pdf

TABLE OF CONTENTS

Directorate-General for Health & Consumers

2010

The TSE Roadmap 2

Brussels, 18.7.2010
COM (2010) 384 final

One example of use of EFSA opinions

BSE testing

BSE TESTING: MAIN EU MEASURES

- May 1998: Surveillance passive/limited active surv.
- January 2001: Increased BSE testing

Current BSE surveillance in the EU

Target group	Age at testing (months)	
	EU25	Bulgaria, Croatia, Romania
Healthy slaughtered (HS)	No test	30
At risk animals (AR)		
• Emergency slaughtered	48	24
• Fallen stock	48	24
• Clinical signs at *ante mortem*	48	24

BSE Testing: Example of use of EFSA opinions

EVOLUTION BSE TESTING IN THE EU 1/3

2001: 30m HS, 24 m AR

Opinion	Conclusion
July 2008: Risk Human and Animal Health related to revision of the BSE Monitoring in EU15 MS http://www.efsa.europa.eu/en/efsajournal/pub/762.htm	< 1 BSE cases missed in the EU15/year if age limit is set to 48 months for both HS and AR cattle.
April 2009: Updated risk human and animal health related to revision BSE monitoring regime in EU15 + Slovenia and Cyprus http://www.efsa.europa.eu/en/efsajournal/pub/1059.htm	< 1 BSE cases missed in the EU15+Slovenia and Cyprus/year if age limit is set to 48 months for both HS and AR cattle

Age limit for BSE testing raised to 48 m for both HS and AR in EU15 + Slovenia and Cyprus - Decision 2008/908/EC, Decision 2009/719/EC and 2010/66/EC

BSE Testing: Example of use of EFSA opinions

EVOLUTION BSE TESTING IN THE EU 2/3

Opinion	Conclusion
December 2010: Second update risk for human and animal health related to revision of the BSE monitoring regime in some Member States http://www.efsa.europa.eu/en/efsajournal/pub/1946.htm	< 1 BSE cases missed in the EU17/year if age limit is set to 72 months in HS. BSE epidemiological situation similar in other 5 MS. Not possible calculate detailed estimates in other 3 MS.
April 2011: Review risk for human and animal health related to revision of BSE monitoring regime in three EU Member States http://www.efsa.europa.eu/en/efsajournal/pub/2142.htm	< 1 BSE cases missed in the 3 EU MS/year if age limit is set to 72 months in HS.

for Healthy animals

Age limit for BSE testing amended to 72 m for HS and 48 m for AR in the EU25 - Decision 358/2011/EC

for RSK animals

BSE Testing: Example of use of EFSA opinions

EVOLUTION BSE TESTING IN THE EU 3/3

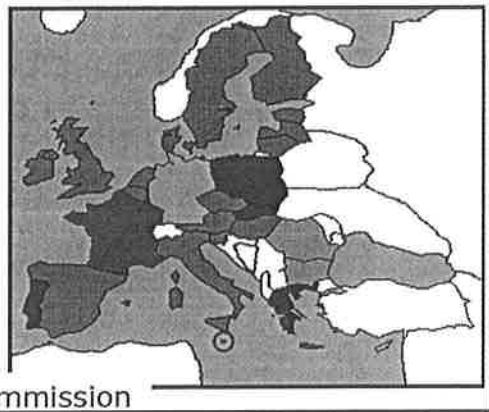
Output	Conclusion
October 2012: Scientific and technical assistance on minim test sh statist be aut slaugh http://www.e	No need to test HS cattle to meet design prevalence of 1/100,000 urveillance). ystem was lence above e to meet 1/4,000,000.

healthy animals

R3K animal

State of play until end of 2013

- Testing has stopped – 17 MS
- No change (testing at 72 months) – 6 MS
- Sampling plan has been amended – 2 MS
  E.g. DE testing at 96 months



Source European Commission

EU25 MS allowed to stop testing healthy slaughtered cattle - Decision 2013/76/EU

Conclusion

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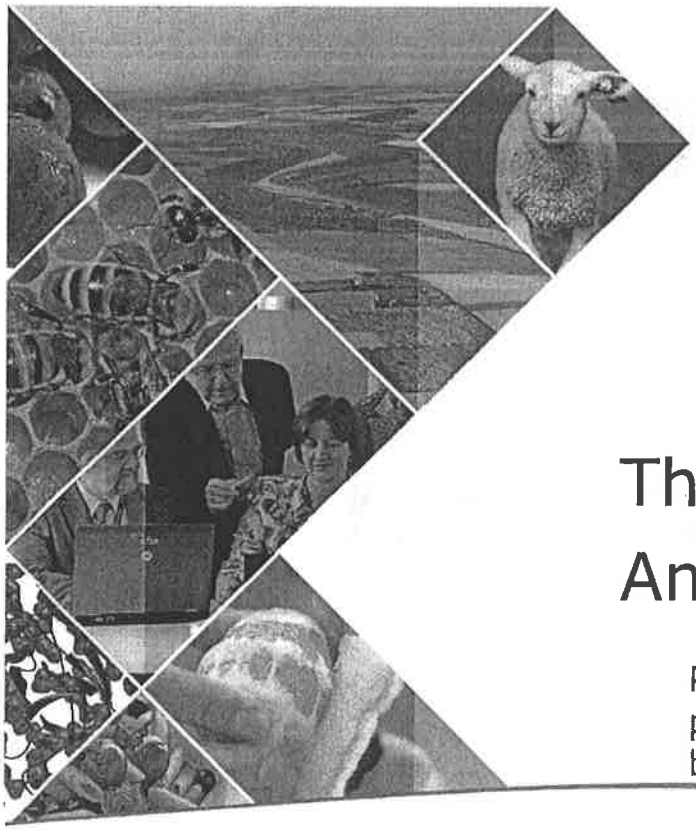
CONCLUSIONS

EFSA'S scientific assessments form the basis for all the EU risk management decisions in the BSE/TSE field



Thank you!
Any questions?

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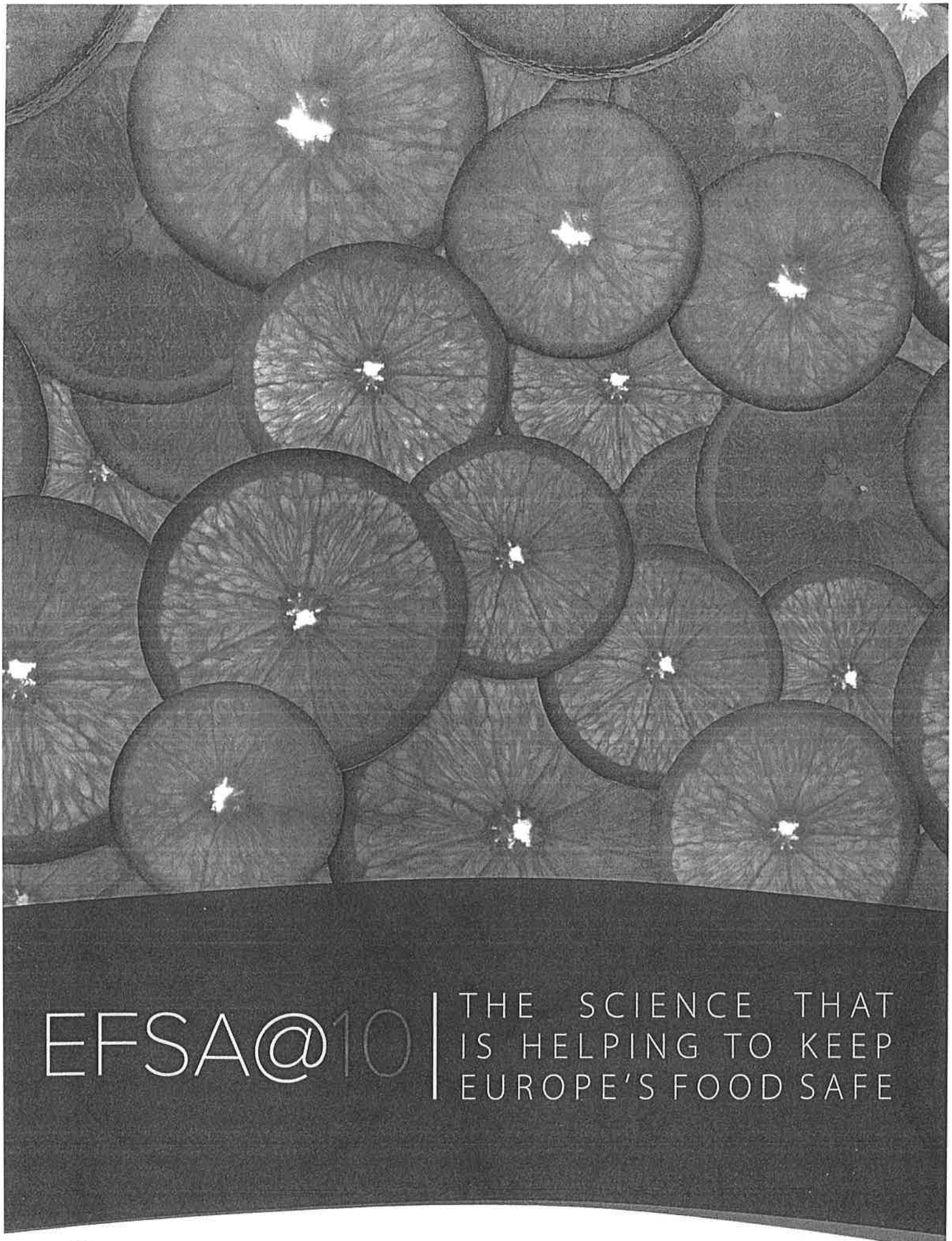

EFSA@10 | THE SCIENCE THAT IS HELPING TO KEEP EUROPE'S FOOD SAFE

efsa anniversary 10 efsa anniversary

Committed *since 2002* to ensuring that Europe's food is safe

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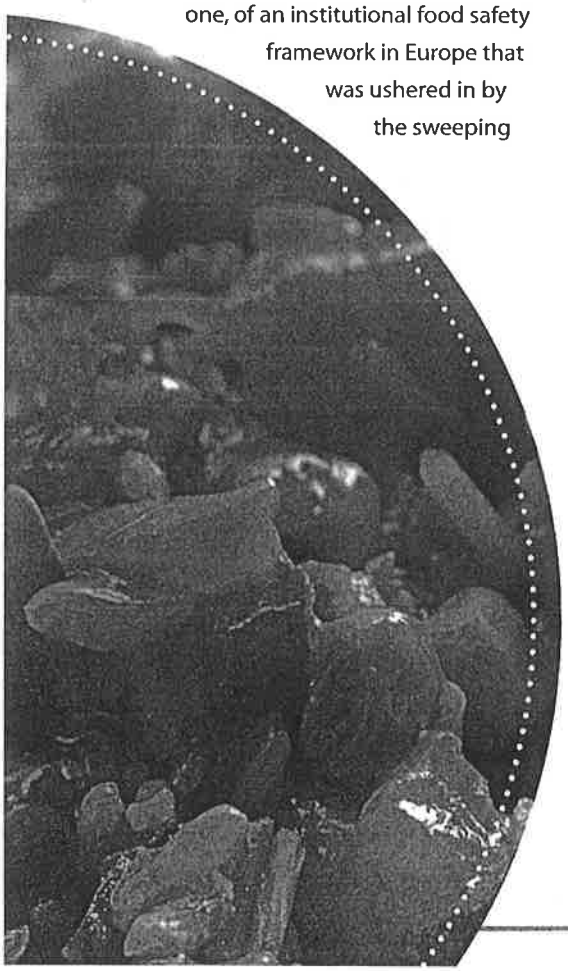
European Food Safety Authority

Science and co-operation – the keys to consumer safety and trust

It is difficult to capture concisely the progress over a decade of an organisation with such a broad remit as the European Food Safety Authority. That is why this brochure largely focuses on a number of key areas that demonstrate the impact of the organisation since its inception in 2002. These include crucial public health and consumer protection issues such as the control of *Salmonella* in the food chain and the safety evaluation of food additives as well as the protection of the environment through, for example, the risk assessment and post-market environmental monitoring of GM plants.

