Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
24,566	87

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

1.6. Other specialised areas and activities

Activity area

This area covers Agency activities in the human-medicines field, other than evaluation and monitoring of these medicines. It includes work in the areas described below.

- **Herbal medicinal products.** The Agency provides scientific opinions on questions relating to herbal medicines, establishes Community herbal monographs for traditional and well-established-use herbal medicines, and drafts the Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. The monographs prepared by the Agency facilitate the granting of traditional-use registrations and well-established-use marketing authorisations for herbal medicines, allowing them to be placed onto the EU market.
- **Antimicrobial resistance** and availability of anti-infective treatment options. The Agency cooperates with European and international partners in exploring opportunities for new and effective anti-infective treatment options to overcome the problem of antimicrobial resistance. Work in the field of antimicrobial resistance is done in regard to both human and veterinary medicines.
- **Pandemic-influenza preparedness.** The 2009 influenza pandemic led to a review of cross-European strategy for pandemic preparedness. The Agency continues to implement actions to improve pandemic preparedness, in collaboration with the network and the EC.
- **Clinical trials.** The growing trend to conduct clinical trials outside the EU/EEA raises the importance of ensuring the trials meet certain clinical, ethical and quality standards, and provide comprehensive, reliable data for assessment and decision-making requirements. Cooperating with international partners, the Agency contributes to improving the design, management, oversight and analysis of the clinical trials, as well as working to provide capacity-building and develop information exchanges and shared planning of GCP inspections.

Key objectives

- Facilitate the development of new antibiotics for treatment of multi-resistant bacteria.
- Assure the quality of data and appropriate protection of participants of clinical trials, through risk-proportionate approaches to the design and management of clinical trials, especially those conducted outside the EU/EEA.
- Improve the safety and continuity of supply chains for medicines. Prevent circulation of falsified medicines.
- Support a high level of coordinated cross-European preparedness to act on public-health threats.
- Enhance international cooperation in the fields of antimicrobial resistance, clinical trials, supply-chain continuity and preparedness for public-health threats.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Develop clinical guidance to support development of new treatments for multi-resistant bacteria. Develop a proposal for streamlined pre-authorisation data requirements and post-marketing surveillance enhancements.
- Provide input into the work of the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) to minimise the risk of antimicrobial resistance arising from use of human or veterinary medicines.
- Contribute to the development of regulatory frameworks on the conduct, monitoring and analysis of clinical trials. This includes input into the clinical-trials legislation, and developing guidance on risk-based approaches to quality management in clinical trials.
- Adjust EPARs to include a standardised set of information on clinical trials conducted in third countries.
- Implement frameworks for ethics experts to advise the Agency.
- Contribute to the development of a coordinated European strategy for ensuring rapid response and decision-making in event of a public-health threat.
- Provide training to the network on the revised pandemic-influenza plan.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Herbal monographs, new*	15	9	15
Herbal monographs, revised	5	7	2
List entries	2	0	0

* Where assessment does not lead to the establishment of a monograph, a public statement will be prepared.

Performance indicators

- **At least 1** workshop/training session on clinical-trial supervision held with international partners.
- **At least 1** workshop held in the area of GMP inspections and quality defects.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
7,378	18

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

1.7. Projects

The main projects that the Agency has planned for 2014 in order to support and improve performance of its core activities are listed below. These projects and their deliverables might be reviewed and clarified according to the Agency's project-prioritisation process; the Agency may also undertake other projects, as deemed necessary.

Programme / Project	Project completion target	Deliverables 2014
Data integration Stage 2	Q4 2014	• Analysis and design of EU ISO Identification of Medicinal Products (IDMP) compliant product-management service and system
Data integration Stage 3	Q3 2015	• First iteration of the organisations-management system • Organisations data cleaned • Managed service for organisations • Integration across EMA systems
Data integration Stage 4	Q1 2016	• Agreement across the Telematics network on the extent of the ISO IDMP substance standards implementation • Analysis and design of an EU substance-management service and system
Pharmacovigilance EudraVigilance Human v7	Q2 2014	• Database that facilitates electronic submission and maintenance of core information on medicinal products by MAHs • Reliable product data available to support calculation and collection of PhV fees • Agency receiving formal notifications of 'withdrawn products' by MAHs
Pharmacovigilance Medical-literature monitoring	Q4 2014	• Procurement for service provider to provide services for medical-literature screening and entry of individual cases in EudraVigilance • Partitioned EV literature repository accessible to the EMA • Forwarding of ICSRs entered in EV to NCAs
Pharmacovigilance Tactical remediation of medicines web portal (for fees)	Q4 2014	• Changes to the existing medicines web portal to allow pharmaceutical companies access to pharmacovigilance fee and invoice information. This is a tactical change to an existing system ahead of the strategic solution to be implemented as part of the Agency's online roadmap
Pharmacovigilance PhV fees implementation	Q2 2015	• Required functionality to: – charge fees for PhV activities and pay NCAs – automate processes (where possible) and minimise the administrative burden of the legislation – provide the performance data requested in the legislation to the EC
EudraCT EudraCT 10	Q2 2014	• Functions to: – publish and manage CT result data – provide visibility for NCAs about the submitted and published results – enable EMA administrators to view and edit result

Programme / Project	Project completion target	Deliverables 2014
		datasets and user rights – allow EMA administrators to 'soft delete' CTAs – include Article 45/46 trials in EudraCT • Enhancements to existing CTA and soon-to-be-released results module • Enhancements of the EU Clinical Trials Register
BI Migration to OBIEE EVDAS DAP (data access policy)	Q3 2014	• EVDAS MIcrostrategy Data Access Policy dashboards (interactive PDFs) migrated to OBIEE

2. Evaluation activities for veterinary medicines

The European Medicines Agency supports and facilitates the development of medicines for veterinary use, evaluates these medicines (through a scientific committee) and advises the European Commission on the marketing authorisation of such products. The Agency also monitors the safety, quality, efficacy and benefit-risk balance of authorised medicines. In addition, the Agency provides support and develops guidelines to stimulate the development and availability of medicines, and to protect public and animal health.

Work in the veterinary-medicines area concerns not only animal health but also public health, through the use of authorised veterinary medicines in food-producing animals, and control of diseases transmissible to man. Hence, the development and evaluation of veterinary medicines must consider the impact on animals, users, the environment and consumers of foodstuffs of animal origin.

2.1. Pre-authorisation activities

Activity area

Pre-authorisation support refers to the services provided prior to submission of a marketing-authorisation application, and aims to facilitate development of veterinary medicines. Activities in this area cover:

- **Scientific advice.** In order to facilitate the development of new veterinary medicines, the Agency provides scientific advice to applicants, during the research and development phase of veterinary medicinal products, on aspects relating to quality, safety or efficacy of these products, and on the establishment of maximum residue limits.
- Support for the authorisation of products for **minor uses and minor species (MUMS)/limited markets.** To stimulate development of new veterinary medicines for minor species and/or for rare diseases in major species, the Agency provides support to applicants submitting applications for products for limited markets. Products for food-producing species that are classified as MUMS are eligible for incentives, which encourage the development of products that would otherwise not be developed in the current market conditions. Product eligibility is reviewed on a five-yearly basis.
- Support the development of **emerging therapies and technologies.** To proactively identify scientific, legal and regulatory issues of emerging therapies and technologies, the Agency provides a discussion platform for early dialogue with applicants within the context of the Innovation Task Force.

Key objectives

- Provide support and incentives to the development of new medicines, especially with regard to medicines for smaller market segments.
- Promote innovation and use of new approaches in the development of veterinary medicines.
- Foster bilateral cooperation with the FDA, especially in the areas of parallel scientific advice and provision of assistance to companies bringing innovative products to the market.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Review the criteria and guidance for MUMS/limited-markets classification, to ensure objective and efficient support for the development of new medicines. Adopt the revised MUMS policy by Q4 2014.
- Review the status of products designated as MUMS/limited market, according to the review cycle.
- Provide access to the Agency's Innovation Task Force, to enable advice to be provided in the early stages of development; benefit from experience gained in the human-medicines field.
- Identify reasons why veterinary medicines — especially those for which scientific advice was given — fail to progress to the application stage, and explore improvements to increase the number of applications submitted.
- Continue to promote the use of scientific advice in the veterinary sector to applicants. Continue to improve the content and procedure of scientific advice to increase its availability and effectiveness.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Innovation Task Force briefing requests	2	0	0
Scientific-advice requests	32	40	28
MUMS applications	18	23	21

Performance indicators

- **100%** of scientific-advice procedures completed within set timeframes.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
1,496	1

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

2.2. Initial evaluation

Activity area

Initial evaluation refers to the process of scientific assessment of applications for veterinary medicines submitted for marketing authorisation through the centralised procedure. Activities within this domain are:

- **Initial evaluation.** The initial-evaluation phase includes pre-submission discussions with future applicants, scientific evaluation of the applications, and issuing an opinion to the European Commission. The Commission grants the marketing authorisation, following which the Agency publishes a European public assessment report (EPAR).
- **Establishment of MRLs.** The use of veterinary medicinal products in food-producing animals may result in the presence of residues in foodstuffs obtained from treated animals. Before a veterinary

medicinal product can be authorised, the safety of its residues must be evaluated. The Agency establishes maximum residue limits (MRLs) for pharmacologically active substances used in veterinary medicinal products, as well as for biocidal products used in animal husbandry, to ensure consumer safety with regard to foodstuffs of animal origin, including meat, fish, milk, eggs and honey.

Key objectives

- Provide high-quality and consistent scientific opinions to the Commission.
- Ensure the establishment of MRLs supports safe use of veterinary medicines with regard to their impact on human health.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Embed the benefit-risk methodology in the veterinary medicines assessment process. Provide assessor training, to ensure consistent use of assessment methodology.
- Implement the revised EMA conflicts-of-interests policy, to ensure the availability of the best scientific expertise, while maintaining independence of the scientific committees' work.
- Increase the quality and consistency of scientific opinions through regular reviews of the quality-assurance of scientific opinions produced.
- Continue the work to resolve the challenge represented by veterinary medicines that persist at sites of injection, in terms of establishing MRLs.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Initial evaluation applications	20	23	12
New MRL applications	3	7	1
MRL extension and modification applications	5	6	5
MRL extrapolations	1	0	0
Art. 9, Biocides	2	0	0
Review of draft Codex MRLs	3	0	5

Performance indicators

- **100%** of procedures completed within legal timeframes. This includes product-application and MRL-application evaluations.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
4,757	13

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

2.3. Post-authorisation activities

Activity area

Post-authorisation activities include all the activities performed by the Agency in order to maintain authorised medicines on the market and ensure that products on the EU market are kept up-to-date with scientific advances and in line with the needs of authorisation holders. Activities covered in this area include:

- **Variations and extensions**. Variations to marketing authorisations can be either minor (type IA or IB) or major (type II) changes to the product information and dossier, with regard to quality, safety and efficacy of the authorised product.

  Extension applications include fundamental changes to the veterinary medicinal product, such as changes to the active substance, changes to the strength or pharmaceutical form, or the change or addition of a food-producing species to the authorisation.

- **Maintenance activities**. Maintenance activities include follow-up on certain obligations that marketing-authorisation holders need to fulfil following the granting of the marketing authorisation. These include re-assessment and renewal of marketing authorisations, as well as marketing-authorisation transfers when the legal entity of the marketing-authorisation holder changes.

Key objectives

- Provide high-quality, consistent post-authorisation support, including scientific assessment of changes to marketing authorisations.

Activities in 2014

No major activities or events outside the regular activities of the Agency are expected regarding post-authorisation of veterinary medicines in 2014.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Extensions and variations applications, of which:	245	320	260
Type-I variations	200	283	200
Type-II variations	40	32	52
Line extensions	5	5	8

Performance indicators

- **100%** of post-authorisation applications evaluated within legal timelines.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
4,649	15

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

2.4. Arbitrations and referrals

Activity area

The Agency conducts referral and arbitration procedures.

- **Arbitration** procedures are initiated for nationally authorised products because of disagreement between Member States (e.g. in granting a variation or a marketing authorisation), or when over the years Member States have adopted different decisions for some medicines, and discrepancies need to be harmonised.
- **Referrals** are initiated regarding centrally and nationally authorised products, either in order to obtain harmonisation within the Community of the conditions of authorisation for products already authorised by Member States, or in cases where there is a Community interest or other safety-related issue. In a referral, the Agency conducts scientific assessment of a medicine (or class of medicines) and makes a recommendation for a harmonised position across the EU. Depending on the type of procedure, the outcome will be implemented by the Member States or the European Commission will issue a decision to all Member States reflecting the measures to take to implement the Agency's recommendation.

The referral of individual antibiotics, or classes of antibiotics that are particularly important for use in human medicine, is expected to remain a priority area in 2014. A number of these referrals are expected to be triggered by the European Commission as part their action plan against the rising threats from antimicrobial resistance.

Key objectives

- Provide high-quality and consistent scientific opinions to the European Commission.

Activities in 2014

Previous trends are expected to continue in 2014, with no major activities or events outside the regular activities of the Agency expected regarding referrals and arbitration of veterinary medicines.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Arbitrations and Community referral procedures initiated	12*	10	12

*It is expected that a substantial proportion of referrals will each relate to a large number of products, sometimes even hundreds of products. This is especially valid for referrals relating to antibiotics.

Performance indicators

- **100%** of arbitration and referral procedures managed within the legal timelines.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
1,043	5

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

2.5. Pharmacovigilance activities

Activity area

Pharmacovigilance covers the science and activities relating to the detection, assessment, understanding and prevention of adverse reactions to medicines or other medicine-related problems. Pharmacovigilance aims to ensure that post-authorisation monitoring and effective risk management are continuously applied to veterinary medicines throughout the EU.

The Agency coordinates the EU pharmacovigilance system and constantly monitors the safety of medicines throughout the EU network, and takes action if information indicates that the benefit-risk balance of a medicine has changed since authorisation. The Agency provides advice to ensure safe and effective use of veterinary medicinal products.

In the case of veterinary medicines, safety relates to the safety of the animal, the user and the environment. Activities covered include:

- Management and assessment of **adverse-event reports (AERs)**;
- Management and assessment of **periodic safety-update reports (PSURs)**.

Key objectives

- Support conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high-quality processes.
- Continue with international cooperation to promote the efficiency and effectiveness of pharmacovigilance for regulators and industry.
- Provide consistent, high-quality information on pharmacovigilance topics to stakeholders and partners.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Work with partners in the European medicines regulatory network to complete and start to implement an agreed strategy for IT support to veterinary medicines, with a particular focus on tools for pharmacovigilance.
- Migrate IT tools used for pharmacovigilance surveillance to a new system, with additional work required for validation and training.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Periodic safety-update reports (PSURs)	150	149	139
Total AERs, of which:	22,500	22,326	22,983
Adverse-event reports (AERs) for CAPs	7,200	8,166	7,783

Performance indicators

- **90%** of PSURs evaluated within the established timeline.
- **95%** of AERs for CAPs monitored within the established timelines.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
1,137	6

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

2.6. Other specialised areas and activities

Activity area

This area covers EMA activities in the veterinary-medicines field, other than routine activities related to evaluation and monitoring of these medicines. This includes work in relation to:

- Revision of the **legislation** governing **veterinary medicines**. The Agency will provide technical support to the European Commission in relation to the discussion of the EC proposals by the European Parliament and the Council, following the publication of these proposals.
- **Antimicrobial resistance**. The Agency adopts a 'One Health' approach in the area of antimicrobial resistance, whereby there is close and integrated cooperation between those working in the human and veterinary fields. In the veterinary area, attention is focused in particular on ensuring the continued availability of antimicrobials for treatment of infectious disease in animals, while recognising the need to preserve the efficacy of certain critically important antimicrobials for human use.

Key objectives

- Support increased availability of veterinary medicines through providing necessary input to the review of veterinary legislation.
- Contribute to minimising the risk to man and animals from the use of antibiotics.
- Foster cooperation between EU and international agencies in the area of antimicrobial resistance.
- Support further development of the VICH Outreach programme.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Provide advice to the European Commission regarding minimising the risk to man and animals from the use of antibiotics in veterinary medicines.
- Provide advice to the European Commission on the requirements for the development of new veterinary antimicrobials that address animal-health issues, while preserving the efficacy of antimicrobials crucial for human use.
- Develop a methodology and initiate a pilot project to measure antimicrobial use per species as part of the ESVAC project. Monitor the use of veterinary antimicrobials through collection and analysis of sales and usage data within the ESVAC project.
- Implement IT systems to facilitate the supply of data to the ESVAC database.
- Provide input to the work of TATFAR to minimise the risk of antimicrobial resistance arising from the use of antibiotics in human and veterinary medicine.

- Continue the development of internationally harmonised guidelines within VICH, to avoid duplication of testing and allow the successful implementation of the '3Rs' goals (reduction, refinement and replacement) with respect to minimising the need for testing of medicinal products in animals.

Workload indicators

Not applicable.