EFSA is but one part, albeit a crucial one, of an institutional food safety framework in Europe that was ushered in by the sweeping changes introduced by Regulation 178/2002. It places science firmly at the centre of food policy-making and gives the Authority the challenging remit of building public trust in European food for which EFSA's remit in risk communication is crucial.



While the European Union has changed significantly since EFSA first opened its doors in Brussels in 2002, the founding principles of the organisation remain constant: scientific excellence, independence, openness, and transparency.

The growth curve of the organisation has been steep and the increase in resources available to it has been matched by the acceleration in the volume of scientific advice the Authority has issued since inception, rising from 174 scientific outputs in 2006 to 658 in 2011. But volume is only one aspect of EFSA's workload: the growing complexity of risk assessments – due to new technologies and the globalisation of the food supply chain, among others – requires new methodologies, more multidisciplinary approaches and the increased engagement of stakeholders.

Furthermore, there is increasing demand on the organisation for the evaluation of applications related to commercial products and claims, important in supporting innovation in the agri-food sector and in realising the vision of the Commission's Europe 2020 Strategy.

All of these factors are taken into consideration in EFSA's Science Strategy 2012-2016 which lays down our vision of how we will continue to support European food safety in the years ahead. The strategy analyses the experience gained in EFSA's first decade and anticipates the future challenges to enable us to plan our resources and prioritise our future work programmes.

None of the activities included here would be possible without the cooperation of the Member States, national food safety agencies, European institutions, stakeholder bodies, scientific organisations and, last but not least, the many experts who contribute to our work every year. We thank them for this essential cooperation as we look forward to another decade of progress in protecting European consumers.

Catherine Geslain-Lanéelle — Executive Director, EFSA

The fruits of 10 years of the EU food safety system

In its White Paper of January 2000, following the BSE crisis, the European Commission identified a wide range of measures that were needed to overhaul the European Union food safety system. It included the setting up of an independent European Food Safety Authority. The Commission's objective was that the new Authority would become an EU-wide point of reference providing risk assessment for EU legislation. The Food Law (Regulation (EC) No 178/2002) was adopted in January 2002, and EFSA duly commenced its activities in May 2002.

The Founding Regulation gave EFSA the building blocks: scientific excellence, independence, transparency and openness. These essential operating principles are enshrined in the various policies and procedures that EFSA has progressively put in place and implemented: the 2011 *Policy on Scientific Independence* is but the latest example.

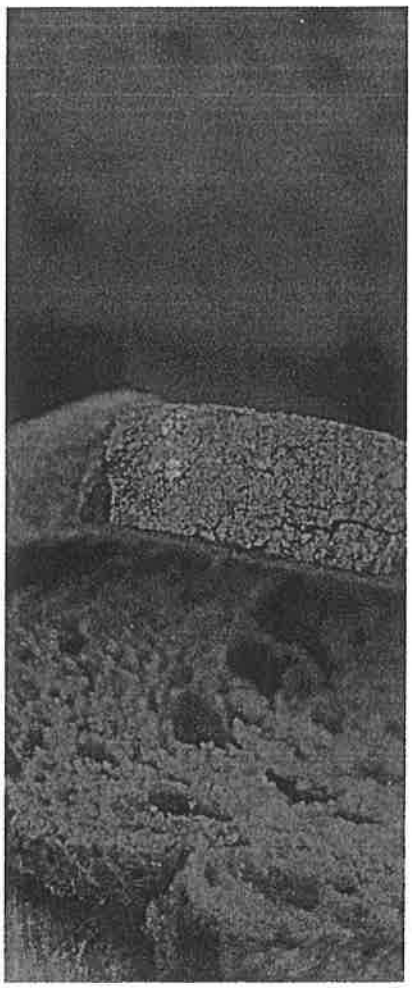
EFSA has made a significant contribution to the progress in dealing with crucial food safety areas such as the reduction in *Salmonella*, limitation of exposure to food contaminants, evaluation of pesticides and setting up of safe levels for their residues, or evaluation of food and feed additives. Its work also ensures that European consumers can have confidence that the claims on their food labels have a sound scientific basis.

After 10 years, Europe can clearly see the fruits of its investment. The Union has continued to experience the highest level of food safety and the effective containment of food related incidents over the past decade, both in terms of public health and economic impact. Cooperation on food safety issues has increased, and networks are now in place across Europe to share information, rapidly if needed, and to respond to any kind of emergency.

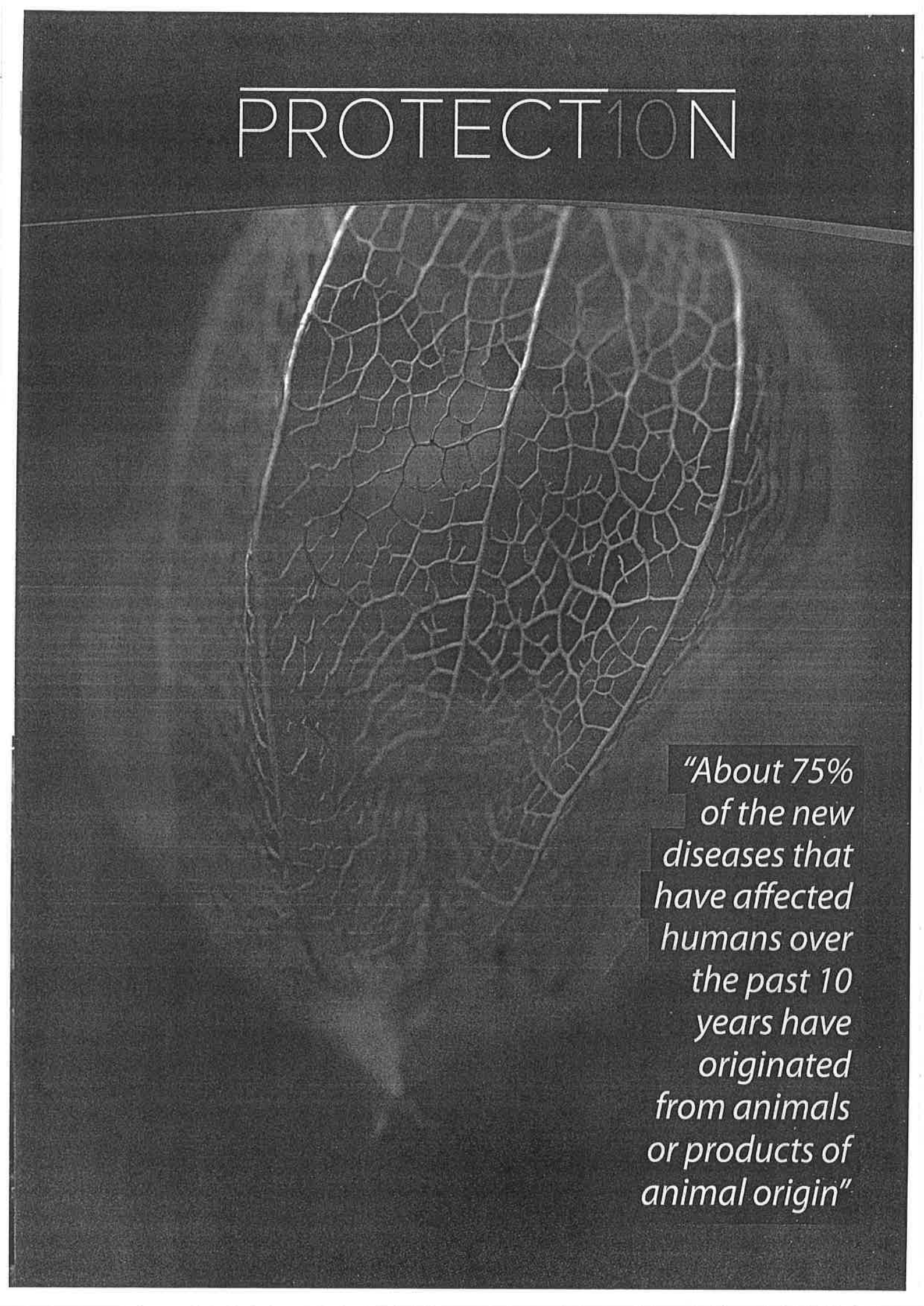
EFSA has achieved much over the last decade but on the occasion of its 10th anniversary, we need not only to look back over past achievements but also look to future challenges. EFSA as a forward looking organisation is, through its strategic documents, planning for the future. Whilst it is not possible to predict the future issues that EFSA will have to deal with, the drivers are becoming increasingly clear. We have confidence that EFSA will continue to respond to such challenges through its ability to anticipate future developments and be in the forefront of implementing novel and advanced risk assessment approaches to ensure both a high level of consumer safety and economic development.

The ultimate measure of the efficacy of the European food safety system is on the plates of European citizens. EFSA is our trusted partner in this respect - an essential element in the equation that leads to the highest possible food safety standards for all in the EU.

Paola Testori Coggi —
Director General of the Directorate-General for Health and Consumers of the European Commission

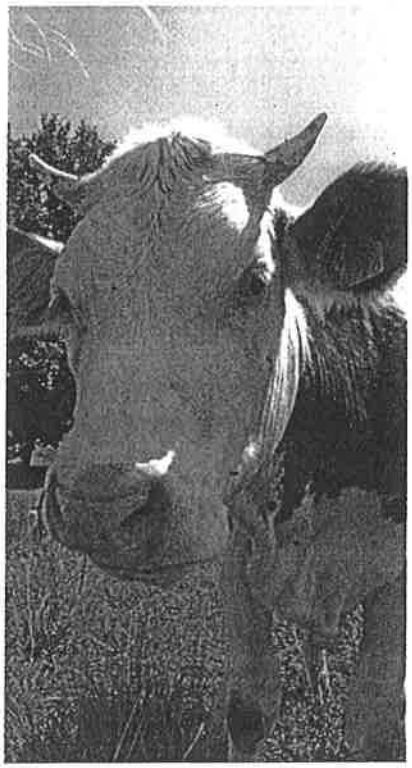


PROTECTION



"About 75% of the new diseases that have affected humans over the past 10 years have originated from animals or products of animal origin"

Protecting Europe's 500m citizens



Europeans enjoy one of the highest levels of food safety in the world. Securing safe, healthy food for a community that now numbers nearly 500 million citizens has been achieved through the continued commitment and innovation of the EU institutions and its independent agencies.

Over the past 10 years EFSA has underpinned the EU's decisions on food safety through its extensive scientific work – grounded in the most up-to-date knowledge and data – in food and feed safety, nutrition, animal health and welfare, plant protection and plant health.

When EFSA was set up, Europe had endured a series of food-related health crises that had undermined consumer confidence in the food production and distribution system. The most dramatic of these was the BSE emergency but there had also been scares concerning *Salmonella*, dioxins and cancer-causing compounds in animal feed, botulism in tinned food, growth hormones in baby food, and the emergence of a virulent new type of *E. coli*, O157:H7.

In addition to these episodes, consumers were becoming increasingly aware of possible safety issues surrounding modern techniques for processing and packaging foods; the addition of new ingredients to foods; the use in labels and advertising of scientifically unsubstantiated claims about the health benefits of food products; and the widespread use of pesticides and other chemicals in food production.

EFSA's scientific remit covers the full range of consumers' "farm to fork" concerns and the work of its experts has been at the core of the EU's success in tackling many of these issues.

For example:

- The number of cases of BSE in cattle reported across the EU dropped from several thousands in the early 2000s to 44 in 2010. In the UK, where the BSE epidemic reached a peak, the incidence of the human variant CJD (vCJD), has declined from 28 deaths in 2000 to about one diagnosis per year. EFSA's risk assessment and monitoring work has been a continual, strong thread in this story.

- The number of cases of *Salmonella* reported in the EU fell by 50 per cent in five years (see case study). This spectacular fall was achieved largely through an integrated effort involving EFSA and other EU agencies such as the European Centre for Disease Prevention and Control (ECDC) as well as risk managers in Member States and the European Commission.

Research indicates that between one third and one half of all human infectious diseases have a zoonotic origin, that is, are transmitted from animals. About 75% of the new diseases that have affected humans over the past 10 years have originated from animals or products of animal origin. As well as addressing specific diseases such as BSE and *Salmonella*, EFSA monitors and analyses the general situation on zoonoses, zoonotic micro-organisms, antimicrobial resistance and food-borne outbreaks. The data, published in annual reports, supports risk management decisions taken by Member States and the European Commission.

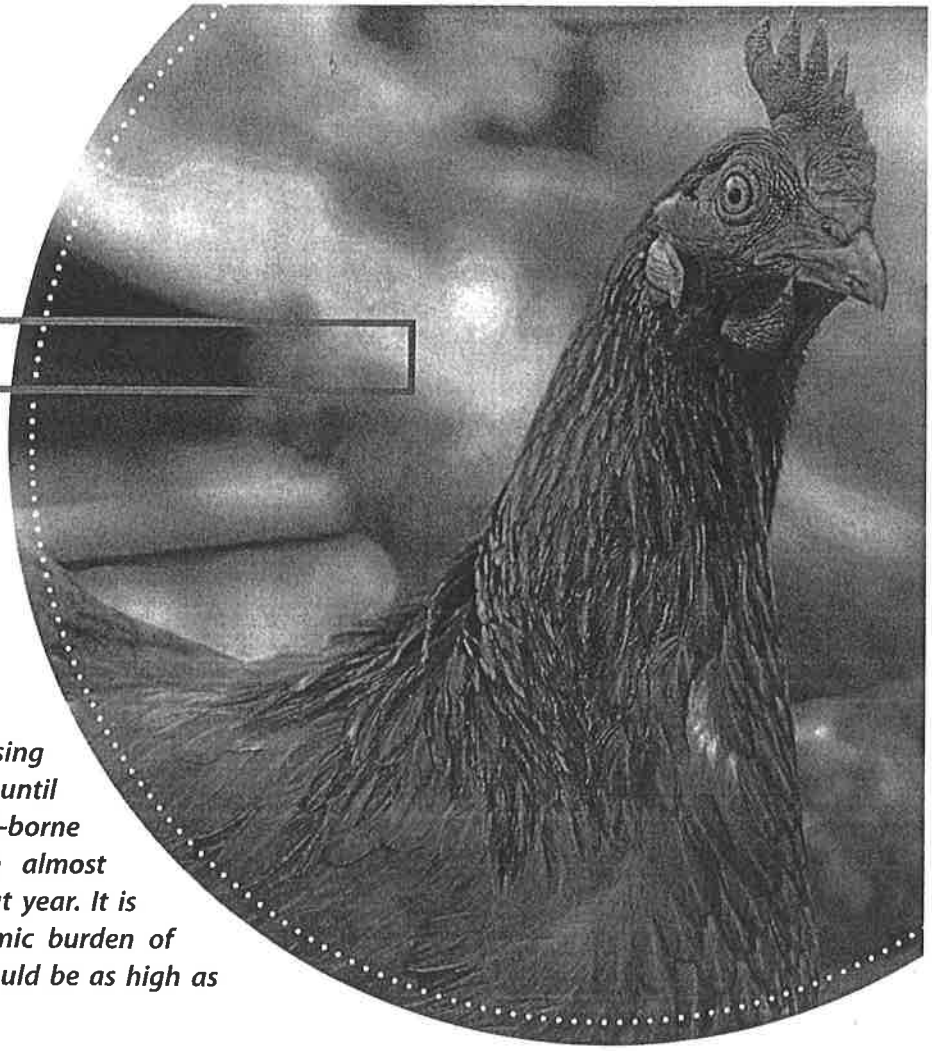
EFSA has also played a major role in EU rapid responses to food-related emergencies such as the contamination of pork by dioxins in Ireland in 2008 and the *E. coli* outbreaks in Germany and France in 2011.

One area in which EFSA's work has changed significantly over the past 10 years is with respect to the evaluation of regulated products such as food additives, GMOs, pesticides and health claims. This work accounts for more than 60% of EFSA's scientific outputs, and the resources committed to this area doubled between 2008 and 2010, from 20% to 40%.

More than 3,000 health claims had been evaluated by the end of 2011, thus protecting European consumers from misleading labelling and advertising of food products. The Annual Report on Pesticide Residues, which EFSA compiles for the EU, gives an increasingly sophisticated overview of the level of compliance with pesticide safety legislation. The most recent report, for 2009, shows that more than 97% of food samples contained safe levels of pesticide residues.

A CASE OF

SALMONELLA



Beating the bacteria

Salmonella – a bacterium causing salmonellosis in humans – was until 2005 the most common food-borne disease in European Union with almost 200,000 reported human cases that year. It is estimated that the overall economic burden of human salmonellosis for the EU could be as high as €3 billion a year.

Salmonellosis is a zoonosis – a disease or infection that can be transmitted directly or indirectly between animals and humans. The bacterium is commonly found in the intestines of healthy birds and mammals. It can spread to humans through contaminated eggs and meat, most often poultry and pig meat. Usual symptoms include fever, diarrhoea and abdominal cramps.

To combat human salmonellosis it is important to reduce *Salmonella* in animals and derived products so that food is safer for consumers. In 2003, the EU set up comprehensive control measures for zoonoses, considering *Salmonella* as a priority. Enhanced *Salmonella* programmes in poultry were implemented in all EU Member States and targets were set for reducing the bacteria in poultry flocks (laying hens, broilers and turkeys).

To support the reduction of *Salmonella* in the food chain, EFSA has advised on the risks for public health from infected animals and provided recommendations and advice on control and reduction measures, such as reduction targets in poultry and poultry meat and the use of vaccines and antimicrobials for the control of *Salmonella*. EFSA has also evaluated the impact of different control measures for *Salmonella* in pigs.

EFSA has assisted decision-makers by analysing the results of EU-wide baseline surveys on the prevalence of *Salmonella* in food and food-producing animals, including evaluating the risk factors that contribute to its prevalence in animal populations and food. In addition, the occurrence of *Salmonella* in humans, animals and food is monitored and analysed in EU Summary Reports prepared by EFSA and the European Centre for Disease Prevention and Control each year to provide up-to-date information on the current situation in Europe.

The coordinated approach by all EU actors has had significant results: human *Salmonella* cases have been reduced by almost 50% in the EU over five years (2004-2009). At the same time, the prevalence of *Salmonella* in poultry decreased significantly, especially in laying hen flocks. The reduction of the bacteria in laying hen flocks is likely to be the main reason for the decline of *Salmonella* cases in humans, since eggs are considered the most important source of human infections in the EU.

EFSA and the European Centre for Disease Prevention and Control continue to analyse the data collected from the Member States on a yearly basis to further monitor the situation and the progress made in meeting reduction targets set for *Salmonella* in various animal populations.

A CASE OF

E. COLI

Rapid response in a crisis

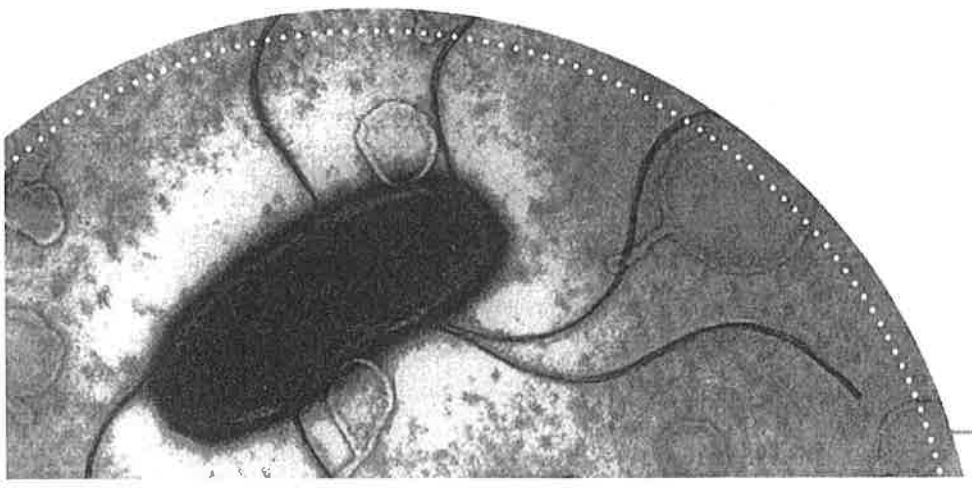
Between the beginning of May and the end of July 2011, there was an outbreak of Shiga-toxin producing Escherichia coli (STEC) in Germany. On 24 June 2011, the French authorities also reported an outbreak in the region of Bordeaux.

Across the EU more than 3,100 cases of bloody diarrhoea and more than 850 of haemolytic uremic syndrome (HUS), a serious condition that can lead to kidney failure, were reported during the two outbreaks; there were 53 confirmed deaths. The outbreak in Germany was the country's biggest food-borne bacterial outbreak for 60 years. Initially the outbreak of *E. coli* O104:H4, a rare strain, was linked through epidemiological investigations to the consumption of fresh salad vegetables. Further investigations identified seed sprouts as the most probable source.

EFSA liaised with German risk managers and assessors, the European Commission, and the European Centre for Disease Prevention and Control (ECDC). The Authority issued a joint statement with ECDC that provided information on STEC infection and transmission modes and advice on how to avoid infection.

EFSA sent senior scientific staff to Germany to provide assistance on data collection and epidemiological analysis. The exchange of information between Member States was facilitated by EFSA through its Advisory Forum and network of Focal Points.

On 6 June, the European Commission asked EFSA to provide scientific assistance and advice on the outbreak. EFSA implemented its established urgent response procedures and published a fast-track risk assessment on the risks to public health from the consumption of raw vegetables.



It also provided advice on options to mitigate the risks of food contamination and human infection. On the same day, EFSA published a technical report with ECDC on the prevalence of STEC in humans, food and animals.

On 24 June, just over a month after the German outbreak had been first reported, the French authorities reported a cluster of cases of patients suffering from bloody diarrhoea. Bacteriological tests identified the probable cause as *E. coli* O104:H4 – the same rare strain that was responsible for the outbreak in Germany.

EFSA's response was two-fold. It jointly prepared with ECDC a rapid risk assessment of the two outbreaks which concluded that fenugreek sprouts were the most likely connection; and, in response to an urgent request from the Commission, it set up a Task Force to trace back the implicated seeds through the EU supply and distribution chain.