Performance indicators

None identified.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
1,598	4

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

2.7. Projects

The main projects that the Agency has planned for 2014 in order to support and improve the performance of its core activities are listed below. These projects and their deliverables might be reviewed and clarified according to the project-prioritisation process; the Agency may also undertake other projects, as deemed necessary.

Programme / Project	Project completion target	Deliverables 2014
BI migration to OBIEE / EVDAS Vet migration	Q3 2014	• Reports in the EV Vet Microstrategy web application migrated to OBIEE.
ESVAC web-based collection of data	Q4 2014	• A web-based system to collect data from NCAs on sales of antimicrobials and on management of data on animal population. • Interactive database with predefined reports.
Veterinary, new initiatives	TBC	• Implementation of recommendations of the IT strategy and implementation plan for veterinary medicines.

3. Horizontal activities and other areas

Horizontal activities of the Agency cover those business-related activities that are not specific to only human or veterinary medicines, but span both areas and define, enable and support the medicines-evaluation activities. These activities are directly linked to and necessary for delivering the core services of the Agency, and include coordinating the committees' work, maintaining necessary IT systems, coordinating inspections, and managing relationships with stakeholders and partners.

3.1. Committees and working parties

Activity area

The scientific-opinion making of the Agency is done primarily through committees and working parties. The Agency has seven scientific committees, each focusing on a specific area of work. Six committees provide scientific opinions regarding human medicines (CHMP, COMP, PDCO, HMPC, CAT and PRAC), and one focuses on veterinary medicines (CVMP). The Agency's committees typically meet on a monthly basis, and the Agency provides all the support in organising these meetings.

The activities within this domain include:

- **Scientific Coordination Board.** The Scientific Coordination Board (SciCoBo) is composed of the chairs of the scientific committees, CMDh and scientific advice working parties, as well as members of the Agency's senior management. It ensures there is sufficient coordination between the committees, so as to increase the robustness and predictability of the outcome of the benefit-risk assessment, by having consistent standards set for the development of medicines across the whole product lifecycle.
- **Committees Secretariat.** The Committees Secretariat provides organisational, secretarial and budget management for the operation of the Agency's scientific committees, as well as necessary regulatory support to the committees. It includes coordinating adequate scientific support and leadership across the Agency's divisions, as well as ensuring coordination and communication across scientific committees, working parties and scientific advisory groups, and facilitating interactions between these groups. In addition, the Committee Secretariat coordinates work-programme proposals and prioritisation, according to the impact of work on the committees and the strategic priorities set in the work programme of the Agency.
- **Working parties' secretariat.** This covers organisational, secretarial and budget management for the operation of the Agency's working parties and scientific advisory groups.
- The Agency also provides the **secretariat for the Co-ordination Group for Mutual Recognition and Decentralised Procedures**, Human (CMDh) and Veterinary (CMDv).
- **Guideline development.** To facilitate the development of medicinal products, the Agency, through its working parties, prepares and reviews guidelines on a variety of scientific topics. The guidelines are consulted upon with stakeholders, and are made available on the Agency's website.
- **Meeting management.** The Meeting and Conference Management Department organises EMA meetings, conferences, workshops and training sessions, including those under the EU enlargement programme. The Department also makes travel and accommodation arrangements for delegates, and provides assistance with logistical and administrative issues.

Key objectives

- Increase the efficiency and effectiveness of the support and coordination of scientific committees and working parties.
- Improve the use and availability of scientific resources across the committees.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Complete the project on centralisation of committee secretariats, including streamlining of scientific support and implementation of harmonised administrative processes for coordination of committee meetings.
- Establish a coordinated secretariat for the working parties.
- Establish a cross-committee oncology scientific advisory group, and deliver analysis of results of this initiative. Explore expanding this pilot initiative to other established scientific advisoy groups.

Workload indicators

The workload of the scientific committees is largely driven by the activities described in the chapters above on evaluation activities for human and veterinary medicines. Thus, the relevant workload drivers are found in the corresponding sections fo this document.

	2014 forecast	2013 actual	2012 actual
Number of meetings	426	354	400
Number of teleconference meetings*	2,850	2,737	2,135
Number of delegates	8,500	6,869	7,341

* Total audio, video and web-conference meetings.

Performance indicators

- **80%** delegate satisfaction with the service level provided by the secretariat.
- **100%** up-to-date electronic declarations of interests submitted by committee members and experts prior to participating in a committee, SAG or other meeting.
- **100%** of first-stage evaluations of conflicts of interests for committee members and experts completed prior to their participation in the first meeting after the submission of a new or updated declaration of interests.
- **80%** of ex-ante verifications of declarations of interests for new experts completed within 2 weeks after upload of the DoI in the experts database.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
5,345	24**

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.
** Resources include Meeting and Conference Management support and CMD activities. Resources related to guideline development and committee coordination are allocated to the relevant human medicines and veterinary medicines activities.

3.2. Inspections and compliance

Activity area

This area covers a number of activities to ensure that medicinal products in the EU are developed, produced and monitored in accordance with the EU's good-practice standards, and comply with the requirements and conditions established in the marketing authorisation. Activities covered include:

- **Inspections.** The Agency coordinates inspections to verify compliance with the principles of good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) and good pharmacovigilance practice (GVP), and with certain other aspects of the supervision of authorised medicinal products in use in the EU. Inspections are initiated following the request of the CHMP or CVMP in connection with the assessment of marketing-authorisation applications or the on-going supervision of authorised products. Similarly, the Agency coordinates inspections of blood establishments within the plasma master file (PMF) certification framework.
- **Quality defects.** The Agency is the primary contact point for the notification of suspected quality defects affecting centrally authorised products. It coordinates the investigation, evaluation and follow-up of the suspected defects, in collaboration with the rapporteur Member State and supervisory authority, to agree, with the necessary urgency, on the implementation of appropriate actions, including communication, in the interest of public health.
- **Sampling-and-testing programme.** The Agency operates a sampling-and-testing programme to supervise the quality of centrally authorised medicinal products placed on the market, and to check compliance of these products with their authorised specifications. Sampling from the market in different Member States is carried out by national inspectorates, and testing is performed by official medicines control laboratories (OMCL), coordinated through the EDQM (European Directorate for the Quality of Medicines and HealthCare). The Agency is responsible for the selection of products to be sampled, and for the follow-up of any findings with the relevant marketing-authorisation holders and rapporteurs.
- **Certificates.** The Agency issues certificates of medicinal products, in accordance with WHO requirements, in order to support the work of health authorities outside the EU, especially in developing countries. Certificates are issued by the Agency, on behalf of the European Commission, to confirm the marketing-authorisation status and GMP compliance of the manufacturing sites of products authorised by the Commission through the centralised procedure, or of products for which a marketing-authorisation application has been submitted to the Agency.
- **Parallel distribution.** Parallel distribution is the distribution of a centrally authorised medicinal product from one Member State to another by a pharmaceutical company independent of the marketing-authorisation holder. The Agency checks the compliance of products distributed in parallel with the conditions laid down in EU legislation and in the marketing authorisation for the products.
- **Supply chain**. Recent years have seen cases of global supply shortages of medicines, caused by manufacturing-process issues. This has led to the development of recommendations to minimise the risks of such shortages occurring in the future, as well as to mitigate the impact of shortages that do occur. The Agency continues to promote proactive risk-management by manufacturers and marketing-authorisation holders, and, within its scope, instilling controls to ensure supply-chain quality and continuity.

Key objectives

- Improve the efficiency, consistency and quality of inspections, through enhanced international cooperation.
- Expand total international inspection coverage through the exchange of information with international partners. Minimise the duplication of inspections performed by regulatory authorities.
- Strengthen collaboration with the NCAs, the WHO and MAHs in relation to certificates and parallel-distribution activities.
- Assure the protection of clinical-trial participants and the quality of data generated in clinical trials destined for submission in marketing-authorisation applications, especially for trials conducted outside the EU/EEA.
- Improve the mitigation of the causes and impact of shortages of human medicines caused by GMP non-compliance and quality defects.
- Promote a global approach to the quality of APIs, finished products and the integrity of the supply chain. Promote adherence to ICH and VICH principles.
- Strengthen and further develop the quality-defects network, procedure and tools for the systematic collection, analysis and follow-up of data.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Coordinate the conduct of inspections with international partners.
- Provide training to support the development of capacity, harmonisation and exchange of best practice on inspections.
- Deliver training and capacity-building for inspectors, assessors and ethics committees. Organise a workshop on GCP inspections.
- Strengthen international collaboration in the area of clinical-trial inspections. Develop tools for information exchange in the GCP network.
- Improve public information on GCP inspections and their impact on the assessment outcome.
- Develop the concept of and initiate a pilot joint-pharmacovigilance-inspection programme.
- Implement procedures for inspections of wholesale distributors and EU-based manufacturers, importers and distributors of active substances.
- Continue the implementation of the action plan on medicine shortages due to manufacturing deficiencies, including the development of recommendations for better and proactive risk management by MAHs, to avoid supply shortages of medicines and raw materials.
- Improve the EU process for handling GMP non-compliance situations, including related supply shortages, and its interaction with global regulatory partners.
- Develop contacts with main countries where the manufacture of APIs or finished products takes place. Provide and host training sessions involving non-ICH regulators.
- Support the expansion of the MRA with Japan to sterile and biological medicinal products, as well as active pharmaceutical ingredients.

- Review the current process for quality defects in collaboration with international partners, and identify areas for improving international cooperation and coordination in managing quality defects.
- Organise meetings with NCAs and companies regarding parallel distribution and certificates, and further develop the available tools to allow simplification and improved transparency with companies submitting requests.
- Organise pharmacovigilance IWG and QWP assessor training sessions. Organise a GCP IWG international workshop, a quality-by-design workshop with stakeholders, and a Qdefect workshop.

Workload indicators

	2014 forecast	2013 actual	2012 actual
GMP inspections	360	397	368
GLP inspections	2	0	0
GCP inspections	71	70	72
Pharmacovigilance inspections	11	13	10
Quality-defect reports	180	178	148
Number of medicinal products sampled	45	45	41
Certificate requests	3,500	3,434	3,041
Urgent certificate requests	350	297	n/a
Parallel-distribution initial notifications	3,000	2,532	2,388
Parallel-distribution notifications of change	1,600	2,563	3,264
Parallel-distribution annual updates*	1,300	1,279	n/a

* Parallel-distribution annual updates have only been introduced since May 2013.

Performance indicators

- **100%** of inspections conducted within established regulatory timeframes.
- **90%** of standard certificates and 100% of urgent certificates issued within the respective legal timelines (10 working days and 2 working days, respectively).
- **90%** of parallel-distribution notifications checked for compliance within the standard timeline.
- **At least 4** training/workshop activities organised in the area of inspections.
- **Additional 10%** of GCP inspections addressed through information exchange on inspections carried out by international partners.
- **Additional 10%** of routine re-inspections of manufacturing sites addressed through exchange of information with international partners.
- **100%** of outcome reports of the sampling-and-testing programme for centrally authorised products followed up with the MAH within one month of receipt.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
12,457	39

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

3.3. Partners and stakeholders

Activity area

Activities covered in this area include:

- **Interactions with partners.** In order to deliver its mission, the Agency collaborates with national competent authorities in Europe, the European Commission, other EU institutions and EU agencies, non-EU competent authorities and regulators (U.S. FDA, Japanese PMDA/MHLW, Australian TGA, Health Canada and others), as well as international organisations (such as EDQM, WHO, ICH, VICH, OIE, ISO, HL7, IPRF and others) and health-technology-assessment bodies (HTAs). These interactions range from exchanges of information, collaboration on guideline development and capacity building to providing scientific expertise in the evaluation processes, cooperation on inspections, various international initiatives and other activities. In addition, the Agency has a specific legislative responsibility to support the evaluation of medicines intended for use in developing countries through its 'Article 58' provision.
- **Stakeholder interactions** with patients, healthcare professionals, industry organisations and academia. As part of these interactions, the Agency works together with patients and healthcare professionals and involves them in its activities, in particular in the scientific work of the Agency, and in preparing and reviewing information on human medicines for the public.
- **Support for small and medium-sized enterprises (SMEs).** The Agency has an office specifically dedicated to supporting smaller companies — the SME Office. It provides eligible SMEs with access to various incentives and regulatory assistance, including fee reductions, deferrals and conditional exemptions, and administrative and procedural support, as well as assistance with translations of the product-information documents submitted in applications for marketing authorisation. Around 1,000 SMEs are registered with the Agency.
- **Information and transparency.** The Agency places high importance on the transparency, openness and efficiency of its interactions with partners and stakeholders. The Agency maintains and manages specific communication and information-exchange platforms, and provides information on its work and outputs, as well as other relevant information. Public access to documents and information is provided in accordance with Regulation (EC) No 1049/2001.

Key objectives

- Enhance cooperation within the European medicines regulatory network.
- Enhance international cooperation activities towards the development of greater work-sharing.
- Implement the Agency's transparency and open-data commitments.
- Provide stakeholders and partners with consistent, high-quality, targeted and accessible information on the Agency's work, outputs and medicinal products.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- In collaboration with national authorities, set up and run a training and competency-development centre for the network, covering scientific, regulatory and procedural topics.
- Expand the national visiting experts programme.

- Develop a programme to gather data to inform the future revision of the general fee legislation. Develop the new public-hearings concept for human medicines.
- Implement a framework for interacting with pharmaceutical-industry organisations and launch a corporate-stakeholder function to coordinate contacts with industry stakeholders.
- Launch the policy on proactive publication of clinical trials, considering the outcomes of the court case and legislative proposals on clinical trials.
- Review the process of handing requests for access to documents.
- Promote the EU regulatory system for veterinary medicines at an international level in the FAO, OIE, WHO and VICH Outreach.
- Cooperate with the FAO, OIE and WHO to promote harmonisation of the requirements for authorisation of veterinary medicines at international level, and participate in VICH Outreach and other training activities.
- Deliver training activities related to veterinary medicines to the network as part of the package of measures delivered by the Agency.
- Contribute to the reform and reorientation of ICH governance and scientific-harmonisation activities, and contribute to the development of the IPRF and other emerging international coalitions.
- Support the EC on scientific and technical aspects of trade negotiations with third countries, including the FTA with Japan, the CETA with Canada and the TTIP with the US.
- Further develop and streamline Article 58 activities in close cooperation with the WHO. Evaluate the possibility of using this activity for capacity-building for non-EU regulators.
- Develop and launch a new extranet to facilitate cooperation and collaboration with delegates and other national-competent-authority groups.
- Establish a web managers' network with Member State authorities, to promote cooperation on digital issues relating to the online provision of information on science, medicines and health.
- Review the coordination of medicines information, particularly safety information, within the network and with international partners.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Requests for SME qualification	500	401	684
SME status renewal requests	1,000	808	602
Requests for access to documents	350	307	281
Pages released following requests for access to documents	400,000-700,000	308,931	685,489
Requests for information	6,500	5,840	5,065
Number of EMA activities involving patients and consumers, of which:	575	550	525
Information to the public reviewed by patients	300	200	162

Performance indicators

- **100%** of declarations of interests updated prior to set deadlines.

Resources

Area of activity	Financial resources (cost, thousand euro)*	Human resources (FTEs)
Partners and stakeholders	5,904	23
Transparency and access to documents	2,050	14
Information	4,766	25

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

3.4. Data-management support

Activity area

Data and information on medicinal products is one of the Agency's fundamental assets, and it is a priority to share this data and information with our partners and stakeholders who rely on it to do their work.

Data-management is an ongoing, centralised support function that comprises the planning and execution of policies, practices and projects that acquire, control, protect, deliver and enhance the value of data and information assets.

Activities covered in this area include: data governance, data quality, master-data management, data architecture, data development, data security, data warehousing and business intelligence.

Key objectives

- Engage the Agency's stakeholders in the governance of data, and promote a wider and deeper understanding of the value of data assets.
- Continually improve the quality of data and information, including through creating an effective master-data management service.

Activities 2014

Agency activities to achieve the objectives set for this area:

- Implement a 'data governance' structure at the Agency, aligning people, processes and technology, and involving partners and stakeholders, to enable the Agency to leverage data as an enterprise asset.
- Create a master-data management service (initially for substances and referentials), available for the Agency and its stakeholders to ensure and check quality, accuracy and completeness of data, and provide faster, better resolution of problems. This service will be the foundation for managing other types of master data.
- Coordinate data-management projects across the Agency in order to meet new legislative requirements or other strategic goals with a higher success rate and more value.

- Identify opportunities to use centralised services for the collection and maintenance of data related to veterinary medicines.

Performance indicators

- Effective master-data management service:
  - **90%** of substance and referentials data registered in 24 hours. **99%** of these data registered in 48 hours.
  - **No more than 3%** of calls reopened due to incorrect handling.
- **Over 80%** of stakeholders satisfied with the responsiveness, cooperation and communication of data-management services.