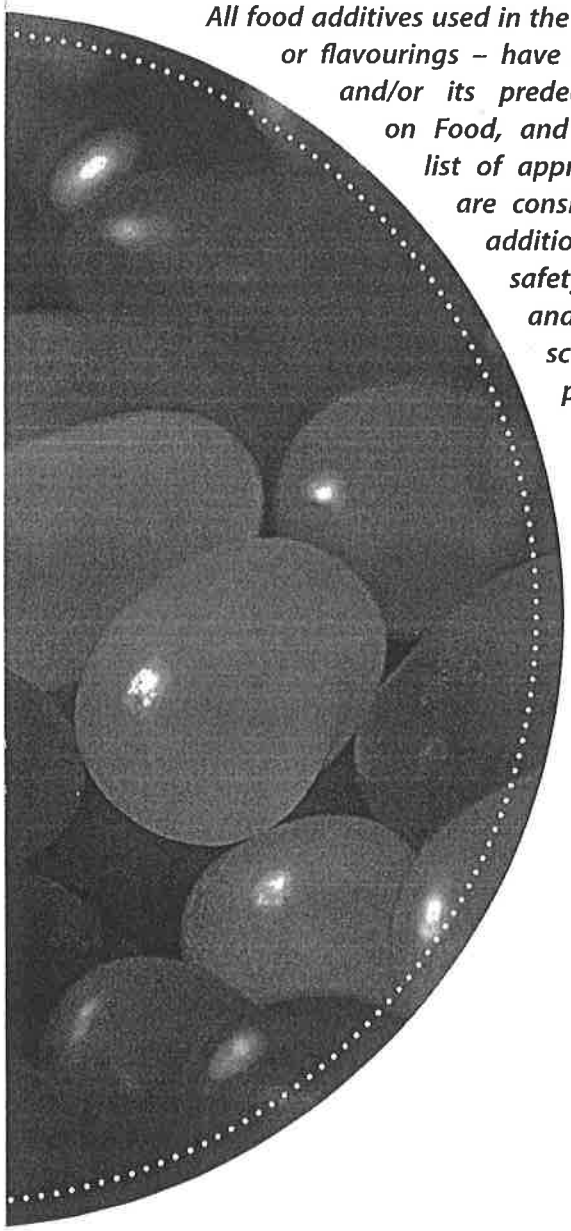
The Task Force, which included specialists from Member States and the Commission, and scientists from ECDC, the World Health Organization (WHO) and the Food and Agriculture Organization (FAO), delivered its report on 5 July, concluding that one lot of fenugreek seeds imported from Egypt and used to produce sprouts was the likely link between the two outbreaks.

Based on the Task Force findings, EFSA recommended to the Commission that all efforts be made to prevent further consumer exposure to the suspect seeds and that forward-tracing be carried out in all countries which may have received seeds from the suspect lots. After the Task Force published its report, the EU was able to take immediate measures to protect European consumers.

A CASE OF

FOOD ADDITIVES

Red light to suspect food colours



All food additives used in the EU – such as colours, preservatives or flavourings – have been assessed for safety by EFSA and/or its predecessor, the Scientific Committee on Food, and are included on the official EU list of approved food additives only if they are considered safe for human health. In addition, whenever necessary, previous safety assessments have been reviewed and updated to take into account new scientific information pointing at a possible concern for health.

To bring this process up to date, the European Commission asked EFSA in 2010 to re-evaluate the safety of all previously authorised food additives by 2020, taking into account the latest science. Based on EFSA's scientific advice, the European Commission and Member States may decide together to change the uses of additives or if needed to remove them from the EU list of authorised food additives in order to protect consumers.

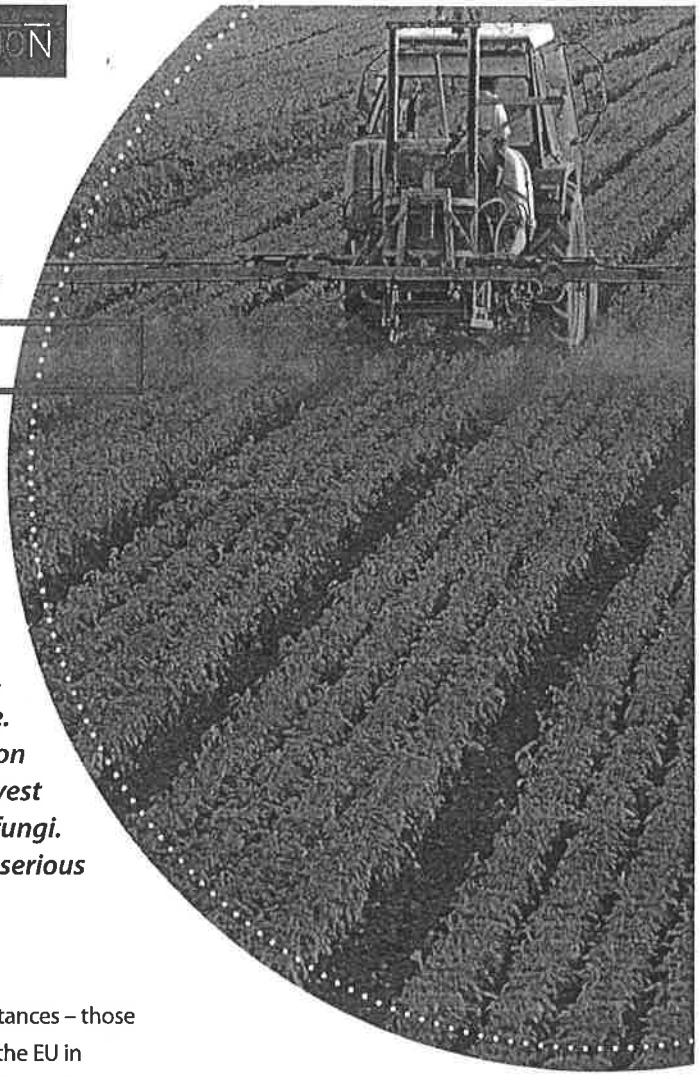
Food colours are being re-evaluated first as they were among the first additives to be authorised for use in the EU. Many sweeteners, in contrast, were approved more recently and are scheduled for review after 2015. EFSA, together with the European Commission, can also choose to re-prioritise a food additive in light of new information; for example, the deadline for the artificial sweetener aspartame was brought forward from 2018 to 2012 due to concerns raised regarding recent studies.

EFSA's ability to re-evaluate the safety of a food additive depends greatly on the availability of scientific data. EFSA has already launched more than ten calls for data covering entire groups or classes of food additives and/or specific to one or a small number of related food additives. Through careful planning EFSA screens and organises the scientifically relevant data in advance of their consideration by EFSA's experts.

As of 2012, EFSA has completed the re-evaluation of most food colours and adopted its first non-food colour re-evaluation in 2011: an antioxidant called butylated hydroxyanisole or BHA (E 320). The Authority has made headway in collecting data for the remaining colours as well as for many preservatives, antioxidants, waxes, emulsifiers and gelling agents. However, EFSA is sometimes required to issue further calls for data due to a lack of sufficient information being available.

Among the food additives re-evaluated, EFSA decreased the acceptable daily intake (ADI) for several food colours, since it considered in light of new information that human exposure to these colours is likely to be higher than originally assessed. As a result, in March 2012, the European Commission lowered the maximum levels of three of these colours (E 104, E 110, E 124) that can be used in food. The new rules take effect from 1 June 2013.

Another significant impact from this work was the withdrawal of the colour Red 2G (E 128) from the market in 2007. New scientific evidence made available at that time indicated that use of this food additive could be a safety concern: as well being carcinogenic, Red 2G could also cause damage to the genetic material of human cells. EU decision-makers agreed with EFSA's experts that this food additive could not be regarded as safe for humans and it was subsequently suspended from use in the EU.



A CASE OF

PESTICIDES

Actively reducing risk

Plant protection products are a reality of modern times, given the quantity of food that we need to produce. They are used primarily to protect crops from infestation by pests and diseases, which can severely reduce harvest yields, usually working by killing insects, weeds and fungi. However, the chemicals in pesticides could have serious undesirable effects if they are not strictly regulated.

In the EU no plant protection products can be used unless it has been scientifically established that they have no harmful effects on consumers, workers or bystanders; they do not damage the environment; and they are sufficiently effective.

Crucially, the level of residues found in food must be safe for consumers and must be as low as possible. In the EU this safety threshold is maintained through a system of maximum residue levels (MRLs), which is underpinned by EFSA's scientific evaluations.

Since 2003, EFSA has been responsible for the EU peer review of active substances used in plant protection products. An active substance is the essential chemical component that enables a pesticide to protect a plant.

This task is carried out by EFSA's Pesticides Unit following procedures set out in EU legislation and the latest scientific standards and methods. By December 2008 EFSA's work had enabled the Commission to conclude the review process for all existing substances – those that were on the market in the EU in 1993 – and draw up a list of those that may be included in plant protection products. EFSA then embarked upon the peer review of "new" active substances (those placed on the market after 1993), for which the Commission had requested advice on the risk assessment.

The review has led to the removal from the market of pesticides which cannot be used safely. Of about 1,000 active substances on the market in at least one Member State before 1993, 26%, corresponding to about 250 substances, passed the harmonised safety assessment. The majority (67%) were removed from the market because dossiers were either not submitted, incomplete or withdrawn by industry. About 70 substances failed the review.

EFSA has also been central to the harmonisation of MRLs across the EU. Legislation that became effective in 2008 repealed the previous fragmentary legislation and replaced all national MRLs with harmonised MRLs across the EU.

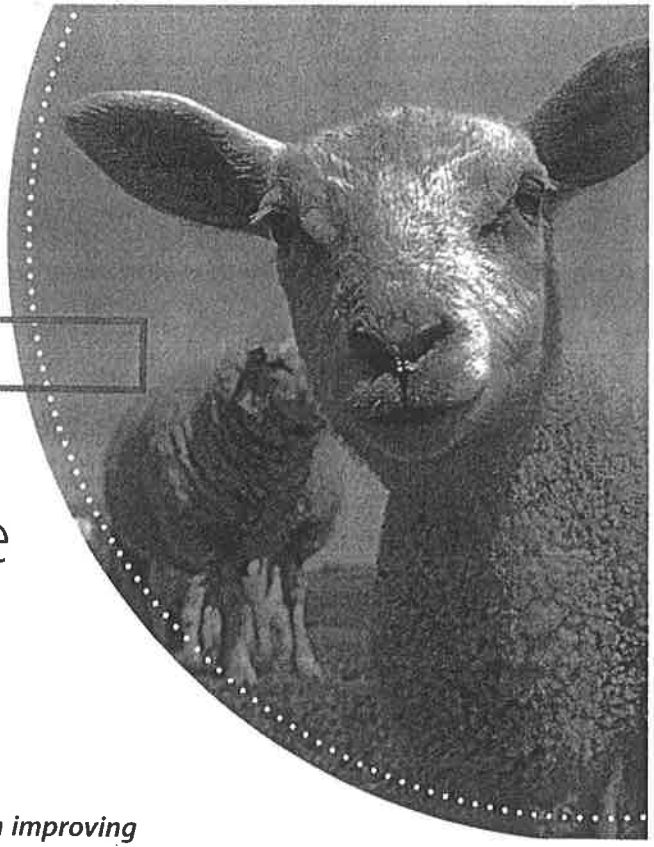
To enforce compliance with MRLs, Member States have to carry out official controls on pesticide residues. The results of the controls are reported to the Commission, other Member States and EFSA.

Every year, EFSA publishes an Annual Report on Pesticide Residues in the EU based on the monitoring information received from the EU Member States as well as Iceland and Norway. The EU MRL monitoring programmes are one of the most comprehensive food surveys in the world, covering more than 60,000 food samples which are analysed for up to 800 pesticides. The report also assesses the exposure of European consumers to pesticide residues through their diets.

The 2009 report shows that compliance rates continue to rise, with 97.4% of the samples analysed falling within the permitted MRLs, a rise of about one percentage point since 2008.

A CASE OF

ANIMAL HEALTH AND WELFARE



Driving animal welfare forward: the case of animal transport

In the last 10 years, EFSA has played an important role in improving the welfare of animals in the EU. Led by its Panel on Animal Health and Welfare (AHAW), a group of leading experts with experience in areas such as veterinary sciences and animal behaviour, EFSA provides scientific advice on the welfare of farm animals, including pigs, fish, broiler chickens and dairy cows. It examines a wide range of issues affecting the welfare of each animal species, such as housing and husbandry systems, nutrition and feeding, transport and stunning and killing methods.

The work on the welfare of animals during transport is one example of the important contribution the AHAW Panel has made over the last 10 years. In 2004, the Panel published two scientific opinions on the welfare of transported animals. The first outlined general principles related to all animal species as well as detailed conclusions and recommendations on the transport of individual species. The second looked at factors that affect the micro-climate of animal road transport vehicles, such as temperature and humidity of the air, air velocity or air quality. These factors are known to significantly influence welfare and health of animals if they are not kept within an appropriate range. The advice from both opinions had a direct impact on related EU legislation that came into force in the following year.