3.5. Process improvements

Activity area

This area covers all those activities that the Agency is currently undertaking to improve the processes that support the evaluation, maintenance and safety monitoring of medicines.

Key objectives

- Enable evaluation, maintenance and safety-monitoring of medicines by simplified and efficient processes, designed to deliver scientific opinions in accordance with legal and regulatory requirements.
- Optimise expert and committee input by mobilising the appropriate expertise at the right time and providing support through appropriate systems and competent staff.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Review the current processes ('as is' state) and identify improvement areas.
- Redesign processes with a quantifiable improvement that can produce outcomes of intended quality.
- Review and define procedures related to the authorisation of veterinary medicines, benefiting from the use of Agency-level centralised services.
- Define quality metrics to monitor process performance.
- Consult internal and external stakeholders to estimate the impact of process-improvement change and ensure that their expectations are met.
- Implement the revised processes and build in a culture of continuous improvement.

Workload indicators

Not applicable.

Performance indicators

- **80%** of existing regulatory procedures reviewed and improvement areas identified by the end of 2014.

Resources

Process-improvement activities cover a wide range of Agency activities with the relevant resources being involved, as required. Hence, these are covered in relevant sections of this document.

3.6. Projects

The main projects that the Agency has planned for 2014 in order to support and improve the performance of its core activities are listed below. These projects and their deliverables might be reviewed and clarified according to the project-prioritisation process; the Agency may also undertake other projects, as deemed necessary.

Programme / Project	Project completion target	Deliverables 2014
eSubmissions Gateway v3	Q3 2014	• Processing all mandatory submissions from 1 March 2014 • Processing other procedure types (e.g. paediatrics, veterinary medicines and referrals) • Maximum size of incoming submissions increased to 25Gb • Changes to the Gateway Filehandler to simplify file naming and allow use for any type of procedure • Further automation of registration of submissions
eSubmissions Gateway – CESP integration study	Q2 2014	• Options identified for integrating CESP with the eSubmission gateway and the Common Repository • Initial release of the eSubmissions gateway integrated with CESP
eSubmissions eAF – change requests	Q4 2014	• Relevant change requests incorporated into eAF functionality that will allow the network to mandate their use
eSubmissions eAF – SIAMED integration study	Q4 2014	• Options identified for automated upload of data from eAFs to SIAMED
eSubmissions Common repository v2	Q3 2014	• A PSUR repository (with minimum functionalities)
eSubmissions ECTD – definition of ECTD v4 standards	Q3 2014	• An eCTD standard suitable for the EMA
eSubmissions ECTD – Prep roadmap for compliance with network systems	Q4 2014	• Roadmap on how the EMA will comply with the new eCTD4 standard
eSignature eSignature	Q3 2014	• A solution for authorised EMA signatories (incl. all committee/WP chairs) to digitally sign all documents

Programme / Project	Project completion target	Deliverables 2014
		requiring a legally binding signature • A solution to receive electronically submitted documents that require a signature, and to verify their veracity • Other change requests as appropriate and affordable within the assigned budget • Integration with DREAM
Online roadmap Technologies proof of concept	Q2 2014	• Developed reference architecture, showing how the products will work together in the technology stack and how they integrate with other systems in the Agency
Online roadmap Social collaboration pilot	Q1 2014	• Prove feasibility of options for discussion forums, groups, document collaboration, etc. to staff members of the Agency and external teams (NCAs, HMAs)
Online roadmap Intranet/extranet	Q2 2015	• Platform for improved collaboration among the staff in the Agency and NCAs, to deliver business-critical tasks in an efficient, effective and controlled manner • Platform to allow deployment of the intranet/extranet solution
Online roadmap Interface design for intranet/extranet	Q2 2014	• Detailed requirements for, and design of the new look & feel of, the Agency's intranet/extranet
2014 programme Data-centre upgrade	Q4 2014	• Upgrades to existing infrastructure in the new premises' data centre
Review and reconnect	Q4 2014	• Process and data-management improvement initiatives outlined in different parts of the work programme

4. Support and governance activities

Activity areas

This area covers all the general functions and activities performed that are necessary to ensure the continuous operations of the Agency, but are not business-specific. These include:

- **Management and planning.** These activities cover management of the Agency and corporate planning. They include support to the Management Board and senior management of the Agency, the corporate planning cycle, including the planning processes (strategy, annual work programmes, link to the budget) and the following monitoring and reporting activities.
- **Finance.** Finance refers to budget processes (planning, monitoring and reporting), maintenance of the accounts, payment management and collection of revenue, as well as management of cash resources and ex ante verification of transactions.
- **Information and communications technology.** IT services include the development of necessary IT systems, provision and maintenance of ongoing operations, and IT data management.
- **Legal services.** Legal activities within the corporate governance and support area refer to legal advice on internal matters, such as contracts and procurement, staff-related matters, data protection and corporate-governance matters. These also include dealing with complaints submitted to the European Ombudsman and representing the Agency before the European Court of Justice, General Court or Civil Service Tribunal. Legal services deals regularly with legal officers of the Commission on the core activities and also provide advice and support on the implementation of the new legislation and legal scrutiny of the scientific opinions.
- **Human resources.** Human resources deals with all staff-related matters, including developing and maintaining HR strategy and policy, conducting recruitment and procurement, managing personnel administration and payments, running the trainee programme, managing staff declarations of interests, providing staff support and training, and dealing with staff complaints and appeals.
- **Quality and risk management,** and internal control coordination. Quality management includes both the integrated quality-management activities and risk management within the Agency. Conducting self-assessment as part of the EU agencies benchmarking programme, annual reviews of sensitive functions, and ex post controls and register of exceptions also fall within this area.
- **Internal audit.** Internal audit reviews and evaluates risk-management, governance and internal-control processes of the Agency, in order to provide, to the executive director and the Management Board, independent and objective assurance and consulting services designed to add value and improve the Agency's operations.
- **Infrastructure services.** These cover activities related to the Agency's premises and office accommodation, security, reception and switchboard, mail management, reprographics and catering.
- **Communication (corporate).** These are corporate communication activities, such as corporate-website management, press office and information centre.
- **Programme Design Board.** The Programme Design Board ensures that the Agency's business projects are aligned with the Agency's strategy and meet customer expectations.

- **Policy issues.** Chief Policy Adviser Division is responsible for defining and implementing the Agency policies. This division also takes part in implementation and monitoring of legislation changes, and liaises with and coordinates EMA interactions with the EU institutions.

Key objectives

- Ensure and further improve the efficiency and effectiveness of the Agency's corporate activities.
- Promote and maintain a positive reputation among stakeholders and partners as an authoritative and open source of information on medicines in the European Union.
- Ensure communication activities are in line with and support the Agency's strategy.

Activities in 2014

Corporate governance and support activities will continue as 'business as usual', ensuring continuity and efficiency of the Agency's work. Specific activities in 2014:

- Complete the project to relocate the Agency to new premises in August 2014.
- Continue implementing corporate-efficiency initiatives identified in the Review & Reconnect programme.
- Complete the staff-engagement survey.
- Perform self-assessment of the Agency's operations as part of best-practice benchmarking within the European medicines regulatory network.
- Perform audit and consultancy activities in line with the annual audit plan.
- Develop and launch a new EMA intranet to support staff and management communications.
- Improve the regulatory content on the EMA corporate website in order to provide more support to business users on achieving their goals with the Agency.
- Streamline and rationalise the Agency's web-publishing processes to ensure cost-effectiveness and efficiency.
- Develop a social-media strategy and reinforce the Agency's social-media presence, including an appropriate search-engine marketing strategy.
- Reinforce the Agency's media relations, with a focus on increasing the Agency's outreach to new audiences across EU Member States.

Performance indicators

- **97%** of posts on the Agency establishment plan filled.
- **99%** of revenue appropriations and 99% of expenditure appropriations implemented.
- **97%** of appropriations carried over from year N-1.
- The maximum rate of carryover to year N+1, of total commitments within the title:
  - Title 1: **2%**
  - Title 2: **20%**
  - Title 3: **28%**

- **97%** of payments made within 30 days' time.
- Telematics and corporate IT systems available **98%** of the time.
- IT service desk: meeting SLAs / issue resolution per system / priority level:
  - Critical (resolution time 4 hours): **80%**
  - Severe (resolution time 1 business day): **80%**
  - Important (resolution time 10 business days): **80%**
  - Minor (resolution time 120 business days): **80%**
- **100%** of IT projects delivered on time.
- **100%** of IT projects delivered within budget.
- **100%** of IT projects delivered to original specification.

Resources

Area of activity	Financial resources (cost, thousand euro)*	Human resources (FTEs)
Governance, quality-management and internal audit	6,920	33
Finance	4,392	28
ICT	11,548	63**
Legal services	1,883	12
Human resources	4,906	35
Infrastructure services	2,530	19
Communication	2,570	15

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.
** Includes resources allocated to IT projects.

Annexes

Annex 1: Revenue and expenditure 2014 — key figures

Figure 1. Revenue evolution 2009–2014

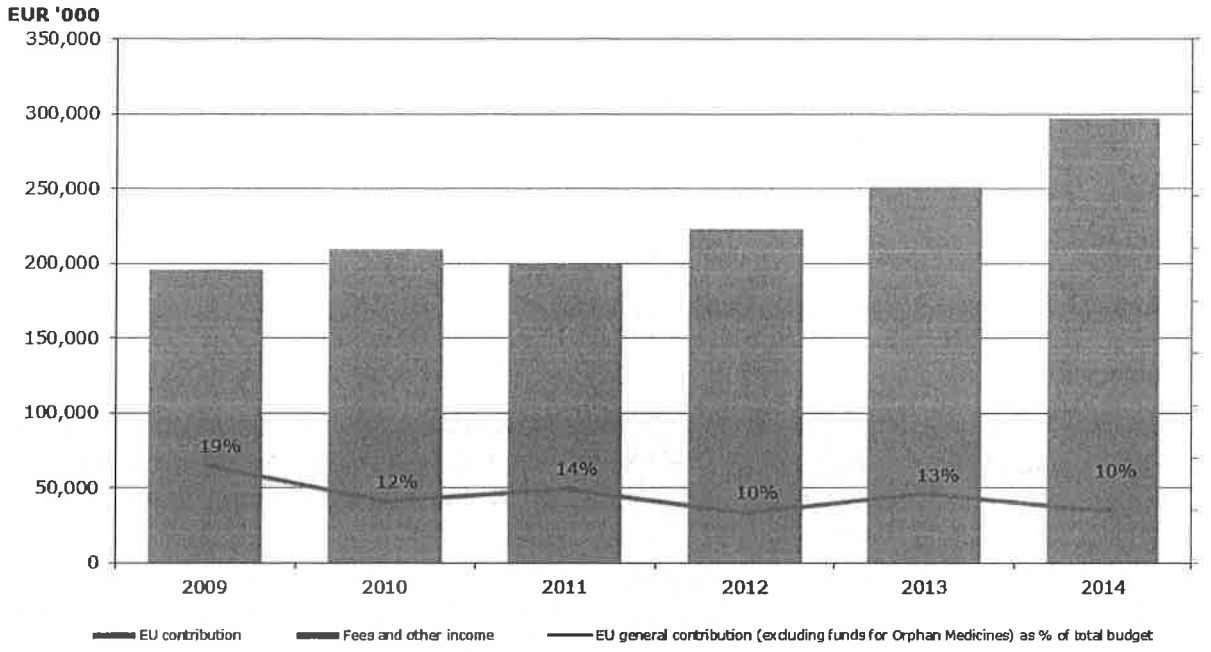
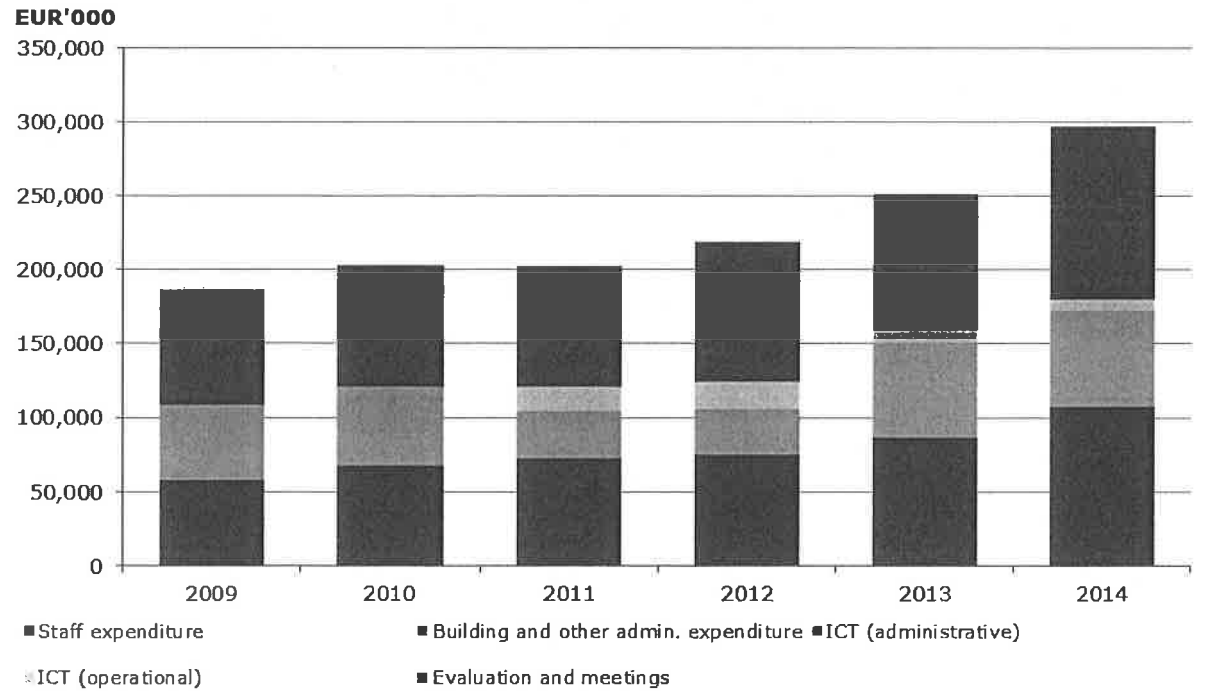


Figure 2. Expenditure evolution 2009–2014



Annex 2: Revenue and expenditure overview 2012–2014

		2012 (outturn)[1]		2013 (budget)[2]		2014 (budget)[3]	
		€ '000	% of total	€ '000	% of total	€ '000	% of total
	Revenue						
100	Fees and charges	182,912	*81.8%*	210,587	*83.7%*	236,156	*79.5%*
200	General EU contribution	21,466	*9.6%*	33,230	*13.2%*	29,777	*10.0%*
200	Surplus of previous year	9,875	*4.4%*	0	*0.0%*	3,453	*1.2%*
201	Special EU contribution for orphan medicinal products	7,491	*3.4%*	6,000	*2.4%*	6,000	*2.0%*
300	Contribution from EEA	753	*0.3%*	1,098	*0.4%*	1,084	*0.4%*
600	External assigned revenue	128	*0.1%*	520	*0.2%*	20,524	*6.9%*
5+9	Other	902	*0.4%*	125	*0.0%*	175	*0.1%*
	TOTAL REVENUE	**223,527**	*100.0%*	**251,560**	*100.0%*	**297,169**	*100.0%*
	Expenditure						
	Staff						
11	Staff in active employment	69,457	*31.7%*	80,841	*32.1%*	99,945	*33.6%*
13	Mission expenses	575	*0.3%*	465	*0.2%*	605	*0.2%*
14	Socio-medical infrastructure	557	*0.3%*	641	*0.3%*	758	*0.3%*
15	Exchange of civil servants and experts	2,293	*1.0%*	2,428	*1.0%*	3,724	*1.3%*
16	Social welfare	236	*0.1%*	306	*0.1%*	320	*0.1%*
17	Representation expenses	15	*0.0%*	28	*0.0%*	38	*0.0%*
18	Staff insurances	2,118	*1.0%*	2,255	*0.9%*	2,395	*0.8%*
	Total Title 1	**75,251**	*34.4%*	**86,964**	*34.6%*	**107,785**	*36.3%*
	Building/equipment						
20	Investment in immovable property, renting of building and associated costs	21,066	*9.6%*	40,997	*16.3%*	39,530	*13.3%*
21	Expenditure on corporate data processing	7,108	*3.2%*	17,141	*6.8%*	19,776	*6.7%*
22	Movable property [..]	1,351	*0.6%*	3,986	*1.6%*	3,210	*1.1%*
23	Other administrative expenditure	785	*0.4%*	1,118	*0.4%*	1,591	*0.5%*
24	Postage	401	*0.2%*	514	*0.2%*	184	*0.1%*
25	Expenditure on other meetings	105	*0.0%*	125	*0.0%*	136	*0.0%*
	Total Title 2	**30,817**	*14.1%*	**63,881**	*25.4%*	**64,427**	*21.7%*
	Operational expenditure						
300	Meetings	6,759	*3.1%*	7,117	*2.8%*	8,035	*2.7%*
301	Evaluation of medicines	81,992	*37.5%*	77,247	*30.7%*	97,151	*32.7%*
302	Translations	3,958	*1.8%*	5,452	*2.2%*	5,532	*1.9%*
303	Studies and consultants	2,044	*0.9%*	2,300	*0.9%*	6,399	*2.2%*
304	Publications	76	*0.0%*	106	*0.0%*	116	*0.0%*
305	Community programmes	298	*0.1%*	400	*0.2%*	0	*0.0%*
31	Expenditure on business related ICT projects	17,662	*8.1%*	8,093	*3.2%*	7,724	*2.6%*
	Total Title 3	**112,790**	*51.5%*	**100,715**	*40.0%*	**124,957**	*42.0%*
	TOTAL EXPENDITURE	**218,858**	*100.0%*	**251,560**	*100.0%*	**297,169**	*100.0%*