More recently, following a 2010 request from the European Commission for scientific advice, the Panel collected the latest scientific information in relation to welfare risks for transported animals and presented its findings and recommendations in a new scientific opinion. EFSA also organised a technical meeting to exchange views with relevant stakeholders, including transporters, livestock breeders and animal welfare NGOs. This exchange of information proved invaluable to the Panel as it helped to improve its understanding of stakeholder concerns and ensure that its advice and recommendations reflected current operating practices.

Importantly, the opinion also evaluated animal-based welfare indicators and their possible use as an alternative to the assessment requirements set out in the current legislation. Most of the current legislation on the protection of animals focuses on the assessment of factors that impact on welfare rather than on the animal's response to these factors. In the case of animal transport, such factors might include the length of the journey or the number of times the animal is allowed to rest or take water. An approach using animal-based measures, on the other hand, focuses on the response of the animal to factors in its environment and can be used as an alternative or sometimes complementary approach to assessing the factors themselves. For example, if after inspecting an animal, an inspector believes it is suffering from high body temperature or making abnormal respiratory sounds, he or she could declare the animal unfit for transport.

The rationale for this approach is that animal-based measures aim to directly determine the actual welfare status of the animal and therefore include both the effect of the environment as well as how the animal copes with it.
In the last couple of years, EFSA's work in this area has not been confined to animal transport: by the end of 2012, it will have produced a series of scientific opinions on the use of animal-based measures to assess the welfare of the main farm species: dairy cows, cattle, pigs, and broiler chickens.

A CASE OF

TRUST

Trust in the EU food supply chain

The series of food crises in the late 1990s prompted recognition among European public authorities and policy makers that the EU food safety system needed to be recast. The introduction of the General Food Law in 2002 separated the functions of risk assessment and risk management and led to the creation of EFSA. This new approach sought to ensure the highest levels of consumer protection and restore the confidence of consumers and trading partners. Almost 10 years after EFSA published its first scientific opinion, the approach is well established. Today, the advice that the Authority provides to risk managers underpins many of the laws and regulations in place to protect European consumers from food-related risks.

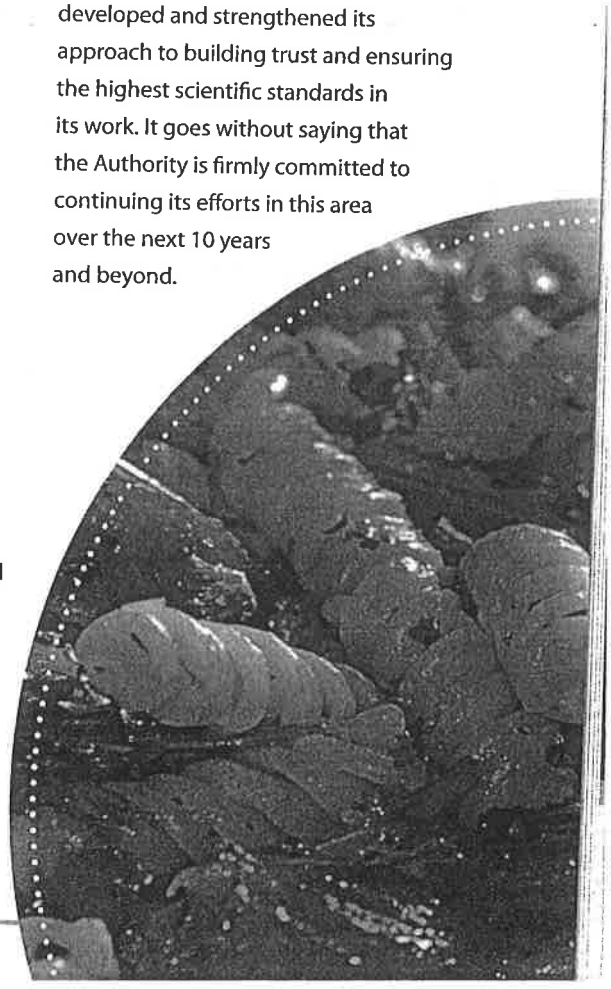
According to a Eurobarometer report on perceptions of food-related risk in 2010, EU citizens have a high level of trust in scientists (73%) and national and European food safety agencies (64%) as sources of information on food risks. There is also broad agreement that public authorities do a lot to ensure that food is safe in Europe, that they are quick to act, base their decisions on scientific evidence and do a good job in informing people about food-related risks. The level of agreement in the 2010 Eurobarometer report is higher than that in a similar survey carried out in 2005. A qualitative research study with EFSA's stakeholders on the image of the Authority carried out in 2010 highlighted the fact that its stakeholders would not want to return to the pre-EFSA food safety system.

Nonetheless, the 2010 Eurobarometer also raised potential areas of concern. Less than half of EU citizens (47%) think that scientific advice on food-related risks is independent of commercial or political interests. As a risk assessor evaluating the safety of products subject to regulation, for example genetically modified organisms or the active substances found in pesticides, EFSA must pay particular attention to these figures. Indeed, the Authority is acutely aware that public trust in the organisation and its scientific experts is fundamental to the value of the scientific advice that it provides.

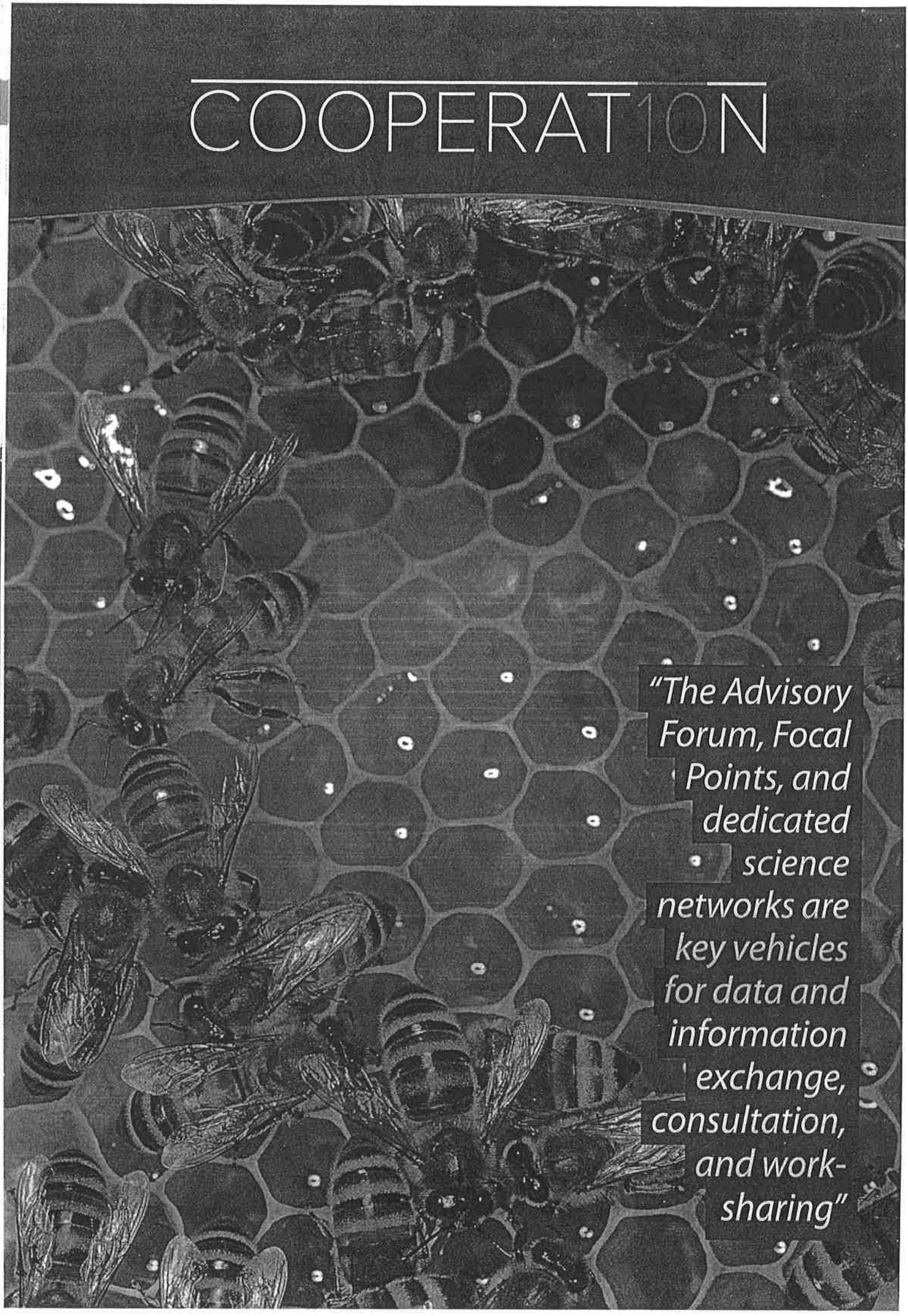
An example of EFSA's approach to building trust can be seen in the related actions and decisions it took in 2011. In total, the Authority screened more than 8,000 Declarations of Interest from external experts and staff, scrutinised more than 40,000 agenda items, prevented 356 potential conflicts of interest and initiated two 'breach of trust' procedures. In the same year, the Authority also adopted a Policy on Independence and Scientific Decision-Making Processes. The new policy, which was subject to a public consultation and discussed at length with stakeholders and interested parties, integrates in one document the wide range of initiatives EFSA has put in place since its creation to foster trust in its work.

Independence and transparency, in particular, are issues that are addressed in depth in this document, for example in proposal to simplify and clarify the rules related to potential conflicts of interest for staff and scientific experts engaged in the Authority's work. It also increases information on how decisions on conflicts of interest are reached, it strengthens procedures concerning breaches of trust and it amends the definition of conflict of interest to better reflect guidelines from the Organisation for Economic Co-operation and Development (OECD).

Over the last 10 years, EFSA has developed and strengthened its approach to building trust and ensuring the highest scientific standards in its work. It goes without saying that the Authority is firmly committed to continuing its efforts in this area over the next 10 years and beyond.



COOPERATION



"The Advisory Forum, Focal Points, and dedicated science networks are key vehicles for data and information exchange, consultation, and work-sharing"

Working together, working for Europe's citizens

Scientific cooperation between EFSA and EU Member States is a central pillar of EFSA's Founding Regulation and has therefore been a cornerstone of the Authority's activities since it was set up in 2002. EFSA's relationship with the Member States is critical both from a data collection and information exchange perspective – ensuring that a high calibre of evidence can be applied to risk assessment.

Partners include institutions with whom the Authority has a legal obligation to work, specifically risk managers working within the European Commission, the European Parliament and the Member States, risk assessors, stakeholder groups and individuals or groups who feel they can contribute to the Authority's work. This integrated system, with EFSA at its core, has produced high-profile work such as the EU reports on zoonoses and antimicrobial resistance and, further afield, a harmonised approach to Total Diet Studies, developed with the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).

The Strategy for Cooperation and Networking, adopted in 2006, identified four priority areas:

- exchanging and collecting scientific data and information;
- sharing risk assessment practices;
- contributing to the harmonisation of methodologies for risk assessment;
- promoting coherence in risk communications.

The strategy was reviewed in 2008 and a further "taking stock" exercise was completed in 2010. This process has produced a sophisticated and increasingly valuable system of cooperative endeavour between EFSA and the Member States, including medium-term planning of scientific cooperation activities.

The Advisory Forum, Focal Points, and dedicated science networks are key vehicles for data and information exchange, consultation, and work-sharing between EFSA and Member States. The Advisory Forum connects EFSA with the national food safety authorities of all 27 EU Member States, Iceland and Norway, with observers from Switzerland and the Candidate countries. The Forum advises EFSA on scientific matters, its work programme and priorities, and helps the Authority to address emerging risk issues as early as possible. It acts as a risk assessment "umbrella" for Member States, allowing them to concentrate their energies on national priorities and reducing duplication of effort.

Focal Points act as outreach bodies in the Member States, linking EFSA and the national food safety authorities, research institutes, consumers and other stakeholders, supporting national Advisory Forum members.

EFSA's science networks consist of nationally appointed EU Member State organisations with expertise in the fields covered by the network.
They play an invaluable role in assisting the coordination of activities, the exchange of information (e.g. on recent risk assessment activities or on data collection), the development and implementation of joint projects (e.g. scientific events and workshops), and the exchange of expertise and best practice in the fields within EFSA's mission.

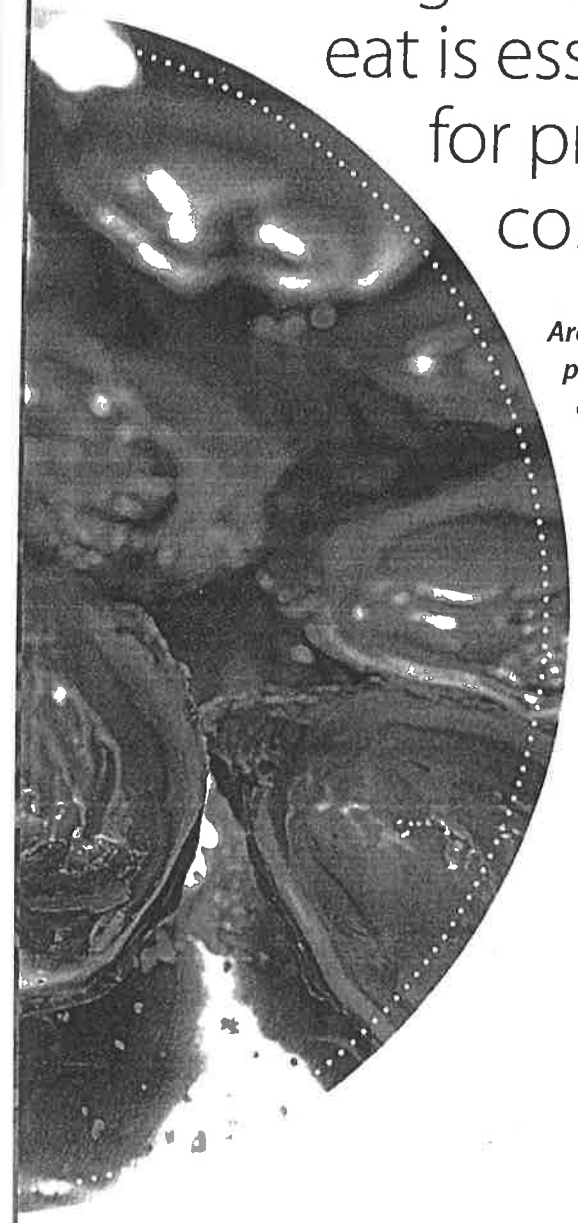
In addition to these formal ties, the Authority awards grants and issues procurement orders to organisations that have been officially nominated by Member States to help EFSA with tasks such as data collection, preparatory work for scientific outputs, and other forms of technical assistance. EFSA has consistently increased its support to data collection and other scientific cooperation with Member States, allocating in 2012 over €9 million to these activities (an increase of almost €1 million compared to the previous year). Effective pooling of excellence is also supported through EFSA's steadily growing Expert Database, which gives EFSA and Member States access to the best experts available.

EFSA has also developed close links with consumer groups, non-governmental organisations (NGOs) and bodies representing groups such as farmers, food producers and distributors and science professionals. It has built on the requirement in its founding statute to establish "effective contacts with consumer representatives, producer representatives, processors and any other interested parties", most notably with the establishment of its Stakeholder Consultative Platform.

A CASE OF

FOOD CONSUMPTION DATA

Knowing what Europeans eat is essential for protecting consumers



Are intakes of food additives safe for all population groups? Are consumers exposed through their diet to high levels of heavy metals such as cadmium? Which populations groups consume most shellfish? Could these foods include marine biotoxins which may be harmful to health? Does the food we eat provide us with the nutrition we need?

These are some of the many questions that EU risk assessors at EFSA and in Member States address in their work every day. Food consumption habits also differ in EU countries. When a new hazard is found in the food chain scientists must quickly assess who is exposed, through which foods and by how much. Accurate, comprehensive and comparable data on food consumption are crucial to accomplishing this task.

EFSA has made considerable progress in recent years to bring together data on food consumption habits. In 2007, the Authority initiated the collection of data from national dietary surveys in all Member States and its compilation in a new Concise European Food Consumption Database. This tool provided data on food consumption for adults in EU countries according to broad categories (e.g. milk and dairy-based products) and subcategories (e.g. cheese) and was primarily used for exposure screening (identifying patterns or habits of consumption).

It also served as a starting point for EFSA to develop the Comprehensive European Food Consumption Database which provides more extensive and detailed information for a majority of EU countries in refined food categories and specific population groups, including children. The database enables quick screening and more precise estimates of chronic and acute exposure to substances and possible hazards that may be found in the food chain.

These databases are important tools in EFSA's and other actors risk assessment work. However, EU Member States use different methods to collect food consumption data, which makes it difficult to carry out EU-wide analyses or comparisons between countries.

EFSA has therefore taken steps to harmonise the collection of food consumption data to allow for more comprehensive exposure assessments. The "What's on the Menu in Europe?" (EU Menu) project aims to provide standardised information on what people eat in all countries and regions across the EU. This data will enable even more accurate exposure assessments in Europe and support risk managers in their decision making on food safety.

EFSA continues to extend and update the databases with new data collected by Member States when available. Thanks to this cooperation, food consumption summary statistics for different countries and age groups, previously unavailable at EU-level, are now accessible for use by all food safety and public health experts.

A CASE OF

RISK COMMUNICATIONS

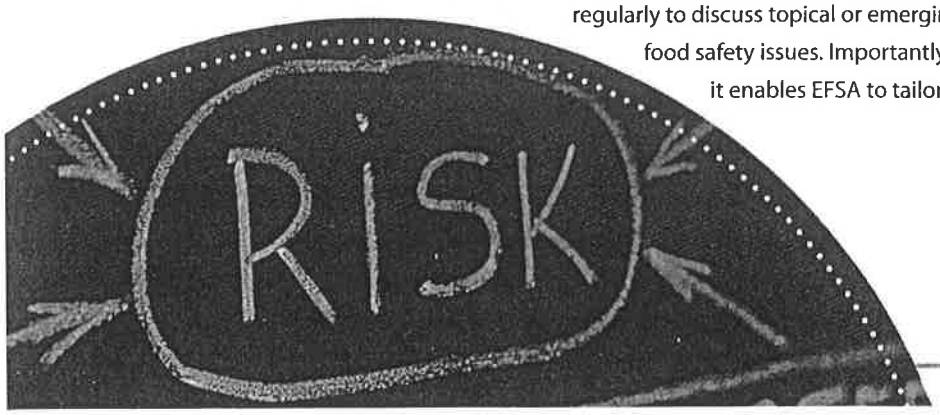
Making it clear, timely and relevant

Communicating on risks associated with the food chain is a key part of EFSA's mandate. By communicating on risks in an open and transparent way based on the advice of its scientific expert panels, EFSA contributes to improving food safety in Europe and to building public confidence in the way risk is assessed.

Fulfilling the Authority's mandate on risk communications and implementing its dedicated communications strategy, presents a number of challenges, not least due to the range and breadth of the audiences with which EFSA communicates. The messages EFSA delivers not only have to be understood by specialist audiences, such as policy-makers, the scientific community and industry but also, on a broader level, to be made relevant to the 500 million consumers of the European Union. It is essential that both these groups have confidence in the decision-making processes underpinning food law, its scientific basis and the structures and independence of the institutions protecting health and other interests.

EFSA cooperates with Member States through its Advisory Forum. The Forum is made up of representatives from each Member State as well as Iceland and Norway and its members advise the Authority on scientific matters, its work programme and priorities and also address emerging risk issues as early as possible. In addition to scientific risk assessment issues, the Forum also has an important role to play in co-ordinating risk communications and messages. This particular aspect of its work is carried out by the Advisory Forum Communications Working Group (AFCWG), which comprises communications professionals from across Europe with expertise in food-related issues.

Established in 2003, the AFCWG promotes coherence in risk communications and provides a mechanism for exchange of information and experiences between EFSA and the Member States. Members meet regularly to discuss topical or emerging food safety issues. Importantly, it enables EFSA to tailor its messages to the specific needs of European Member States and regions.

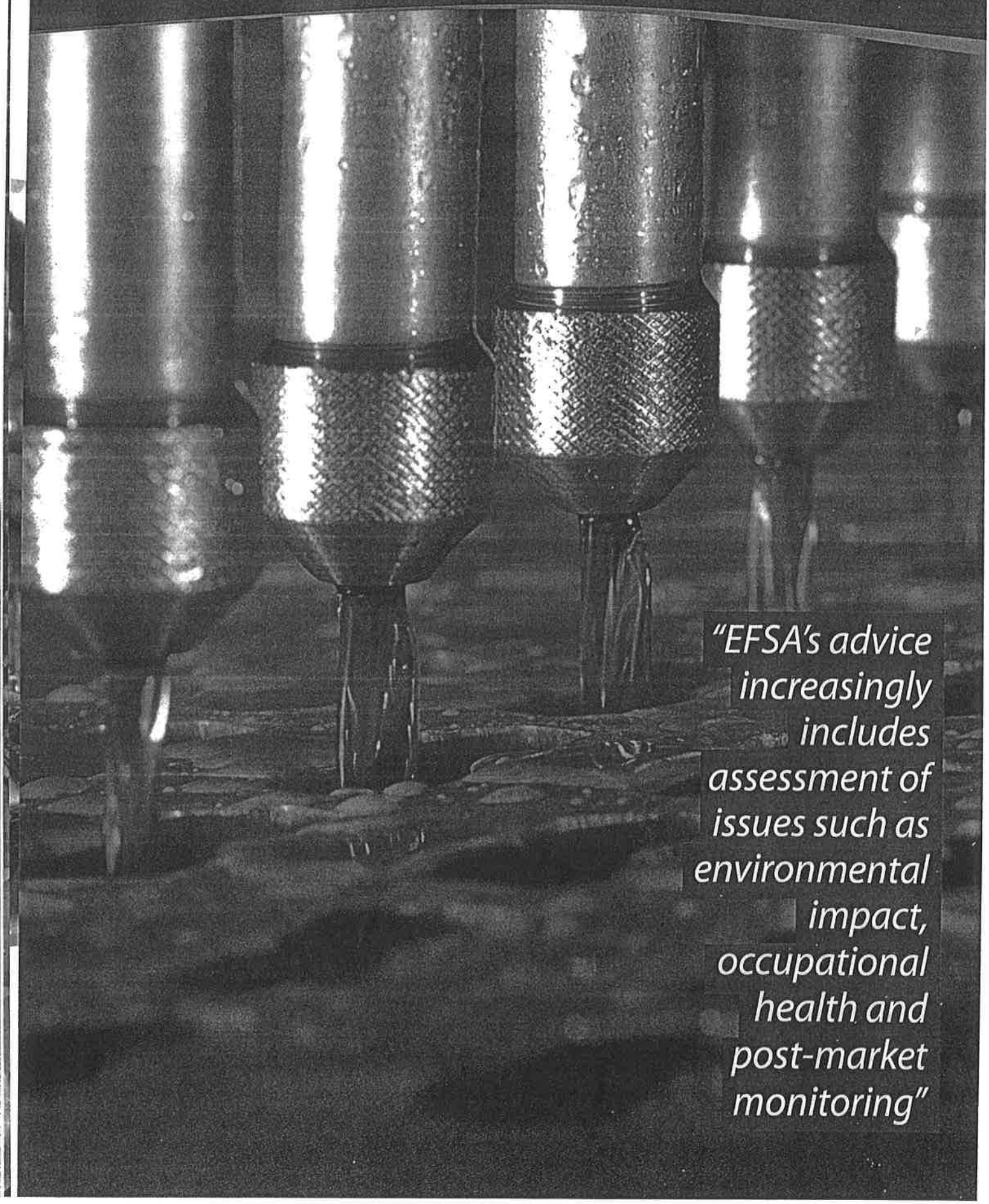


Recently, the network identified the need for a common framework to guide food safety professionals in the area of risk communications. EFSA's AFCWG launched an initiative to develop its own risk communications guidelines. The aim of the guidelines is to provide a framework to assist decision-making about the most appropriate approach to communicating food-related risk. The guidelines have been welcomed by AFCWG members and, as a practical resource and tool, are expected to make an important contribution to the work of European risk communicators.