[1] Financial Year 2012: as per final accounts, rounded to nearest thousand Euro

[2] Financial Year 2013: as per current budget (including transfers and amending budet as of 30.10.2013)

[3] Financial Year 2014: as proposed to Management Board 12 December 2013

Annex 3: Human-resource needs and establishment plan

Function Group & Grade	Authorised for 2012		Occupied as at 31.12.2012			Authorised for 2013		Requested 2014	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts	Permanent posts	Temporary posts
				Grade filled	Actual grade				
AD 16	-	1	-	1	0	-	0	-	0
AD 15	-	4	-	4	2	-	4	-	4
AD 14	-	6	-	6	2	-	6	-	6
AD 13	-	7	-	7	8	-	8	-	8
AD 12	-	38	-	38	32	-	38	-	42
AD 11	-	38	-	36	23	-	38	-	38
AD 10	-	34	-	33	23	-	36	-	36
AD 9	-	39	-	37	30	-	40	-	37
AD 8	-	47	-	44	40	-	47	-	49
AD 7	-	45	-	44	44	-	45	-	51
AD 6	-	37	-	37	73	-	42	-	39
AD 5	-	33	-	33	38	-	42	-	30
Subtotal AD	***0***	***329***	***0***	***320***	***315***	***0***	***346***	***0***	***340***
Total AD	***329***		***0***	***320***	***315***	***346***		***340***	
AST 11	-	2	-	2	1	-	2	-	2
AST 10	-	5	-	4	1	-	5	-	5
AST 9	-	7	-	7	2	-	7	-	7
AST 8	-	13	-	13	8	-	13	-	15
AST 7	-	20	-	20	13	-	20	-	19
AST 6	-	33	-	33	12	-	33	-	36
AST 5	-	35	-	35	27	-	35	-	37
AST 4	-	51	-	50	46	-	51	-	55
AST 3	-	37	-	35	46	-	39	-	39
AST 2	-	40	-	38	38	-	40	-	34
AST 1	-	18	-	18	66	-	20	-	10
Subtotal AST	***0***	***261***	***0***	***255***	***260***	***0***	***265***	***0***	***259***
Total AST	***261***		***0***	***575***	***575***	***265***		***259***	
Grand subtotal	***0***	***590***	***0***	***575***	***575***	***0***	***611***	***0***	***599***
Grand total	***590***		***0***	***575***	***575***	***611***		***599***	

Contract Agents	**2012**		**2013**	**2014**
	Actual FTE as at 31.12.2012	**Actual headcount as at 31.12.2012**	**Planned FTE**	**Planned FTE**
FG IV	42	40	51	46
FG III	11	10	13	12
FG II	63	56	61	72
FG I	0	0	0	0
Total	**116**	**106**	**125**	**130**

National Experts	**2012**		**2013**	**2014**
	Actual FTE as at 31.12.2012	**Actual headcount as at 31.12.2012**	**Planned FTE**	**Planned FTE**
Total	**15**	**16**	**15**	**25**

Annex 4: Operational-procurement decisions

Activity statement:	**Monitoring of medical literature**
Objective:	See WP2014, heading 1.5.
Budget:	€ 1.0 - €2.0 million per year over 4 years (total: € 7.0 million); € 800,000 in 2014
Financial year:	2014 - 2017/18
Description of action:	Implementation of Pharmacovigilance legislation
Type of contract:	Framework Contract - Operational consultancy; Specific contracts
Number of contracts:	5
Indicative timeframe for contract:	Commencing in 2014
Indicative timeframe for procurement:	1st quarter 2014
Indicative budget for procurement:	€ 4.0 million
Legal basis:	Article 27 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B3030

Activity statement:	**EudraVigilance data management**
Objective:	See WP2014, heading 1.5.
Budget:	€ 1.6 million per year over 4 years (total: € 6.5 million)
Financial year:	2015-2018/19
Description of action:	Data management and cleaning to ensure individual case reports are accurate, retrievable and analysable for safety signal detection and evaluation
Type of contract:	Framework Contract - operational consultancy; specific contracts
Number of contracts:	5
Indicative timeframe for contract:	Commencing in 2015
Indicative timeframe for procurement:	2nd quarter 2014
Indicative budget for procurement:	€ 1.6 million per year over 4 years (total: € 6.5 million)
Legal basis:	Article 24 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B3030

Activity statement:	**ENCePP studies**
Objective:	See WP2014, heading 1.5.
Budget:	€ 344,000
Financial year:	2014
Description of action:	Ensuring best evidence is available to support the EMA committees assessments of the benefits and risks of authorised medicines (studies of risks and benefit risk)
Type of contract:	Call for Expression of Interest; Specific contract per study
Number of contracts:	3
Indicative timeframe for contract:	Three procurements of approximately 115,000 Euros each, one in each of the first three quarters of 2014
Indicative timeframe for procurement:	each of the first three quarters of 2014
Indicative budget for procurement:	€ 344,000
Legal basis:	Regulation 726/2004 and Directive 2001/83 notably articles 31 and 107i - k
Budget line:	B3030

Activity statement:	**Subscription to medical database**
Objective:	See WP2014, heading 1.5.; page 16
Budget:	€ 500,000 over 4 years
Financial year:	2015 - 2018
Description of action:	Access to and use of primary care data set (UK)
Type of contract:	Service contract
Number of contracts:	1
Indicative timeframe for contract:	March 2015 - March 2019
Indicative timeframe for procurement:	1st quarter 2014
Indicative budget for procurement:	€ 500,000 over 4 years
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B3031

Activity statement:	**Information Centre**
Objective:	See WP2014, heading 4.
Budget:	€ 245,000 over 4 years
Financial year:	€ 2,014
Description of action:	Upgrade of Agency's current printing services, promotional material and exhibition systems.
Type of contract:	Separate restricted procedure for a) printing services; and negotiated procedures for b) promotional material; c) exhibition systems
Number of contracts:	3
Indicative timeframe for contract:	2nd quarter 2014
Indicative timeframe for procurement:	Commencing in 2015
Indicative budget for procurement:	€ 245,000 over 4 years
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B3040

Activity statement:	**Business IT development for IT network and security**
Objective:	See WP2014, heading 4.
Budget:	€ 4.0 million over 4 years; of which € 3.5 million administrative and € 500,000 operational
Financial year:	2014 - 2017/18
Description of action:	IT network and security consultancy services.
Type of contract:	Framework Contract + Specific contracts
Number of contracts:	14 - 20
Indicative timeframe for contract:	Commencing in 2014
Indicative timeframe for procurement:	2nd quarter 2014
Indicative budget for procurement:	€ 4,000,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B2114/2115/3105

Activity statement:	**Business IT development for internet & back-up data centre**
Objective:	See WP2014, heading 4.
Budget:	€ 5.0 million over 4 years; of which € 4.0 million administrative and € 1.0 million operational
Financial year:	2014 - 2017/18
Description of action:	Business continuity planning services, communication services (internet access and related web services) and off-site highly secure back-up data centre.
Type of contract:	Framework Contract + Specific contracts
Number of contracts:	10-Dec
Indicative timeframe for contract:	Commencing in 2014
Indicative timeframe for procurement:	1st quarter 2014
Indicative budget for procurement:	€ 5,000,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B2114/2115/3105

Activity statement:	**Service provider for applications on on-line transactional processing**
Objective:	See WP2014, heading 4.
Budget:	€ 70.0 million over 4 years; of which € 25.0 million administrative and € 45.0 million operational
Financial year:	2014 - 2017/18
Description of action:	External service providers for software applications - Provision of resources for on-line transactional processing systems
Type of contract:	Framework Contract + Specific contracts
Number of contracts:	30 - 40
Indicative timeframe for contract:	Commencing in 2014/5
Indicative timeframe for procurement:	2nd quarter 2014
Indicative budget for procurement:	€ 70,000,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B2114/2115/3105

Activity statement:	**Business IT development for software and related services (SACHA III).**
Objective:	See WP2014, heading 4.
Budget:	€ 15 million over 4 years; of which € 13.5 million administrative and € 1.5 million operational
Financial year:	2014 - 2017/18
Description of action:	Software channel for licences and licences support and related services (consultancy)
Type of contract:	European Commission tender procedure, Framework Contract + Specific Contracts
Number of contracts:	300 - 350
Indicative timeframe for contract:	Commencing in 2014
Indicative timeframe for procurement:	tbc by EC
Indicative budget for procurement:	€ 15,000,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B2110/3105

Annex 5: Activity-based budget

Chapter	Staff expenditure	Infrastructure, ICT and project exp.	Meeting exp. (incl. overhead)	Evaluation Service (NCAs)	Other operational expenditure	Total expenditure	
	€'000	€'000	€'000	€'000	€'000	€'000	%
	Title 1	Title 2 & Bud. Item 3105	Bud. Item 3000	Bud. Item 3010	Reminder Title 3		
1 Evaluation activities for human medicines	**46,651**	**23,538**	**14,334**	**87,949**	**10,537**	**183,008**	**70%**
1.1 Pre-authorisation activities	11,054	3,685	4,807	13,638	550	33,735	13%
1.2 Initial evaluation activities	9,020	2,783	2,011	12,485	1,426	27,724	11%
1.3 Post-authorisation activities	10,393	8,835	1,821	59,413	3,266	83,727	32%
1.4 Arbitrations and referrals	2,744	922	643	395	1,175	5,878	2%
1.5 Pharmacovigilance activities	10,910	5,689	1,975	2,018	3,973	24,566	9%
1.6 Other specialized areas and activities	2,529	1,624	3,077	-	148	7,378	3%
2 Evaluation activities for veterinary medicines	**5,736**	**2,125**	**2,726**	**3,859**	**234**	**14,680**	**6%**
2.1 Pre-authorisation activities	300	75	743	288	90	1,496	1%
2.2 Initial evaluation activities	1,981	499	466	1,702	110	4,757	2%
2.3 Post-authorisation activities	1,610	927	242	1,870	0	4,649	2%
2.4 Arbitrations and referrals	625	194	224	-	0	1,043	0%
2.5 Pharmacovigilance activities	592	205	340	-	0	1,137	0%
2.6 Other specialized areas and activities	628	224	711	-	34	1,598	1%
3 Horizontal activities and other areas	**15,126**	**5,431**	**3,329**	**5,344**	**1,290**	**30,521**	**12%**
3.1 Committee coordination	2,469	1,186	1,690	-	0	5,345	2%
3.2 Inspection and Compliance	3,775	1,992	1,346	5,344	0	12,457	5%
3.3 Partners and Stakeholders	4,035	849	282	-	738	5,904	2%
3.4 Transparency and access to documents	1,543	506	-	-	0	2,050	1%
3.5 Information	3,305	898	11	-	552	4,766	2%
4 Support and governance activities	**25,498**	**8,007**	**818**	**-**	**426**	**34,748**	**13%**
4.1 Governance, Quality Management and Internal Audit	4,949	1,218	595	-	158	6,920	3%
4.2 Finance	3,202	1,183	-	-	7	4,392	2%
4.3 Information and Technology	9,011	2,312	-	-	225	11,548	4%
4.4 Legal Services	1,432	450	-	-	0	1,883	1%
4.5 Human Resources	3,317	1,589	-	-	0	4,906	2%
4.6 Infrastructure	1,820	710	-	-	0	2,530	1%
4.7 Communication	1,767	545	223	-	35	2,570	1%
Total	**93,011**	**39,101**	**21,207**	**97,151**	**12,488**	**262,958**	**100%**

* Excluding exeptional costs

Annex 6: Draft cash-flow forecast

Note: this forecast excludes exchange-rate variances and VAT payments/receipts.

CASH FLOW FORECAST YEAR 2014	Estimated Budget C1	Estimated RAL C8	Total Annual	Dec (pre-pay) estimated	Jan - Mar estimated	Apr-Jun estimated	Jul - Sep estimated	Oct - Dec estimated
	€ '000	€ '000	€ '000	€ '000	€ '000	€ '000	€ '000	€ '000
Fees and charges C1	236,156		236,156		32,964	61,749	66,216	75,226
Euopean Union contribution to the operating budget C1	29,777		29,777		0	0	20,481	9,296
Orphan contribution C1	6,000		6,000		0	2,056	721	3,223
Surplus from previous year C1	3,453		3,453		0	3,453	0	0
External assigned revenue R0	20,524		20,524		20,524	0	0	0
Other revenue C1	1,259		1,259		148	255	257	600
A - TOTAL RECEIPTS	**297,169**	**0**	**297,169**		**53,636**	**67,513**	**87,675**	**88,345**
Title I : staff								
Payments expected on C1 credits	106,186		105,336		28,814	16,842	26,081	33,598
Payments expected on R0 credits		350	350		96	56	87	112
Payments expected on C8+R8 credits (RAL)		850	850		561	99	189	1
Title II : administrative expenses								
Payments expected on C1 credits	44,427		34,427	2,800	7,389	6,235	9,775	8,228
Payments expected on R0 credits		20,000	20,000		10,000	10,000	0	0
Payments expected on C8+R8 credits (RAL)		10,000	10,000		3,816	3,814	1,548	822
Title III : operational expenditure								
Payments expected on C1 credits	124,757		99,757		13,471	29,579	23,667	33,041
Payments expected on R0 credits		200	200		27	59	47	66
Payments expected on C8+R8 credits (RAL)		25,000	25,000		15,560	5,788	2,049	1,603
B - TOTAL CASH OUT	**275,370**	**56,400**	**295,920**	**2,800**	**79,734**	**72,472**	**63,444**	**77,470**
Opening balance, cash and bank accounts			**57,000**		**57,000**	**30,901**	**25,943**	**50,174**
+ Total receipts (A)			297,169		53,636	67,513	87,675	88,345
- Total payments (B)			295,920	2,800	79,734	72,472	63,444	77,470
Closing balance, cash and bank accounts			**58,249**	**-2,800**	**30,901**	**25,943**	**50,174**	**61,049**
- Total anticipated carry-over - commitments not paid by year-end (C8 n+1)								56,400
Closing balance					**30,901**	**25,943**	**50,174**	**4,649**

Annex 7: Terms and abbreviations

Term/abbreviation	Definition
3Rs	'3 R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
ADR	adverse drug reaction
AE	adverse event
AER	adverse-event report
Agency	European Medicines Agency
AMR	antimicrobial resistance
API	active pharmaceutical ingredient
ATMP	advanced therapy medicinal product
BI	business intelligence
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
CESP	Common European eSubmission Platform
CHMP	Committee for Medicinal Products for Human Use
CMD	Co-ordination Group for Mutual Recognition and Decentralised Procedures
CMDh Coordination group	Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human
CMDv Coordination group	Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary
Commission	European Commission
committee(s)	scientific committee(s) of the Agency
Council	European Council
COMP	Committee for Orphan Medicinal Products
CT	clinical trial
CTA	clinical-trial application
CVMP	Committee for Medicinal Products for Veterinary Use
DREAM	document records electronic archive management system
eAF	electronic application form
eCTD	electronic common technical document
EDQM	European Directorate for the Quality of Medicines and HealthCare
EEA	European Economic Area
EC	European Commission
EMA	European Medicines Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EP	European Parliament
EPAR	European public assessment report
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EudraCT	European Union Drug Regulating Authorities Clinical Trials
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance

Term/abbreviation	Definition
EVDAS	EudraVigilance data analysis system
FAO	Food and Agriculture Organization
FDA	United States Food and Drug Administration
GCP	good clinical practice
GLP	good laboratory practice
GMP	good manufacturing practice
GVP	good pharmacovigilance practice
HCP	healthcare professional
HL7	Health Level 7
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HTA	health technology assessment
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSR	individual case safety report
IDMP	identification of medicinal products
IPRF	International Pharmaceutical Regulators Forum
ISO	International Organization for Standardization
ISO IDMP	ISO Identification of Medicinal Products project
IT	information technology
ITF	Innovation Task Force
IWG	Inspectors Working Group
MA	marketing authorisation
MAH	marketing-authorisation holder
Member State	Member State of the European Union
MHLW	Ministry of Health, Labour and Welfare, Japan
MRA	mutual-recognition agreement
MRL	maximum residue limit
MUMS	minor use, minor species
NAP	nationally authorised products
NCA	national competent authority
Network	European Medicines Regulatory Network
OBIEE	Oracle Business Intelligence Enterprise Edition
OIE	World Organisation for Animal Health
OMCL	Official Medicines Control Laboratories
PA	protocol assistance
PAES	post-authorisation efficacy study
PASS	post-authorisation safety study
PDCO	Paediatric Committee
PhV	pharmacovigilance
PIP	paediatric investigation plan
PMDA	Pharmaceuticals and Medical Devices Agency, Japan
PMF	plasma master file
PRAC	Pharmacovigilance Risk Assessment Committee
PSUR	periodic safety-update report
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)