Another important EFSA network in this area is the Advisory Group on Risk Communications (AGRC). The AGRC is made up of experts in the areas of sociology, consumer science, stakeholder relations, psychology and communications. One of the issues addressed by this group is consumer perception of food and food-related risks. In understanding this more, EFSA is able to tailor communications appropriately to different target audiences to ensure their needs and concerns are met.

To this end, in the last 10 years, EFSA has commissioned two Eurobarometer surveys on risk perception in the EU. The findings of the reports show that most Europeans view national and European food safety agencies as reliable sources of information on possible risks associated with food. The surveys have proved invaluable in guiding and informing EFSA's communications. They underpin the approach we take to communicating on certain issues and the manner in which we seek to engage with our different target audiences.

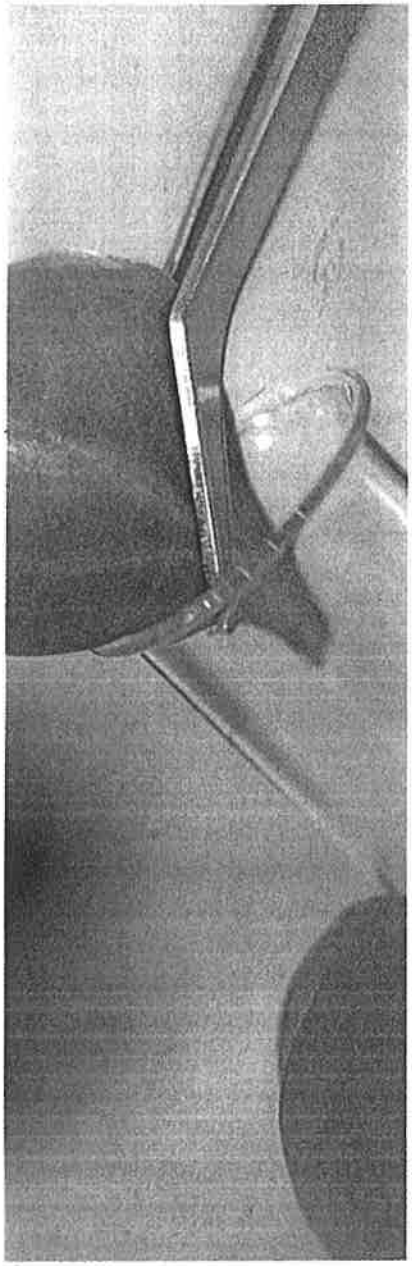
INNOVATION



"EFSA's advice increasingly includes assessment of issues such as environmental impact, occupational health and post-market monitoring"

New tools for the tasks ahead

In the second decade of the 21st century EFSA faces new expectations and demands on its resources which reflect emerging issues such as climate change, the changing demographics of Europe, and the rapid expansion of global trade. The latter development has led to a sharp rise in the range and volume of goods being imported into Europe from emerging markets.



In addition, the EU's 2020 Agenda has re-emphasised the importance of innovation as a means of increasing the competitiveness of Europe. The Commission has also highlighted the need to ensure food security within Europe and internationally, the desirability of environmental, social and economic sustainability, and Europe's obligations to its ageing population.

All of these trends are affecting the nature and volume of EFSA's work and the evolution of its risk assessment methods. EFSA's advice increasingly includes assessment of issues such as environmental impact, occupational health, post-market monitoring, risk comparisons and health benefits.

As outlined in the Strategic Plan 2009-2013 and the Science Strategy 2012-2016, the Authority is increasingly focusing on integrated multi-disciplinary advice in areas such as meat inspection, nutrition and animal welfare. It will continue to ensure it meets the highest standards through the development of state-of-the-art, harmonised methodologies and the collection and analysis of high-quality data.

Major progress has been made during the past decade in developing methodologies, but further harmonisation is required within EFSA, with Member States, with other EU agencies and internationally. EFSA will be at the forefront of this vital work.

A broadening of the scientific discourse can be seen in the work of EFSA on the modernisation of meat inspection, antimicrobial resistance, antimicrobial treatments and feed additives involving several of EFSA's Scientific Panels.

EFSA will also further develop its proactive, integrated approach to identifying and evaluating emerging risks. Greater cooperation at national and international level will be needed to address the risks posed by, for example, increased international trade, global warming, and changes in consumer behaviour.

At an organisational level the Authority will seek to optimise its resources by leveraging its internal scientific expertise and reducing the workload of its external scientific experts related to routine scientific work. The Applications Desk Unit, which is dedicated to handling applications and queries related to regulated products, should increase efficiency in this growing area of work.

As the organisation enters the next stage of its development it aims to continue protecting Europe's citizens while at the same time providing the science to support a regulatory environment for food producers, processors and distributors that is demanding but predictable. This will foster technological innovation in the economically important agrifood sector and support sustainable growth and development in the Europe of the future.

A CASE OF

MEAT INSPECTION

Making risk a factor in meat inspections

The main purpose of meat inspection is to assure consumers about the safety, sound hygiene and nutritional value of their food. Through checks on the live animal, carcass, offal, abattoirs, equipment, personnel and transport meat inspection can also help to detect and prevent public health hazards such as food-borne pathogens or chemical contaminants in food of animal origin.

Meat inspection also plays an integral part in the overall monitoring of many animal diseases and of compliance with animal welfare standards. Traditional practices in many countries involve sensory checks (by sight, touch and incision) for the presence of gross lesions or flaws such as bruises or broken bones. However, these are not always suitable for detecting food-borne diseases such as campylobacteriosis, salmonellosis and virulent strains of *E.coli*, or contamination by chemical substances such as steroids or veterinary drug residues.

In the light of requests received from Member States, the European Commission decided that meat inspection practices in the EU should be modernised. Consequently, in May 2010, EFSA was asked for scientific advice on the possible introduction of a risk-based approach to meat inspection, at all relevant stages of the meat production chain.

To fulfil this complex mandate, EFSA is drawing on its expertise in a wide range of fields within its scientific remit (risk assessment and data monitoring of biological hazards, chemical contaminants, animal health and welfare) to deliver scientific opinions and reports for the following six animal species/ groups of species: domestic swine, poultry, cattle, domestic sheep and goats, as well as farmed game and domestic solipeds (single-hoofed animals such as the horse, donkey or ass).

EFSA's role is to: identify and rank public health hazards – biological and chemical – in meat; assess the strengths and weaknesses of the current inspection methodology; recommend methods for spotting hazards not addressed by current meat inspection; and recommend adaptations of methods and/or frequency of inspections based on the hazard rankings and new harmonised epidemiological indicators (which EFSA must also propose). The Authority is also required to consider the implications for animal health and welfare of any proposed changes to current inspection practices.

In October 2011, EFSA made its first major contribution by publishing its scientific opinion on the public health hazards covered by inspection of swine meat, and the accompanying scientific report on harmonised epidemiological indicators for this type of meat inspection.

EFSA's experts concluded that current inspection methods do not enable the early detection of the first three of these hazards and, more broadly, do not differentiate food safety aspects from meat quality aspects, prevention of animal diseases or occupational hazards.

To reduce biological hazards, they recommended the abolition of touch and/ or incision techniques in post-mortem inspection of pigs subject to routine slaughter because of the risk of bacterial cross-contamination.

When EFSA and its partners complete this work, risk managers will have the best scientific information and advice possible for establishing a comprehensive meat inspection regime across the EU, potentially bringing far-reaching benefits to consumers.

A CASE OF

ENVIRONMENTAL RISK ASSESSMENT

Protecting humans, protecting the environment

Environmental Risk Assessment (ERA) is a specialised field of science that considers the impact on the environment caused by, for example, the introduction of GM plants, the use of certain substances in food and feed products or the spread of plant pests.

In the case of GM plants, the law requires that GM plant developers carry out an ERA and submit it as part of their application for authorisation on the EU market. EFSA is responsible for evaluating this assessment and makes recommendations to risk managers such as the European Commission (EC) and Member States about the environmental safety of the GM plant in question.

The ERA has to be performed in line with EFSA guidance, which gives GM plant developers clear instructions for this type of assessment. In 2008, the EC asked EFSA to update its guidance to applicants on the ERA of GM plants.

ERA of GM plants is an area which generates significant scientific and political debate, with a wide divergence of opinions among both non-governmental and institutional stakeholders across Europe. Although EFSA has no part to play in the political process concerning the authorisation of GM plants in the EU, in updating its guidance the Authority sought to ensure that all relevant views from stakeholders and interested parties were considered.

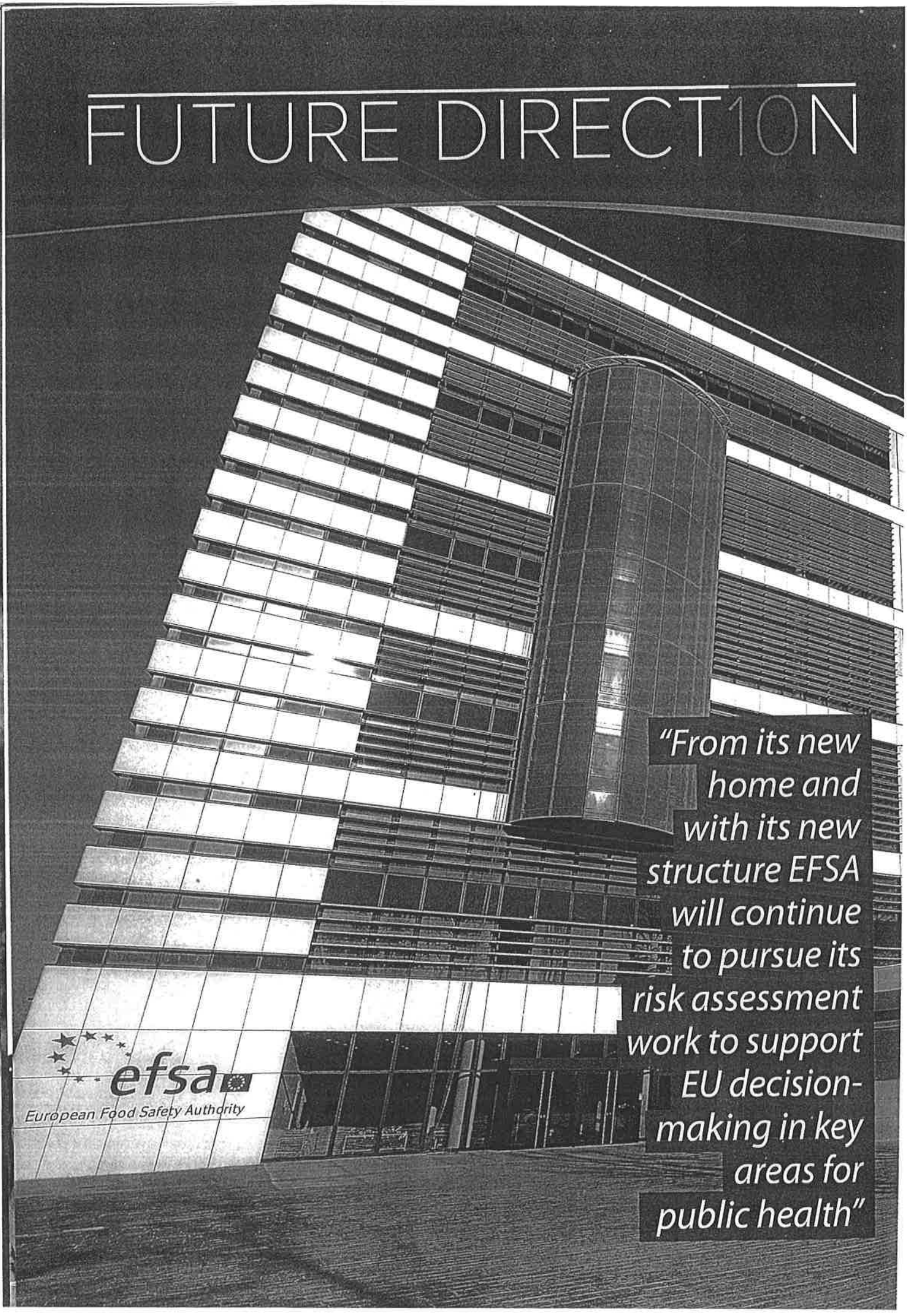
In summer 2009, EFSA held a three-day consultative workshop in Berlin to share its preliminary work on the guidance and to give stakeholders the opportunity to discuss their views and concerns directly with the EFSA GMO Panel. Further stakeholder input was sought towards the end of 2009 during a two-day European conference on "GMO risk assessment for human and animal health and the environment", where presentations were given by Member State experts, environmental NGOs and industry associations.