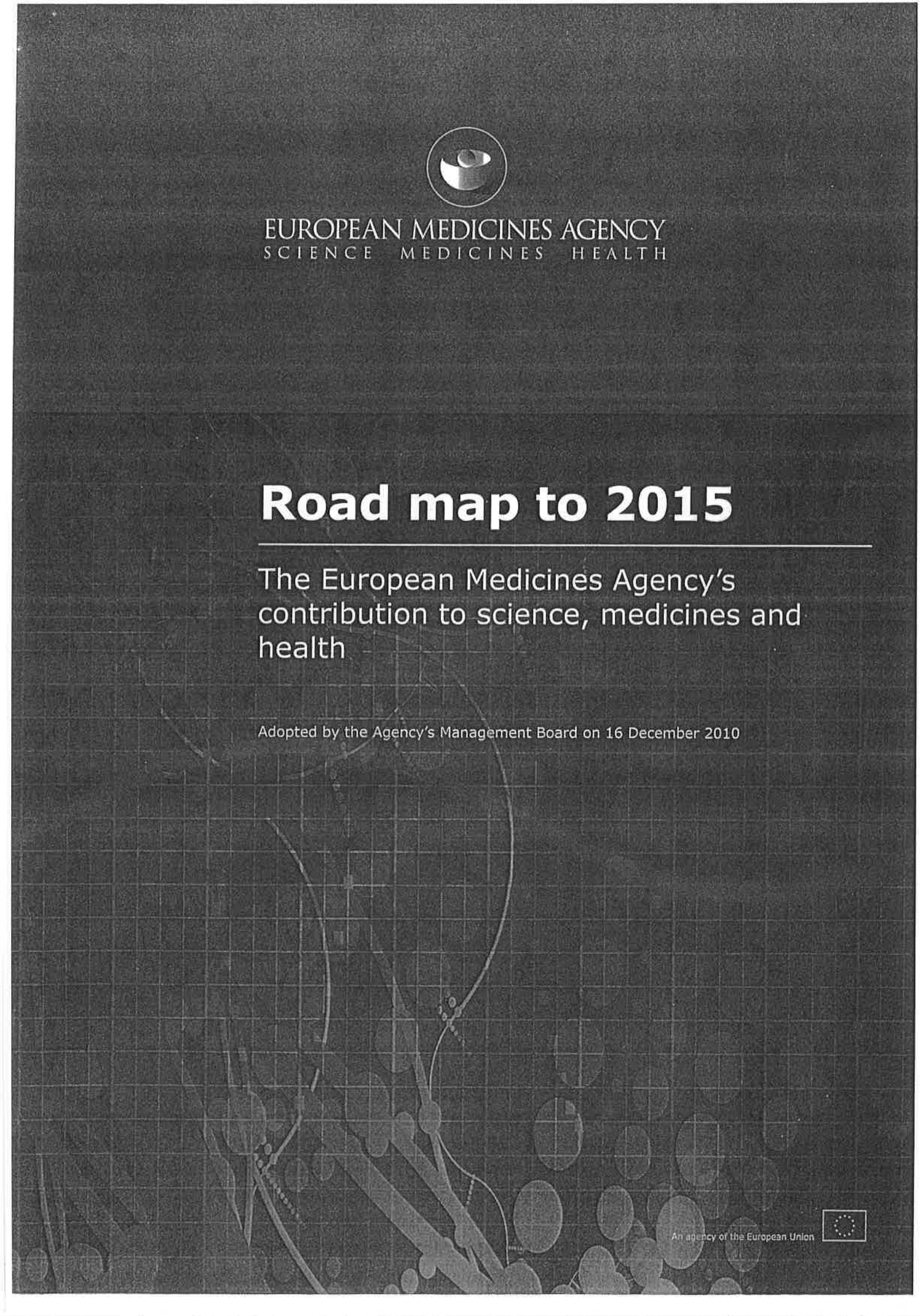
Term/abbreviation	Definition
QWP	Quality Working Party
R&R	'Review and Reconnect' programme
RMP	risk-management plan
SA	scientific advice
SAG	scientific advisory group
SciCoBo	Scientific Coordination Board
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SME	small and medium-sized enterprise
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
US	United States
TGA	Therapeutic Goods Administration, Australia
VAMF	vaccine antigen master file
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organization
WP	working party

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Road map to 2015

The European Medicines Agency's contribution to science, medicines and health

Adopted by the Agency's Management Board on 16 December 2010



An agency of the European Union

The mission of the European Medicines Agency is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health.

Legal role

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

The Agency provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

Principal activities

Working with the Member States and the European Commission as partners in a European medicines network, the European Medicines Agency:

- provides independent, science-based recommendations on the quality, safety and efficacy of medicines, and on more general issues relevant to public and animal health that involve medicines;
- applies efficient and transparent evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorisation granted by the European Commission;
- implements measures for continuously supervising the quality, safety and efficacy of authorised medicines to ensure that their benefits outweigh their risks;
- provides scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;
- recommends safe limits for residues of veterinary medicines used in food-producing animals, for the establishment of maximum residue limits by the European Commission;
- involves representatives of patients, healthcare professionals and other stakeholders in its work, to facilitate dialogue on issues of common interest;
- publishes impartial and comprehensible information about medicines and their use;
- develops best practice for medicines evaluation and supervision in Europe, and contributes alongside the Member States and the European Commission to the harmonisation of regulatory standards at the international level.

Guiding principles

- We are strongly committed to public and animal health.
- We make independent recommendations based on scientific evidence, using state-of-the-art knowledge and expertise in our field.
- We support research and innovation to stimulate the development of better medicines.
- We value the contribution of our partners and stakeholders to our work.
- We assure continual improvement of our processes and procedures, in accordance with recognised quality standards.
- We adhere to high standards of professional and personal integrity.
- We communicate in an open, transparent manner with all of our partners, stakeholders and colleagues.
- We promote the well-being, motivation and ongoing professional development of every member of the Agency.

Table of contents

1. Executive summary

This road map sets out a strategic vision for the operation of the European Medicines Agency (hereinafter 'the Agency') over the five-year period from 2011 to 2015.

It has been drafted in consultation with the Agency's European partner organisations and with the public, to ensure as broad a consensus as possible on the best approach to the Agency's fulfilment of its public mandate to protect and promote public health[1] in the European Union (EU) over the coming years.

After a brief overview of the main European and international factors that characterise the evolving operational environment of the Agency, the document sets out in some detail the key drivers for progress and change to which the Agency is subject, namely the needs to:

- ensure **efficient operation of its core business**, which is of critical importance to the continuing success of the Agency in the face of the increasing scope and complexity of its responsibilities under EU legislation;
- address **public-health needs**, through measures that include: promoting the availability of medicines for rare diseases, unmet medical needs and paediatric use; promoting the rational and better-targeted use of medicines to reduce morbidity and mortality; investigating the impact on public health of decisions taken by regulators; facilitating the availability of veterinary medicines; promoting closer coordination of activities in human and veterinary areas;
- further develop the regulatory framework for **new and emerging science**, in particular with respect to benefit/risk evaluation, potential safety issues, and ethical and environmental considerations;
- address the **impact of globalisation** in the pharmaceuticals sector, characterised by: the increasingly global nature of research, development, manufacturing and clinical-trial activities; challenges relating to the movement of clinical research to developing countries, to ethical standards and to regulatory and supervision arrangements in non-EU countries; the attendant need for closer and more intense cooperation between international partners;
- continue to review the **model for regulation of medicines** in the EU, particularly with regard to: the development of medicines; the benefit/risk balance; the point of decision-making for authorisation; post-authorisation follow-up; the growing importance of health technology assessment bodies; specific considerations relating to herbal medicines; a possible reconsideration of the extent to which legislation governing veterinary medicines is tailored to the specific requirements of this sector;
- ensure **patient/consumer and animal-health protection**, with particular emphasis on: progressing the implementation of initiatives within the framework of the European Risk Management Strategy and the European Surveillance Strategy; implementing the new pharmacovigilance legislation to address increased public demands for more refined pharmacovigilance tools and better communication on the benefits and risks of medicines; supporting the European Commission's development of a legislative framework that is more appropriate to the needs of modern veterinary medicine;
- meet **public demands for greater transparency and openness** with respect to the Agency's activities, its decision-making processes and the ready availability of up-to-date information on medicinal products, adverse drug reactions and clinical trials.

1 Throughout this document, the term 'public health' is used to refer to both human and animal health, unless otherwise stated.

To address these drivers for progress and change, the Agency's first priority over the next five years will continue to be the successful delivery of its core business. In addition, the Agency has identified three strategic areas within which it will focus its efforts in the years ahead:

- **Addressing public-health needs,** by pursuing the following objectives:
  - stimulate medicines development in areas of unmet medical needs, neglected diseases and rare diseases, and for all types of medicines for veterinary use;
  - facilitate new approaches to medicines development;
  - apply a more proactive approach to public-health threats where medicines are implicated.
- **Facilitating access to medicines,** by pursuing the following objectives:
  - address the high attrition rate during the medicines-development process;
  - reinforce the benefit/risk-balance assessment model;
  - continue to improve the quality and the regulatory and scientific consistency of the outcome of the scientific review.
- **Optimising the safe and rational use of medicines**, by pursuing the following objectives:
  - strengthen the evidence base in the post-authorisation phase to enable better regulatory decision-making;
  - enhance patient safety by avoiding unnecessary risks to patients as a result of the use of medicines;
  - become a reference point for information on medicines evaluated by the Agency;
  - improve the decision-making process by taking due account of patient experience, thus contributing to the rational use of medicines.

Specific indicators of the expected impact/result of each of the activities in these strategic areas are identified in the body of this road map, while a separate 'From vision to reality' document (to be published in the course of 2011) will set out detailed information on the Agency's planned implementation of these activities.

The success of the Agency in implementing the vision set out in this road map will be contingent upon the availability of the necessary resources, as well as upon the continuing support and cooperation of the Agency's partners in the EU regulatory network.

2. Introduction

In 2005, the European Medicines Agency developed a longer-term strategy[2] to guide its proactive approach to the continuing evolution of the pharmaceutical arena in the European Union (EU). This strategy focused mainly on contributing to better promotion and protection of public health, improving the regulatory environment for medicinal products, and helping to stimulate innovation, research and development in the EU.

The Agency's 'Road map to 2015' is a continuation of this longer-term strategy, building on current achievements, but also taking due account of the changing environment in which the Agency will have to operate over the next five years. In further developing its road map project, the Agency will ensure that its vision is consistent with and complementary to strategic directions provided by the European Commission[3,4,5,6], the Council of the European Union[7] and the Heads of Medicines Agencies[8].

The 'Road map to 2015' sets out the Agency's vision, elaborates on the main drivers for progress and change that will impact on it, and explores the main initiatives to be undertaken to successfully meet the challenges it will face. This vision encompasses the Agency's strategy for both medicines for human and veterinary use, in line with the joint responsibility of the Agency[9]. It should be noted that the successful delivery of the Agency's vision is dependent on the availability of the necessary resources. Detailed information on the implementation of the road map will be provided in the document 'From vision to reality', to be published shortly.

Striving for as broad a consensus as possible on the best way forward, the Agency discussed the 'Road map to 2015' with its partners and stakeholders. Following public consultation in 2010, which included face-to-face discussions, and subsequent consideration of the comments received, this revised version of the road map was adopted by the Agency's Management Board at its 16 December 2010 meeting, and subsequently made public.

2 The European Medicines Agency Road Map to 2010: Preparing the Ground for the Future (EMEA/H/34163/03/Final).

3 European Commission's Better Regulation strategy (see Better Regulation website).

4 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector (COM(2008) 666 final).

5 Future Challenges Paper: 2009-2014, European Commission Health & Consumer Protection Directorate-General.

6 Communication from the Commission to the European Parliament and the Council: European agencies – The way forward (COM(2008) 135 final).

7 Draft Council Conclusions on Innovation and Solidarity in Pharmaceuticals (16586/1/10).

8 A Strategy for the Heads of Medicines Agencies, 2011-2015.

9 An explicit reference to either sector will only be made where necessary.

4. The Agency's drivers for progress and change

The following business drivers are shaping the future tasks of the Agency and the environment in which it operates.

4.1. Efficient operation of the Agency's core business

The main focus for the Agency over the coming years will continue to be the operation of its core business[11], in line with the tasks described in current and upcoming EU legislation. The Agency's roles and responsibilities have further expanded since the drafting of the 'Road map to 2010', and now cover a wide range of activities. The European Commission's impact assessments of new legislative provisions in the areas of falsified medicines and pharmacovigilance have indicated that the consequences will be very important for the EU regulatory network – and for the Agency in particular, given its coordinating role.

Efficiency will, therefore, be even more key to the successful operation of the Agency's core business. An important consequence of the growing area of responsibilities is that the Agency's tasks have become much more complex. The Agency currently comprises six scientific committees and some 35 working parties and other (scientific) fora, to which it provides scientific support. A particular challenge in this area relates to the interactions and interdependencies that exist at various levels between these fora.

4.2. Addressing public-health needs

As highlighted in the European Commission's white paper[12], there are several challenges to public health that require a new strategic approach. These cover demographic changes (including population ageing), emerging public-health threats, antimicrobial resistance, climate change (particularly in view of the emergence of new diseases) and the rapid development of new technologies (including e-health), which will heavily impact on existing healthcare systems. An aspect that will remain high on the public-health agenda relates to the availability of medicines for rare diseases and other current unmet medical needs, such as medicines for the paediatric population. Rational and better-targeted use of medicines has been identified years ago as an important factor in reducing morbidity and mortality. Another aspect that requires careful consideration is the need to investigate the impact on public health of decisions taken by regulatory authorities, and to subsequently introduce the necessary remedial actions.

In the area of animal health, the European Commission will be implementing during the period covered by this road map the revised Community Animal Health Strategy (CAHS)[13]. The Agency is a key partner in terms of facilitating the availability of medicines for veterinary use that will be needed to deliver parts of this strategy.

The Agency's contribution to the CAHS needs to be seen within the 'One World, One Health' concept[14], whereby promotion of health in animals promotes health in humans. Being an Agency with responsibility for medicines for both man and animals, it is well placed to promote closer coordination between activities in the human and veterinary areas, bringing together relevant expertise to pursue shared objectives.

4.3. New and emerging science

While new and emerging science (such as personalised medicine, nanotechnologies, novel-novel drug development, regenerative medicine and synthetic biology[15], as well as advances to streamline non-clinical and clinical development) is becoming increasingly established as part of the new wave of medicines development, providing new ways to address current unmet medical needs, there are still aspects of this field that require careful consideration, primarily

11 Core business is defined as the Agency's involvement in the authorisation and supervision of medicinal products for human and veterinary use, in accordance with EU legislative provisions, including the processes supporting these tasks.

12 White Paper – Together for Health: A Strategic Approach for the EU 2008-2013 (COM(2007) 630 final).

13 Animal Health Strategy for the EU (2007-2013): 'Prevention is Better than Cure' (ISBN 978-92-79-06722-8).

14 'One World, One Health' website.

15 Synthetic biology refers to two main activities: the design and construction of new biologically based parts, novel devices and systems, and the redesign of existing, natural biological systems for useful purposes.

the appropriateness of the current legal/ regulatory framework, in particular with respect to the benefit/risk evaluation and the development of tools for the anticipation of potential safety issues. There is thus a need for debate on how best to support and translate the new science into regulatory requirements. Further thought will also have to be given to aspects such as ethical and environmental considerations. Such important scientific progress will require regulators to be attuned to the new technologies in both human and veterinary fields, and to learn from research and experience in other industry sectors.

In addition, the Agency is likely to be confronted within the next few years with challenges stemming from a reappraisal of the device legislation in the EU and, in particular, activities focusing on the interaction between medical devices/ diagnostics and medicinal products. Interaction between the sectors of medicinal products, medical devices and diagnostics should be facilitated to nurture a synergistic approach.

4.4. The impact of increasing globalisation

The importance of globalisation has increased over time and will continue to do so. One of the main drivers is the global nature of medicines development and research. Manufacturing and clinical-trial activities will continue to see an increased international focus over the coming years. The movement of clinical research to developing countries presents particular challenges, such as safeguarding the integrity of the data, ensuring equivalent ethical standards are met, the threat of double standards, and the need to have confidence in local regulatory and supervision arrangements. Another field of growing concern relates to the increasing manufacture of active pharmaceutical ingredients (APIs) outside the EU, and in particular the potential for substandard material to enter the supply chain.

In the area of regulation of medicines for veterinary use, the impact of globalisation will also become increasingly noticeable in terms of closer and more intense cooperation with international partners. During the next five years, particular efforts will be needed to develop, with the OIE, an appropriate approach to extending the influence and uptake of VICH guidelines beyond the existing member and observer countries. Also, in light of the recently revised EU legislation governing maximum residue limits (MRLs), closer cooperation will be required with international partners, particularly Codex Alimentarius, in setting acceptable limits for residues of veterinary medicines in animal foodstuffs, and in risk-assessment methodologies. An increased focus on international cooperation recognises the fact that EU consumers are only really protected from risks related to products of animal origin when the same standards are applied, irrespective of whether animals are reared in the EU or elsewhere.

4.5. The model for regulation of medicines

The model for regulation of medicines is a complex concept, encompassing elements such as the requirements for medicines development, the benefit/risk balance, the point of decision-making for granting a marketing authorisation, and post-authorisation follow-up. Added complexity comes from a split of activities undertaken at national level (clinical-trial responsibility, scientific-advice handling, etc.) and at EU level (equally scientific-advice handling, assessment of paediatric investigation plans, etc.). Over the past few years, there have been several developments in each of the areas cited above that de facto mean that the current model for medicines regulation is being reviewed. A recent development in the pharmaceutical arena is the growing importance of health technology assessment (HTA) bodies on the access to market of novel medicines, due largely to increased pressure on healthcare budgets. Of particular note in this respect is the work already undertaken within the framework of the European Network for HTA Joint Action (EUnetHTA JA) on the relative effectiveness of pharmaceuticals.

More specific considerations relate to the field of herbal medicinal products, where it needs to be acknowledged that the innovative concept of list entries and monographs has not really been followed up in terms of subsequent marketing-authorisation applications, and that remedial action is therefore necessary. Furthermore, aspects related to borderline issues with nutritional supplements still require resolution.

The past thirty years have seen a gradual convergence of the legislation governing medicines for human and veterinary use, leading to an improvement in the quality of veterinary medicines but also to an overall increase in regulatory requirements and in their complexity. In 2009, the European Commission recognised the need for a review, and launched an impact assessment of the veterinary medicines legislation that covered, among other

issues, whether or not there is a need to reconsider the extent to which the legislation governing veterinary medicines should, in future, be tailored to the specific requirements of this market sector.

4.6. Ensuring patient/ consumer and animal-health protection

For several years, the focus within the EU has been directed towards a more proactive approach in ensuring patient safety, while continuing efforts to further improve the spontaneous reporting scheme. This resulted, in 2005, in a number of legislative changes for medicines for human use, introducing new tools such as the novel concept of risk-management plans. In addition, strategic initiatives were launched in the EU within the framework of the European Risk Management Strategy (medicines for human use) and the European Surveillance Strategy (medicines for veterinary use). In both cases, the aim is to achieve high standards of human and animal-health protection with respect to the use of medicines. Work is under way[16] to further progress the implementation of the various initiatives. It needs to be recognised, however, that public opinion over time has become much more risk-averse, resulting in increased demands for more refined pharmacovigilance tools for medicines for human use, as well as better communication on the benefits and risks of medicines. The new pharmacovigilance legislation will provide an appropriate framework to address these demands. Likewise, the European Commission's review of the veterinary medicines legislation provides an opportunity to develop a framework more appropriate to the needs of modern veterinary medicine.

4.7. Demands for greater transparency and openness

For any public body in the field of medicines regulation, transparency and openness are important factors in its ability to gain, maintain and strengthen the trust of its stakeholders. Demand for information and openness on the Agency's activities will increase over the coming years, so action is needed both in terms of the tools available (for accessing documents and public database information) and the content of information available (e.g. information on the opinion/decision-making process for the evaluation and supervision of medicinal products, on adverse drug reactions and on clinical trials).

Efforts will have to be strengthened to make up-to-date medicinal product information readily available. Providing greater transparency will entail specific challenges, such as finding the right balance between making more information and documents available more quickly and protecting commercially confidential information, while also complying with personal-data legislation. More openness of operation and increased transparency should go hand in hand with efficient and targeted communication. This becomes even more important in situations that require a coordinated approach, such as emerging public-health threats.

16 Implementation of the Action Plan to Further Progress the European Risk Management Strategy: Rolling Two-Year Work Programme (EMEA/280089/2007).

5. Addressing the drivers for progress and change

5.1. Current achievements

The 'Road map to 2010' clearly states that its ultimate objective is to ensure that the Agency adequately prepares the ground for further success in the future, building on the achievements of its first 10 years. At regular intervals[17,18], the Agency has reported on progress made with the implementation of its 'Road map to 2010'. Overall, the Agency largely succeeded in delivering the planned activities and initiatives and in meeting its 2010 priority objectives of top-quality scientific assessment, timely access to safe and effective medicines, continuous monitoring of medicinal products, access to information, and specific needs for veterinary medicines. Although it can be concluded that the Agency has now successfully prepared the ground for the future, further progress on the 2010 road-map objectives is still needed[19]. Where further work remains to be done to complete these objectives, this has been incorporated in the objectives and priorities for the next five years, as outlined in Section 5.2.

In addition, the Agency has been at the forefront in other fields, for instance the development of scientific guidelines for biosimilar and advanced-therapy medicinal products, thus paving the way for access by EU citizens to these new types of medicines. Scientific excellence (as a result of EU-wide pooling of expertise and data) has been a key strength. In this respect, it should be stressed once again that such excellent progress has been highly dependent on close collaboration between the Agency and the national competent authorities within the context of the EU regulatory network, and in particular on the valuable input of high-quality specialist expertise provided by the Member States. Another important enabler has been the Agency's continuing review of the operation of its core business, which has identified efficiency gains and allowed process improvements to be introduced.

5.2. Objectives and priorities for the next five years

5.2.1. Performing the Agency's core tasks

To address the aforementioned business drivers, the Agency's first priority over the next five years will continue to be on the successful delivery of its core business in accordance with current and new EU legislation. While the Agency's tasks have further expanded over the past years in the field of innovative medicines, access to the centralised procedure for both generic/biosimilar and non-prescription medicines has now also become a reality, and in fact constitutes an important part of the Agency's core business activities and thus its workload. It also needs to be acknowledged that the scope of the work to be undertaken in other areas did not significantly increase. This is for instance the case in the field of herbal medicinal products, although the past years have indicated the need for remedial action to address aspects such as adjusting the priority list of herbal substances, preparations and combinations thereof to the needs of the market operators, and to undertake initiatives to facilitate the uptake of the traditional-use registration scheme[20].

Since 2005, additional challenges have had to be addressed as a result of new legislation in the fields of paediatric and advanced-therapy medicinal products. This resulted in a marked increase in workload. From 2011 onwards, the Agency will be faced with the implementation of two new pieces of EU legislation in the fields of pharmacovigilance and falsified medicines, which will require careful planning, in collaboration with the Agency's partners and stakeholders, because of the important impact these new provisions will have on the regulatory environment.

Taking into account concerns voiced with respect to the current regulatory framework for medicines for veterinary use, the Agency will work with the European Commission and other partners in the EU regulatory network to analyse the outcome of the Commission's impact assessment and develop firm proposals designed to simplify

17 Status Report on the Implementation of the Road Map (EMEA/171321/2006).

18 Second Status Report on the Implementation of the Road Map (EMEA/359050/2007).

19 A third and final status report on the implementation of the 'Road map to 2010' will be prepared and published in 2011.

20 Action Plan for Herbal Medicines 2010-2011 (EMA/831327/2009).

the framework for veterinary medicines and ensure it is tailored to the specific requirements of this sector.

Efforts to strengthen the Agency's efficiency will continue in line with the European Commission's Better Regulation strategy, thereby further reducing the administrative burden. Taking into account the need to strive for the most cost-efficient way of operating, the Agency will continue to work on re-engineering and improving the processes supporting its core business. More detailed information on the measures to be taken is provided in the 'From vision to reality' document.

Successful delivery of the Agency's objectives and priorities also requires that operational and organisational aspects be carefully reviewed to verify their adequacy for the years to come. Following the publication of the European Commission's report on its evaluation of the Agency[21], a conference was held at the Agency on 30 June 2010 to discuss the findings and recommendations made. Several recommendations relate to the complexity of interactions within the Agency's scientific fora and to the Agency's architectural capacity to deal with an ever-increasing workload. Recommendations not requiring legislative changes are addressed in the 'From vision to reality' document.

Acknowledging the Agency's achievements so far, the focus for the next period will also be directed more towards the quality of the outcome of the Agency's work, and in particular on how to increase this quality. It should also be recognised that there will be other developments and challenges in the fields of science, medicines and health that the Agency will have to face, and to which it believes it can provide an important contribution. Pivotal in achieving this aim will be to further strengthen the close collaboration and cooperation with the Agency's partners in the context of the EU regulatory network, building on the excellent progress made over the past years. In addition, in some areas the scientific and technical developments may be so important that they require coordinated consideration and debate by the wider (scientific) community, where relevant at international level, to find the best-possible answers to challenging questions on regulation and science. In these situations, the existing concept of putting in place dedicated discussion fora involving regulatory authorities, pharmaceutical industry, academia and patients/consumers/users of medicines will be more systematically used, thereby strengthening the role of the Agency in promoting discussions with all of its stakeholders on important regulatory and scientific challenges.

5.2.2. The Agency's strategic areas 2011-2015

To address the business drivers listed in Section 4, the Agency has identified three strategic areas for the future:

- addressing public-health needs;
- facilitating access to medicines;
- optimising the safe and rational use of medicines.

Objectives in the area of addressing public-health needs will include stimulating the development of medicines for unmet medical needs (particularly novel anti-biotics), medicines for rare and neglected diseases, and all types of veterinary medicines. Tackling challenges posed by the steady integration of new and emerging science into modern medicine will be a further focus of activities in this strategic area, as will the need to learn from recent public-health threats and further improve preparedness mechanisms for future threats or crises.

The Agency's focus in the area of facilitating access to medicines will be on activities designed to reduce the productivity gap that currently exists in the development of medicines. Activities in this area will include investigating the underlying reasons for the productivity gap, encouraging the use of scientific advice during the development process, and promoting early interaction between regulators and sponsors. The Agency will also explore how regulatory pathways can best align market access of new medicines with the growing knowledge over time of benefits and risks.

In the area of optimising the safe and rational use of medicines, the Agency's focus will be on minimising the risks to public health that are inherent in the 'real-world' use of medicines. Extrapolating the positive benefit/risk balance identified in a clinical-trial setting for a medicine in a given therapeutic indication for a well-defined target population to the real-life use of the medicine should be further explored. Consideration must also be given here to off-label use of medicines, which can result in adverse events that trigger (important) regulatory remedial action. It needs to be acknowledged that the Agency is limited in

21 European Commission – Evaluation of the European Medicines Agency – January 2010 – Final Report.

its contribution to addressing this issue, but it has a role to play in raising better awareness at the level of the wider community on the rationale for its opinion/ decision-making. Other activities such as improved risk-minimisation tools, post-authorisation follow-up and outcomes research will complete the Agency's initiatives in this area.

For each of the three strategic areas identified, the Agency has set specific objectives that it will target through its activities over the course of the period of this road map, together with impact/result indicators by which the Agency can measure its success in achieving those objectives, as described in detail in the following sections.

Strategic area 1: addressing public-health needs

Objectives[22]	Impact/result indicators
Stimulate medicines development in areas of unmet medical needs, neglected diseases and rare diseases, and for all types of medicines for veterinary use.	• Increase in the number of scientific-advice requests for medicines for unmet medical needs, neglected diseases and rare diseases, and for all types of medicines for veterinary use. • Increase in the use of specific procedures such as Article 58 procedures (under Regulation (EC) No 726/2004).
Facilitate new approaches to medicines development.	• Existing model for medicines regulation is adapted to enable integration of new and emerging science.
Apply a more proactive approach to public-health threats where medicines are implicated.	• Effective preparedness mechanisms that take due account of learnings from previous public-health threats/crisis situations are available. • The 'One World, One Health' concept is applied to link the protection and improvement of animal health with the protection and improvement of human health. • The Committee for Medicinal Products for Veterinary Use (CVMP) Strategy on Antimicrobials 2011-2015[23] is successfully completed.

Gaps in medicines development

An important public-health challenge currently faced is the lack of medicines for unmet medical needs, neglected diseases and rare diseases. One of the most critical areas concerns the limited availability of novel antibiotics for human use, often caused by unfavourable conditions for developing new effective antibiotic agents, and of strategies to limit the development of antimicrobial resistance. In addition to infectious diseases, other fields of concern with regard to gaps in medicines development are rare and neglected diseases, leading in particular to challenges for developing countries.

To address these findings, research should not only focus on the development of new medicines, but equally target known substances (looking for new therapeutic areas or improved ways of administration), thereby benefiting from a well-known safety profile as a result of wide population exposure.

The Agency plans to take the following actions:

- Investigate and analyse, in close collaboration with the pharmaceutical companies concerned, the reasons for discontinuing the development of medicines for human use, starting with selected designated orphan medicines, and propose remedial action. Any solution should favour a holistic approach, including the use of novel endpoints, different study designs and a more appropriate use of the accelerated assessment scheme for medicines intended for unmet medical needs, rare diseases and neglected diseases in the EU and beyond.

22 Only longer-term objectives, with corresponding impact or result indicators, are described in this document. Further information will be provided in the document 'From vision to reality' and the Agency's annual work programmes.

23 CVMP Strategy on Antimicrobials 2011-2015 (EMA/CVMP/287420/2010).

- Assume a more proactive role in advising the European institutions on any gaps in medicines development, taking into account the Agency's knowledge-base on medicines under development, and on better incentives to stimulate medicines development. This should result in the establishment of a list of prioritised unmet needs, on which the public would be consulted before sending it to the responsible European Commission services. This approach could also be taken for neglected diseases in developing countries, to complement existing initiatives such as Article 58 opinions (under Regulation (EC) No 726/2004). Recent experience with the supply shortage of radiopharmaceuticals[24] has indicated that it would be appropriate to also carefully consider the need for the development of new imaging agents.

- Explore how best to contribute towards tackling challenges stemming from demographic changes, in particular population ageing. Taking into account current achievements in this field, the Agency will make additional efforts to ensure that the needs of elderly people are considered in the development and evaluation of new medicines and in the post-authorisation follow-up of already approved medicines.

- Launch initiatives to address the lack of development of antibiotics and the potential threat of antimicrobial resistance arising from the (mis)use of antimicrobials in human and veterinary medicine. Reference is in this respect made to the work performed within the context of the Trans Atlantic Task Force on Antimicrobial Resistance (TATFAR), to which the Agency will contribute, as well as to activities jointly undertaken by the Agency and other EU agencies such as ECDC and EFSA[25,26]. Initiatives already launched outside the EU (e.g. in the field of tuberculosis) should also be taken into account. Specific consideration will be given in the veterinary field to clarifying the prospects for developing novel antimicrobials for animals, taking into account the need to retain the efficacy of critically important antimicrobials in human medicine.

- Support the European Commission in implementing the revised CAHS 'Prevention is Better than Cure', by continuing its efforts within the EU regulatory network to promote the availability of medicines for veterinary use that will be needed to deliver the strategy, and those indicated for minor use and minor species in particular. In this context, the Agency will pursue approaches to facilitate authorisation of vaccines against epizootic diseases and assist where possible with bringing novel tools for disease control to market (i.e. those diseases identified as priorities within the European Technology Platform for Global Animal Health's DISCONTOOLS project).

New and emerging science

Scientific progress over the next five years will be an important driver for change. Building on current experience with advanced therapies (cell therapy, gene therapy and tissue engineering), the Agency will have to address new challenges on the horizon relating to nanotechnologies, novel-novel drug development, synthetic biology, and regenerative and personalised medicine. The concept of personalised medicine is steadily evolving from a theoretical concept into an integral part of modern medicine. The Agency has already been confronted with this concept, primarily in the oncology field. Some centrally authorised products already have personalised (pharmaco-genomics) indications in the approved product information. Many different applications of novel nanotechnologies to medicines development are also a reality, but experience is still very limited. In addition, the field of nanotechnology is very diverse. Likewise, only a small number of applications may be seen over the next years for regenerative medicine. For these novel scientific approaches, the scientific/technical and regulatory challenges will be very significant.

The Agency plans the following actions to address these challenges:

- To advise in the field of human medicines, through pooling of specialist expertise, on the necessary adaptation of the regulatory framework to the new technologies. This will complement

24 Workshop Outcome and Recommendations – Current Use and Future Needs of Radio-pharmaceuticals Labelled with Radionuclides Produced in Reactors and Possible Alternatives (EMA/150127/2010).