The extensive stakeholder feedback gathered through these events was, where scientifically relevant, incorporated by the GMO Panel into its draft ERA guidance document. This was launched for public consultation at the beginning of 2010 and attracted a large number of comments. Key contributors to the consultation were invited by EFSA to take part in technical meetings, giving the GMO Panel the opportunity to hear again directly from interested parties, including those with differing points of view. Following these technical meetings, the GMO Panel finalised the guidance document which was eventually published in November 2010.

This extensive consultation allowed differing views and opinions to be heard by the GMO Panel and considered in the development of the document. In particular, the series of technical meetings also gave stakeholders and interested parties the opportunity to discuss scientific issues directly with Panel members and to understand more about the possibilities and limitations of the pre-market ERA for GM plants.

The guidance has been complemented by further EFSA guidelines on post-market environmental monitoring (PMEM). Monitoring is a key feature of the legislative framework on GM plants and, taken together with a rigorous pre-market environmental risk assessment and risk management, forms an important part of the cycle of measures in place to detect and limit possible adverse effects, including those that may occur over a long period of time.

FUTURE DIRECTION



"From its new home and with its new structure EFSA will continue to pursue its risk assessment work to support EU decision-making in key areas for public health"

Scientific excellence in a changing world

The European Union has changed significantly since EFSA was established in 2002. The number of Member States has risen from 15 to 27 and the EU has become the largest importer and exporter of foodstuffs, especially processed goods, in the world. The admission of 12 new Member States in the first decade of the 21st century increased the total area of the EU to 4.4 million km² and took the population up to around 500 million. At the same time, issues surrounding food production have become ever more complex with the emergence, for example, of new technologies such as "novel foods" and genetically modified organisms.

EFSA has grown and the nature of its work has evolved to reflect this new environment. The number of Scientific Panels has risen from eight to ten and the Scientific Committee plays an increasingly important role in developing and harmonising risk assessment methodologies across the EU. The Authority has also built a sophisticated data-collection capacity and devotes an ever-increasing proportion of its resources to carrying out scientific evaluations of regulated substances, products and claims submitted for market authorisation in the EU.

The Authority marked its 10th anniversary by moving out of its temporary headquarters in Parma to new, purpose-built premises on 5 January 2012. The Authority was fully operational from the first day, and meetings with scientific experts resumed smoothly in the first week of the year.

The new seat is technologically equipped to enhance networking with experts, generate quick response to emerging threats, and guarantee business continuity under all foreseeable conditions, thus reinforcing EFSA's capacity for fulfilling its mission. Remote participation in meetings will increase cost efficiency, help to strengthen transparency and, importantly, reduce the carbon footprint of EFSA's activities.

EFSA has also carried out a thorough re-organisation programme, to make better use of its resources to reflect an ever increasing workload, strengthen efficiency and provide a higher-quality service to its clients.

From its new home and with its new structure EFSA will continue to pursue its risk assessment work to support EU decision-making in key areas for public health. Central to the Authority's work in the immediate future will be the implementation of the Science Strategy 2012-2016, which highlights how the Authority has grown into its pivotal position within the European food safety system and lays out a vision for further developing EFSA's scientific excellence and strengthening the scientific basis for risk assessment and monitoring across the European Union.

The world has changed since EFSA's inception and EFSA is changing with it. The Authority continues to enjoy the trust of European consumers and stakeholders, trust that reflects the degree to which EFSA has, over the first 10 years of its existence, successfully implemented its core values of scientific excellence, independence, transparency, openness and responsiveness.

EFSA@10

THE SCIENCE THAT IS HELPING TO KEEP EUROPE'S FOOD SAFE

efsa
European Food Safety Authority

2002

EFSA is established to protect European consumers following a series of food crises in Europe. **Stuart Slorach** chairs the first meeting of the **Management Board**.

EFSA becomes an **operational EU agency**, based in Brussels. **Geoffrey Podger** appointed Executive Director.

2003

The **Scientific Committee and Scientific Panels** are established, composed of risk assessment experts from across Europe. First **Scientific Opinion** published.

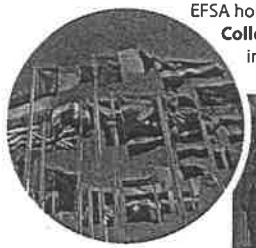
First meeting of the **Advisory Forum**, the body that connects EFSA with the national food safety authorities of EU Member States.

72 Number of staff

2004

Task Force on Zoonoses Data Collection set up comprising representatives of EU Member States, the WHO and the World Organisation for Animal Health.

EFSA holds its first **Scientific Colloquium** in Brussels.

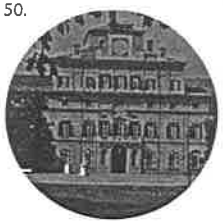


EFSA's Management Board, September 2004

2005

Stakeholder Consultative Platform created.

EFSA moves into new premises in **Parma**, Italy. Number of staff reaches 150.



150 Number of staff

2006

Adoption of **strategy for cooperation and networking** with EU Member States.

Communications Strategy adopted, formalising EFSA's commitment to communicate advice to its principal partners, stakeholders and the public.

First **public consultation** on a Scientific Opinion.

2007

Catherine Geslain-Lanéelle appointed as Executive Director.

300 Number of staff

2008

Pesticide Steering Committee is created, made up of representatives from EFSA, the European Commission and Member States.

Expert Database created, establishing a pool of external scientific experts on whom EFSA can call.

Panel on Dietetic Products, Nutrition and Allergies starts evaluating science behind **health claims** submitted for approval in the EU.

Emerging Risks Unit set up.

2009

First **annual pesticides report** published. **1,000th Scientific Opinion** completed.

EFSA Journal – the new online platform for EFSA's open-access scientific journal becomes fully operational.

500th Scientific Opinion published. Number of staff reaches 300.

Focal Points set up to act as an interface between EFSA and national food safety authorities, consumers and other stakeholders.

2010

430 Number of staff

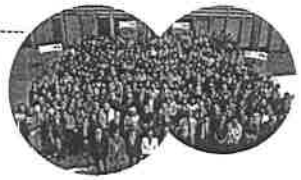
2011

Scientific Committee holds 50th plenary meeting.

Annual **summary report on zoonoses** shows that human cases of Salmonella have fallen by 50% in five years.

Number of **staff employed: 430.**

Applications Helpdesk set up to coordinate safety assessment of regulated products, substances and claims submitted for authorisation in the EU.



2012

EFSA moves into new, **purpose-built premises** in Parma.

Adoption of **Science Strategy** for **2012-2016.**

efsa anniversary 10 efsa anniversary

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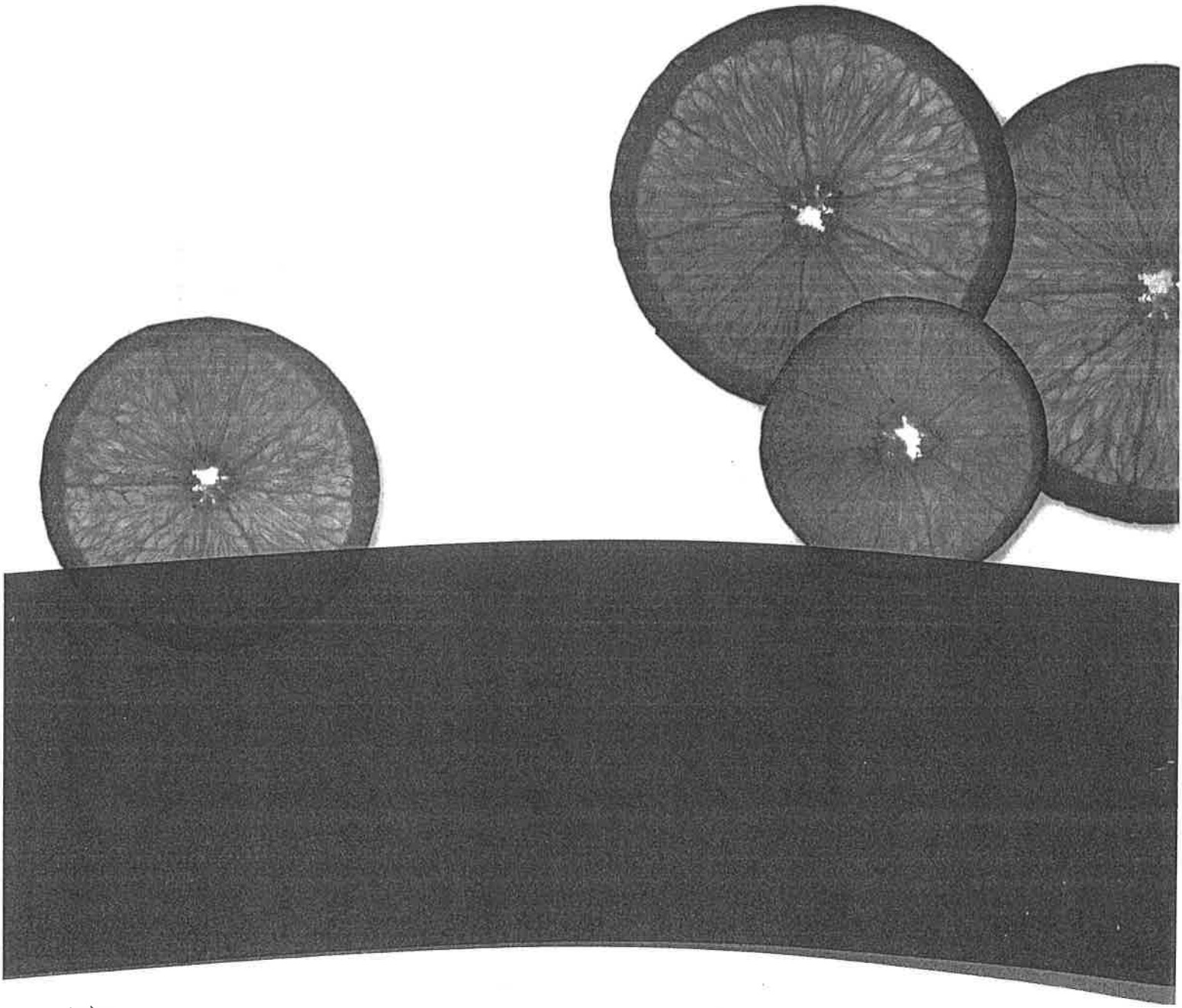

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