25 ECDC/EMEA Joint Technical Report: The bacterial challenge: time to react. A call to narrow the gap between multidrug-resistant bacteria in the EU and development of new antibacterial agents.

26 ECDC/EFSA/EMEA/SCENHIR Joint Report on Antimicrobial Resistance (AMR) Focused on Zoonotic Infections.

existing initiatives such as the setting-up of a dedicated biomarker-qualification procedure and the provision of regulatory and scientific support to the Innovative Medicines Initiative (IMI).

- To explore, within the forthcoming review of the legislation governing veterinary medicines, to what extent the requirements of evolving science (stem-cell technology, growth factors and other biologically active molecules, and tissue engineering) can be met within the existing legal framework and to what extent new legislation would be required. While recognising that it is impractical to develop a framework as comprehensive as in the field of advanced therapies for human use, a lack of legislation should not be allowed to be an impediment to the development of novel veterinary medicines, particularly as there is currently great interest in adapting advanced therapies for human use to veterinary applications. The methodology for assessing the safety to consumers of these new technologies and substances when administered to food-producing species will require particular attention.

Public-health threats

The H1N1 influenza pandemic in 2009 underlined the importance of prompt action in response to emerging public-health threats. Putting in place the necessary preparedness mechanisms has proven to be a very complex exercise that involves many aspects, including the availability of a dedicated legal/regulatory framework for the authorisation and supervision of medicines, rapid scientific-assessment processes, and a targeted and coordinated communication strategy. In addition, it requires the Agency to expand its interaction beyond the EU regulatory network in which it operates. Excellent collaboration between all parties in the wider EU public-health environment has been and will continue to be pivotal in addressing this challenge. While experience in this field is growing, with lessons being learned from previous pandemic-like situations and bioterrorism strategies being taken into account, there is also a need to prepare for new communicable-disease patterns caused by climate change and increased, unrestricted travel.

Recent experience with public-health threats such as the H1N1 pandemic, the contamination of rotavirus vaccines, the emergence of bluetongue, the contamination of medicinal products containing or derived from heparin and the shortage of radiopharmaceuticals have demonstrated the need for preparedness if regulatory authorities are to be able to cope adequately with public-health threats/crises. This requires the availability of dedicated processes and systems, as well as efficient coordination not only across the EU regulatory network, but also with non-EU regulators and with the pharmaceutical industry. Although each of these emerging situations has its own characteristics, they often have three elements in common: the complexity of the problem (including communication aspects), the global dimension and the need to find a solution quickly.

Another area of major concern is the growing threat of substandard active substances and falsified medicines. While the development of specific EU legislation is under way in these fields, the issue will remain high on the political agenda until implementation of the new legislative proposals.

Several public-health threats require the application of the 'One World, One Health' concept to be effectively addressed, whereby promoting health in man is linked with promoting health in animals. Antimicrobial resistance is one such threat that requires a coordinated approach, in terms of minimising the potential for resistance to arise from the use of antimicrobial agents in both man and animals. From the veterinary perspective, this approach is recognised within the CAHS and the CVMP Strategy on Antimicrobials.

Planned actions:

- Acknowledging that it will never be possible to have a 'one size fits all' response, the Agency will investigate – on the basis of accumulated experience, and in close collaboration with its partners and stakeholders – whether its preparedness mechanisms should be revised.
- The Agency will conduct, in collaboration with its partners and relevant stakeholders, a 'lessons learned' exercise after each major event, to further improve existing preparedness mechanisms.
- The Agency will foster the implementation of the actions proposed within both the CVMP Strategy on Antimicrobials and the CAHS, in terms of continuing and enhancing its interactions with all relevant stakeholders, as well as with the European Commission, the Codex Alimentarius and OIE, to promote prudent use of veterinary antimicrobials.

Strategic area 2: facilitating access to medicines

Objectives	Impact/result indicators
Address the high attrition rate during the medicines-development process.	• Increase in the percentage of successful marketing-authorisation applications for new medicinal products by encouraging that scientific advice is sought and adhered to. • Scientific information on failed medicines-development processes is made available to the scientific community.
Reinforce the benefit/risk-balance assessment model.	• Increased inclusion of quantitative elements, alongside an improved elaboration of the rationale for the decision/opinion in the benefit/risk considerations, for subsequent publication in the European public assessment reports (EPARs) (medicines for human use). • The concept and practice of benefit/risk assessment are embedded as part of the scientific-review process and subsequently communicated in EPARs as part of the methodology used for assessment (medicines for veterinary use).
Continue to improve the quality and the regulatory and scientific consistency of the outcome of the scientific review.	• Structured external surveys performed by the Agency's stakeholders on the outcome of the scientific reviews demonstrate an increase in the quality and the consistency.

Medicines-development process, early assessment and continuing dialogue

Despite the increase in research efforts in previous years, the pharmaceutical sector is confronted with the widely recognised phenomenon of the medicines-development productivity gap. Feedback has indicated that both the suboptimal management of the medicines-development process by sponsors in some instances and new requirements for medicines development have been identified as important contributing factors. In order to address the high attrition rate during the medicines-development process and the increasing productivity gap, the Agency is of the view that a number of initiatives could be undertaken to improve the situation:

- Although the concept of preparing guidelines on medicines development in the fields of both human and veterinary medicines has been in place for several years, it would seem timely to strengthen the involvement of stakeholders (and in particular pharmaceutical industry, academia/learned societies and patients' organisations) in this process, for instance by organising workshops at a very early stage of guideline development, so that stakeholders can actively contribute towards developing guidelines of the highest quality in medical, regulatory and scientific thinking. This would be beneficial both in areas that require further guideline development and in fields where existing guidance should be adapted to take account of evolving science.

- Furthermore, although the Agency is already collaborating with the European Commission, and in particular Directorate-General Research, on research-related aspects, its involvement has so far been rather fragmented. The Agency would therefore like to create a platform for dialogue with the Commission, to improve its input into the EU research agenda for medicines. This would complement current initiatives on fostering innovation in the context of IMI and the European Technology Platform for Global Animal Health, to which the Agency already provides an important contribution, and where efforts over the next years will have to continue.

- Acknowledging that the scientific advice provided by the Agency if adhered to by the sponsor increases the success rate of marketing-authorisation applications, the Agency will continue its efforts to optimise the scientific-advice process.

- Current experience with engagement of regulatory authorities in early-phase development plans of the pharmaceutical industry has indicated that it is advantageous to establish early dialogue with sponsors and to provide regulators with considerable knowledge of the data at an early stage, which in turn facilitates the scientific-review process. While it is recognised that further improvements can be introduced, there is also a need to explore whether the concept of early dialogue in the framework of medicines development could be widened, while maintaining it as a voluntary process. The concept of scientific advice could be expanded to provide continuous scientific support during the development of a medicine, combined with earlier appointment and involvement of (co-)rapporteurs, which would augment the interaction between regulators and sponsors during the development of both human and veterinary medicines. This would require clear roles and responsibilities to be defined for all parties involved.

- It needs to be recognised that even a failed medicine-development process will generate useful information and scientific knowledge that, in most instances, is currently lost, either because of aspects relating to proprietary information or because of the lack of access to these data by regulators. Taking into account the added value of such data (in terms of avoidance of repetitive and redundant animal or clinical studies, avoidance of the use of inappropriate parameters, etc.), the Agency is of the view that it would seem appropriate to explore, in collaboration with the pharmaceutical industry, what incentives could be offered to make this otherwise lost information available to the scientific community.

- The Agency will continue to strengthen its engagement with the pharmaceutical industry, the European Commission, EDQM and the European Centre for Validation of Alternative Methods (ECVAM) to promote the '3Rs' concept (replacement, refinement and reduction) in the development of medicines, replacing wherever possible the use of animals by validated alternatives.

- With respect to the veterinary sector, measures will be explored to increase both the uptake and the perceived usefulness of the scientific-advice procedure, through discussions with the pharmaceutical industry, taking into account experience gained in the field of medicines for human use, while recognising the particular requirements of the veterinary sector. Pending the development of proposals for amending the current legislative framework to cope better with the requirements of products and approaches entirely new to veterinary medicines, the Agency will promote early dialogue with applicants, to understand the regulatory and scientific challenges that they face in bringing these medicinal products to market.

- Another aspect that needs careful consideration is the area of clinical trials of medicines for human use, and two major initiatives need to be highlighted. The Conference on the Operation of the Clinical Trials Directive, held on 3 October 2007, provided a number of recommendations for further improvement. In addition, in 2009, the European Commission began an impact assessment in view of the introduction of changes to the clinical-trials legislation. An aspect that will require particular attention is the regulatory oversight of medicines development, which should be further improved. The development of new medicinal products and of the underlying basic and translational research required to bring these medicines to patients are key elements of a European Research Policy, which is of great importance in view of the development of Europe as a key location for biomedical research and pharmaceutical development. A

coherent regulatory process that can assist the development of medicines from their inception, through scientific advice, first-in-human trials, and full clinical development is an important element in enhancing the European research environment. There is a need to introduce a clear, risk-based approach so that trials of well-characterised products are simpler and quicker to initiate, and require lesser degrees of regulatory supervision, while trials of new, less well-known products can be given the resources they require and merit. Simplifying and streamlining the current processes are essential to these objectives.

- The impact of the increasing globalisation of clinical research and manufacturing and its movement to developing countries (which may be confronted with limited experience and resources, and a less developed regulatory framework) needs careful consideration. In order to address this challenge, the Agency will undertake a number of initiatives, including the following:
  - In the area of clinical research, further developing and subsequently implementing the Agency's strategy[27] for acceptance of clinical trials conducted in third countries, including the development of advice and guidance on ethical standards and data-quality requirements for clinical trials submitted in the EU. Furthermore, the Agency, in close collaboration with the Member State national competent authorities and its international partners, will invest in supporting capacity-building and local awareness with the regulatory authorities, research communities and pharmaceutical industry of those countries.
  - In the field of the manufacture of APIs and of finished products, the Agency will develop with the Member States the necessary framework for implementing the new anti-falsification legislation. The Agency will also build on existing collaboration with its international regulatory partners. This will not only include exchange of information (on inspection planning and outcomes) and pooling of resources to increase inspection coverage, but will also ensure, through existing platforms where possible, a coordinated approach to improving interactions with developing regulatory authorities and capacity-building to facilitate better implementation of good manufacturing practice (GMP) and supervision for manufacturers, with respect to both medicines for human and veterinary use.

Benefit/risk assessment and communication

To address the regulators' dilemma of balancing access to market vis-à-vis the need for as complete a data package as possible prior to licensing, several factors need to be considered. Pivotal in this respect are benefit/risk assessment and communication. Work on improving the benefit/risk-balance model concentrates on three major aspects: ensuring a consistent approach, providing a better rationale for the outcome of the benefit/risk review and improving the communication with the various stakeholders. This work goes hand-in-hand with the Agency's objective to focus on further improving the quality of the outcome of the scientific review. The following activities are envisaged:

- Optimising the benefit/risk-assessment process for medicines for human use can be undertaken through a variety of initiatives. Building on current achievements, work should now focus, in terms of the methodology used, on the introduction of more quantitative elements. The robustness of the scientific review should be further strengthened through better use of expertise in the areas of statistics, decision-making and communication. Furthermore, patient empowerment and patients' participation in healthcare decisions will further stimulate the ongoing debate on the level of patients' involvement in the scientific-review process. This should lead to patients' utilities being taken into account in a more systematic way for the benefit/risk assessment. Likewise, it would seem an opportunity to debate the level of involvement of relevant practising healthcare professionals and academia/learned societies in the scientific-assessment process throughout a product's lifecycle. Work will be undertaken to align the benefit/risk-assessment methodology with activities performed by other non-EU regulatory authorities in this area.

27 EMEA Strategy Paper: Acceptance of Clinical Trials conducted in Third Countries, for Evaluation in Marketing Authorisation Applications (EMEA/228067/2008).

- Further work is also needed on improving the transparency of the outcome of the scientific review, including the justification for the opinion/decision taken. This is even more important in situations where the Agency's views are not in line with the outcome of the review by non-EU regulatory authorities. Subsequently communicating the outcome of the benefit/risk assessment in the most appropriate way represents a particular challenge. The Agency will, therefore, prepare a strategy on benefit/risk-assessment communication, liaising with all stakeholders to identify their specific needs.

- In the veterinary sector, fundamental differences exist in the approach to benefit/risk assessment, where the direct risk is to the recipient animal whereas the perceptions of benefit derive from the owner, the keeper or the healthcare professional. The databases and infrastructure required for quantitative approaches to benefit/risk assessment do not exist in the veterinary sector and are unlikely to be cost-effective to develop. Current emphasis, therefore, is on the development and documentation of a systematic methodology for benefit/risk assessment, as well as on the provision of training within the EU regulatory network. Therefore, work over the coming years will focus first on more clearly embedding the benefit/risk methodology in the assessment procedure, adapting it to different types of authorisation and medicinal products (e.g. antimicrobials), and on better communication to the Agency's stakeholders about the methodology used. Other challenges will be to demonstrate within the EU regulatory network that a consistent approach to benefit/risk assessment is applied irrespective of the licensing route, and that the methodology can bring benefits in terms of availability when applied to medicines for emergency diseases and limited markets.

- Further improving the quality and the regulatory and scientific consistency of the outcome of the scientific-review processes will be a key objective for the Agency. Activities will concentrate on improving the benefit/risk-balance model as outlined above. In addition, efforts will be directed to regular external surveys with stakeholders, to monitor the outcome of scientific-review processes for medicines for human use. For veterinary medicines, better use will be made of specialised expertise during the assessment phase, and consultation will continue with stakeholders, to identify the key parameters for measuring performance of the marketing-authorisation process and to put in place systems to monitor them.

- An in-depth reflection is also needed on how to further improve the use of the legal tools for the granting of a marketing authorisation. The Agency will ensure that the criteria for a conditional marketing authorisation for medicines for human use are better adhered to, since it needs to be recognised that this concept has not really been applied as initially foreseen. Likewise, consideration should be given to whether, and in what form, the concept of conditional marketing authorisation might be introduced for veterinary medicines.

- In addition, a key issue for regulators will be whether a more 'staggered' approval (or progressive licensing) concept should be envisaged for situations not covered by conditional marketing authorisations or marketing authorisations under exceptional circumstances, for instance characterised by a better-defined or more restricted population of good responders, followed by a broadening of the population post-authorisation when more 'real-life' data are available. The Agency would like to launch a debate with all stakeholders on the appropriateness of introducing such a concept, including a consideration of appropriate incentives to support new medicines development. It should be emphasised that progressive licensing should not lead to a reduced level of evidence for first-time marketing authorisation.

- Strategies on the best way to increase the knowledge of a medicine in the post-authorisation phase need to be set up at the moment of licensing, and subsequently reviewed when new information emerges. Although risk-management plans in the human medicines field meet this aim and have been a real step forward, due account needs to be taken of provisions in the new pharmacovigilance legislation that relate to such risk-management plans, which will allow remaining uncertainties on efficacy and safety at the moment of licensing to be better addressed. Therefore, risk-management plans will be an important tool in supporting continuous benefit/risk assessment throughout a medicine's lifecycle.

Another tool for maximising the value of information generated in the post-authorisation phase – especially for orphan medicines – is the establishment and maintenance of patient registries. Furthermore, work also needs to be undertaken to improve the formulation, implementation and monitoring of post-authorisation commitments for marketing authorisations not benefiting from the conditional marketing authorisation concept, with a view to increasing the efficiency of the system. Particular attention will be paid to ensuring that compliance with these post-authorisation commitments is adhered to.

Facilitation of the relative-effectiveness assessment of medicines for human use

A number of differences have been pointed out when comparing the licensing process with relative-effectiveness and cost/benefit-assessment processes, in terms of the choice of clinical endpoints, efficacy versus effectiveness, and relative efficacy versus placebo-controlled studies. This leads to a situation whereby regulators and HTA bodies, although both aiming for the availability of medicines that make a contribution to public health, are currently applying different approaches. Calls have been made for closer interaction and collaboration between both parties of the healthcare system, while fully respecting their distinct roles and responsibilities. The High Level Pharmaceutical Forum agreed in October 2008 on a set of recommendations[28], including that Member States, with the involvement of the Agency, should continue their efforts to consider how EPARs can further contribute to relative-effectiveness assessments. The Agency aims to make progress in this field, albeit in a stepwise manner, while continuing to ensure that cost/benefit assessment remains distinct and separate from the licensing process. The Agency's work, therefore, will continue to be characterised by the exclusion of any economic considerations.

Two major initiatives are envisaged:

- The Agency will improve as an information provider. HTA bodies rely heavily on EPARs, and the Agency will increase its level of transparency on the outcome of the scientific-review process as summarised in the EPARs, including the rationale for the decision/opinion, whereby more emphasis will also be put on the quantitative aspects of the benefit/risk assessment, as already elaborated upon. Furthermore, the Agency will attempt to ensure that the product-lifecycle concept is better integrated in the EPAR, so that the EPAR better meets the criteria of a 'living' document, providing up-to-date and detailed information on the benefit/risk profile of a medicinal product throughout the marketing phase.
- The Agency will engage with HTA bodies in the early stages of development of a medicine (to avoid as far as possible the appearance of two different medicine-development programmes) and throughout the medicinal product's lifecycle, in terms of alignment of regulators' and HTA bodies' evidence requirements, through initiatives such as joint approaches to scientific advice, mutual input on clinical guidelines and debating evidence requirements (including relative efficacy aspects). In view of the vast amount of data obtained through post-authorisation collection, maintaining the dialogue with HTA bodies throughout a medicinal product's lifecycle is very important, as this facilitates greater alignment of such data collection.

28 High Level Pharmaceutical Forum 2005-2008, Final conclusions and Recommendations.

Strategic area 3: optimising the safe and rational use of medicines

Objectives	Impact/result indicators
Strengthen the evidence base in the post-authorisation phase to enable better regulatory decision-making.	• A regulatory model that facilitates the post-authorisation collection of data on benefits and risks of medicinal products is put at the disposal of the regulatory system. • A pharmacovigilance framework appropriate to the needs and priorities of the veterinary sector is developed as an outcome of the European Commission's impact assessment of the legislation for veterinary medicines.
Enhance patient safety by avoiding unnecessary risks to patients as a result of the use of medicines.	• A revised risk-management concept that targets both novel pharmacovigilance methodologies and a risk-minimisation toolbox better adapted to reduce harm is available.
Become a reference point for information on medicines evaluated by the Agency.	• A high-quality, informative and targeted set of information on medicines falling within the sphere of the Agency's responsibilities is proactively put at the disposal of the EU regulatory network at the moment of licensing/updating of the marketing authorisation.
Improve the decision-making process by taking due account of patient experience, thus contributing to the rational use of medicines.	• Conclusions from outcomes-research projects analysing the impact of regulatory decisions on public health are used to provide input into future regulatory policy decision-making.

Patient safety

Pharmacovigilance and safety of medicines will continue to be a top priority for the Agency, with a strong focus on ensuring that both risks and benefits are monitored throughout a medicinal product's lifecycle. Avoiding unnecessary risks to patients is becoming an increasingly important factor in strategies on the protection of public health, e.g. in the context of antibiotic use. Efforts are undertaken at EU level and internationally to enhance patient safety. In the EU, the focus is on strengthening research in this field and on launching new legislative proposals aimed at rationalising and strengthening the EU framework on safety-monitoring of medicines for human use. In addition, international collaboration on medicine safety as a result of globalisation and the need for best use of resources will result in finding synergies between the European Network of Centres for Pharmaco-epidemiology and Pharmacovigilance (ENCePP, led by the Agency) and Sentinel (led by the Food and Drug Administration) initiatives.

The Agency's initiatives in this field for medicines for human use will, in addition to preparing for the implementation of the new pharmacovigilance legislation, include the following:

- A revision of the risk-minimisation-measures toolbox, in the framework of the current review and learning project on risk-management plans for human use, the aim being to further reduce harm caused by the use of medicines. This should preferably be undertaken using predefined criteria for analysis drafted in collaboration with the Agency's partners and stakeholders. Taking into account the impact of certain risk-minimisation measures on the EU's health workforce (doctors, pharmacists, nurses, etc.) and the pivotal role of healthcare professionals versus patients as regards the use of medicines, particular attention will be

paid to how the risk-minimisation measures impact on the work of healthcare professionals throughout the EU. It should be recognised that this impact may vary according to the healthcare policies and systems in place.

- Progressing the European Risk Management Strategy, thereby complementing the new legislation on pharmacovigilance, targeting aspects such as capacity-building for post-authorisation monitoring; preparing for the introduction of international standards and controlled and internationally agreed terminologies in pre- and post-authorisation phases; involvement in research-related activities on pharmacovigilance methodologies, in particular within the context of the IMI framework, to investigate novel and better ways to monitor the safety and benefit/risk balance of medicines. Another good example of investment in regulatory science relates to further initiatives to be undertaken within the context of ENCePP to support decision-making on the benefits and risks of medicines.

Post-authorisation follow-up

In order to optimise the safe and rational use of medicines, more information has to be obtained in 'real-life' situations:

- As a starting point, and taking into account the provisions on post-authorisation studies in the new pharmacovigilance legislation, the focus should be on the marketing-authorisation holder's post-authorisation development plan, and should include an exploration of the kind of incentives that could be provided to pharmaceutical companies to encourage them to voluntarily include such plans in the Agency's current scientific-advice framework. Secondly, recent developments in the field of human medicines, such as a firm new legal basis to require post-authorisation studies, will augment the initial knowledge on a medicinal product's benefits and risks. This should ultimately lead to an integrated assessment of benefits and risks under real-life conditions. ENCePP is an important tool that will support the development of methods for post-authorisation data collection, the establishment of an inventory of pharmacovigilance and pharmaco-epidemiology research centres, and the creation of a register of post-authorisation studies, thus meeting the needs of both regulators and HTA bodies.
- Taking into account increasing public concern over potential effects on the environment of the use of medicines, and building on extensive experience already gained with veterinary medicines, initiatives should be taken to look into the longer-term impact of medicines for human use on the environment. Particular attention will have to be paid to the environmental risks of nanomedicines.
- In the field of veterinary medicines, the European Commission's impact assessment of the veterinary medicines legislation will provide an opportunity to develop a post-authorisation framework that is particularly suited to the needs and resources of the animal-health sector. The Agency will consult with all involved stakeholders on how best to develop an appropriate risk-management framework, and on the extent to which it is possible to licence medicines for veterinary use at an earlier stage of development, based on the requirement to provide the necessary post-authorisation data.
- With a view to contributing to a more rational use of medicines for human use, the Agency will focus its efforts on raising better awareness among healthcare professionals of the rationale for its opinion/decision-making. The existing forum with healthcare professionals' organisations will be used to debate how this can best be achieved.

Authoritative source of information

The Agency is meeting the demand for greater transparency and openness through initiatives such as the development of policies on access to documents[29], on access to information in the EudraVigilance databases[30], and on transparency[31]. In addition, the Agency holds the following views:

29 European Medicines Agency Policy on Access to Documents (related to medicinal products for human and veterinary use) (EMA/110196/2006).

30 Draft EudraVigilance Access Policy for Medicines for Human Use (EMEA/187439/2008) and Draft EudraVigilance Access Policy for Medicines for Veterinary Use.

31 EMEA Transparency Policy – Draft for Public Consultation (EMEA/232037/2009 – rev*).

- Irrespective of the ongoing political debate on the best way forward for providing information on medicines to patients, the Agency should strive to become the authoritative source of information on all medicines it evaluates, both human and veterinary, for syndication to the EU regulatory network. This should also promote public recognition of the Agency as a leading authority in the field of evaluation and supervision of medicinal products. Initiatives should be directed towards the preparation by the Agency of timely, targeted and high-quality information on the medicines it evaluates. In this way, the Agency can concentrate on the quality and consistency of the information provided, and other parties can focus on ensuring maximum penetration of this information among the target audiences, and in particular patients/consumers/users of medicines and healthcare professionals, thereby fully respecting the characteristics of the EU regulatory network in this field. Strengthening the interaction with the NCAs and with organisations representing patients/consumers and healthcare professionals to build up a network of excellence at EU level will be an important target. Furthermore, joint reflection with the Member States and other interested parties on how best to address technical developments in the field of provision of information on medicines – in particular the link with e-health – is also needed.

- Work should be undertaken to put more emphasis on balanced benefit/risk communication, to contribute to the implementation of the empowered-patient concept. Aspects that will require particular consideration include how best to address the complexity of the data, as this requires careful interpretation, and determining the most appropriate time point for communication on benefits and risks when new information emerges. It will be equally important to clearly communicate to healthcare professionals and patients, using the most appropriate communication tools, the reason why the medicinal product is not indicated for use outside the approved indication.

- For veterinary medicines, the objectives in terms of transparency and communication should be the same as for medicines for human use, although it will be necessary to tailor the messages and the way in which they are delivered to the needs of the veterinary community. This will be done through surveys with the various stakeholders in the veterinary sector to understand better the types of information they would find most useful and how best they can be presented.

Outcomes research

The Agency has identified analysing the impact of regulatory decisions on public health as an important activity for the years ahead. Outcomes research in this field has begun, in line with the Agency's internal control standards, which require it to evaluate its activities. Efforts in this field will continue over the coming years, and will include the following:

- Building on current initiatives (with emphasis initially on the benefit/risk-assessment and communication model), the Agency will further engage in monitoring the use of medicines for human use, in close collaboration with its stakeholders. To gain maximum understanding of the implications of regulatory decisions, the focus for the coming years should be on outcomes research that looks at the actual versus intended use of medicines, the effectiveness of risk-minimisation measures, including aspects of feasibility in healthcare, and investigates whether the current regulatory model contributes to better therapy outcomes. The findings of this research should also be used to provide input to future regulatory policy decision-making.

- Different priorities and data sources apply to regulatory decisions in the veterinary-medicines sector. Where possible, opportunities will be taken to conduct specific outcomes-research projects in the veterinary field, focusing particularly on collecting data at EU level on the sale of antimicrobials in the Member States.

6. Implementing the Agency's road map

The Agency will implement its vision in line with the document 'From vision to reality'. This document will provide information on the prerequisites to be fulfilled and the enablers (including operational and organisational aspects) needed to allow the Agency to successfully contribute over the next five years in the fields of science, medicines and health.

In addition, to optimise the implementation of the road map, the Agency will complement its planning process by applying a multi-annual programming approach, which will equally cover a five-year timeframe. This multi-annual programming will address aspects such as workload and (human) resources forecasts, budget planning, accommodation needs, etc., and will benefit the Agency by allowing decisions to be made in a more effective and predictable way, thus helping to ensure the Agency can gradually implement its vision over the next five years. Following endorsement by the Management Board, the multi-annual planning will feed into the Agency's annual work programmes.

7. Conclusion

It is the Agency's view that the vision outlined in this 'Road map to 2015', together with the proposed solutions for addressing the challenges identified, will allow the Agency to increase its contribution to science, medicines and health, and thus to the protection of the human and animal populations of the European Union.

An important prerequisite for the successful delivery of the road map will be the further development and reinforcement of the EU regulatory network, which has already proven to be of fundamental importance to the EU's pharmaceutical sector.

The Agency is looking forward to engaging with its partners and stakeholders to successfully implement its vision for the next five years.

European Food Safety Authority

ADVISORY FORUM AND SCIENTIFIC COOPERATION UNIT

PESTICIDES UNIT

Visit of Mrs. Su-San Chang, from the Bureau of Animal and Plant Inspection and Quarantine (BAPIQ), Council of Agriculture of Taiwan to EFSA

Meeting date:	25 June 2014
Meeting Venue:	00/M05
Meeting hours:	10.00-16.00

Draft Agenda

Session 1: Microbial pesticides (chaired by Jose Tarazona)		
Time	***No.***	***Items***
10.00	1	Brief introduction to the activities of the EFSA Pesticides (PRAS) Unit • Mr. Jose Tarazona, Head of Pesticides (PRAS) Unit
10.30	2	Brief introduction to the activities of the Bureau in the area of pesticides • Mrs. Su-San Chang, Director General of the Bureau of Animal and Plant Inspection and Quarantine, Council of Agriculture, Taiwan
11.00	3	Discussion on the EFSA risk assessments of microbial pesticides with EFSA scientific staff • Mr. Chris Lythgo, senior officer PRAS Unit
12.00		*Lunch break*
Session 2: Risk assessment methodologies in other areas covered by EFSA (chaired by Marina Koussathana)		
14.00	4	EFSA's role on food safety – EFSA's International Scientific Cooperation • Mrs. Marina Koussathana, Scientific Officer, Advisory Forum and Scientific Cooperation (AFSCO) Unit

14.30	5	Exchange of views on Risk assessment of BSE • Mr. Pietro Stella, scientific officer of Biological Hazards and Contaminants (BIOCONTAM) Unit
15.00	6	Exchange of views on assessment of risks for animal health • Mr. Franck Berthe – Head of Animal and Plant Health (ALPHA) Unit
15.30	7	Discussion and concluding remarks
16.00		*Closure*

Participants list

Taiwan

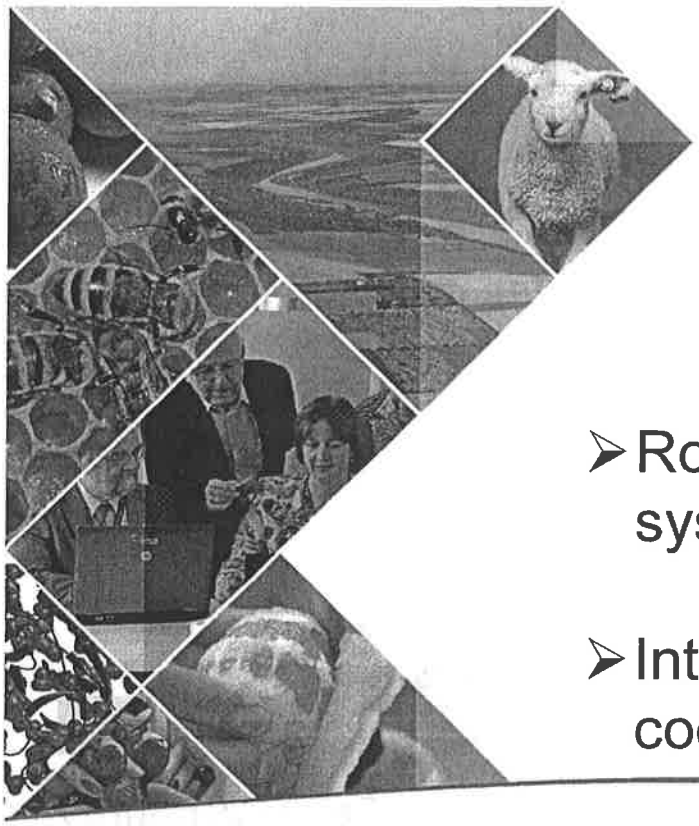
Mrs. Su-San Chang, Director General, Bureau of Animal and Plant Health Inspection and Quarantine, Council of Agriculture, Executive Yuan, Taiwan

EFSA participants

Mr. Jose Tarazona, Head of Pesticides (PRAS) Unit
Mr. Chris Lythgo, senior officer of PRAS Unit
Mr. Pietro Stella, scientific officer of Biological Hazards and Contaminants (BIOCONTAM) Unit
Mr. Franck Berthe – Head of Animal and Plant Health (ALPHA) Unit
Ms. Marina Koussathana, scientific officer of Advisory Forum and Scientific Cooperation (AFSCO) Unit

Observers

Dr. Nicoleta Suciu, researcher Institute of Agricultural and Environmental Chemistry, Sacro Cuore Catholic University.



EFSA today

- Role on food safety system
- International scientific cooperation

efsa
European Food Safety Authority

www.efsa.europa.eu

EFSA WAS SET UP IN JANUARY 2002 AS

- an independent source of scientific advice and communication on risks associated with the food chain
- part of a comprehensive programme to:
  - improve EU food safety system
  - help ensure a high level of consumer protection
  - restore and maintain confidence in the EU food supply
  - clearly separating risk assessment and risk management functions

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

EFSA IS TASKED TO

- Provide independent scientific advice and support for EU law/policies on food and feed safety
- Provide independent, timely risk communication
- Promote scientific cooperation

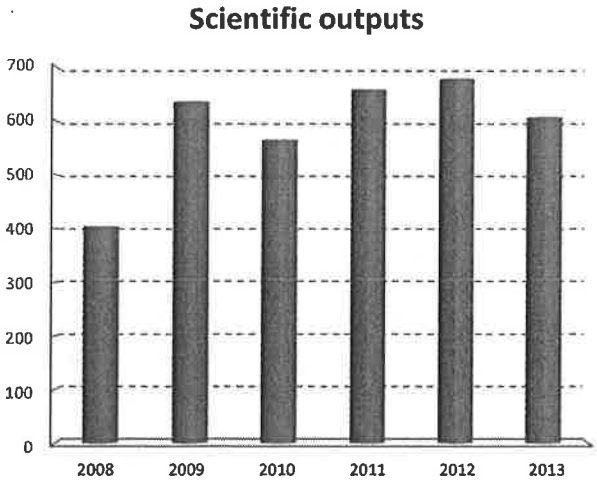
European Food Safety Authority

...WITH HEADQUARTERS IN PARMA

- 2003: scientific work starts
- 2005: moved to Parma from Brussels
- Since 2003 more than 3,300 scientific outputs including 2,330 scientific opinions
- Budget 2014: EUR 79.6 million
- Over 450 staff, 60% engaged in the production of scientific advice

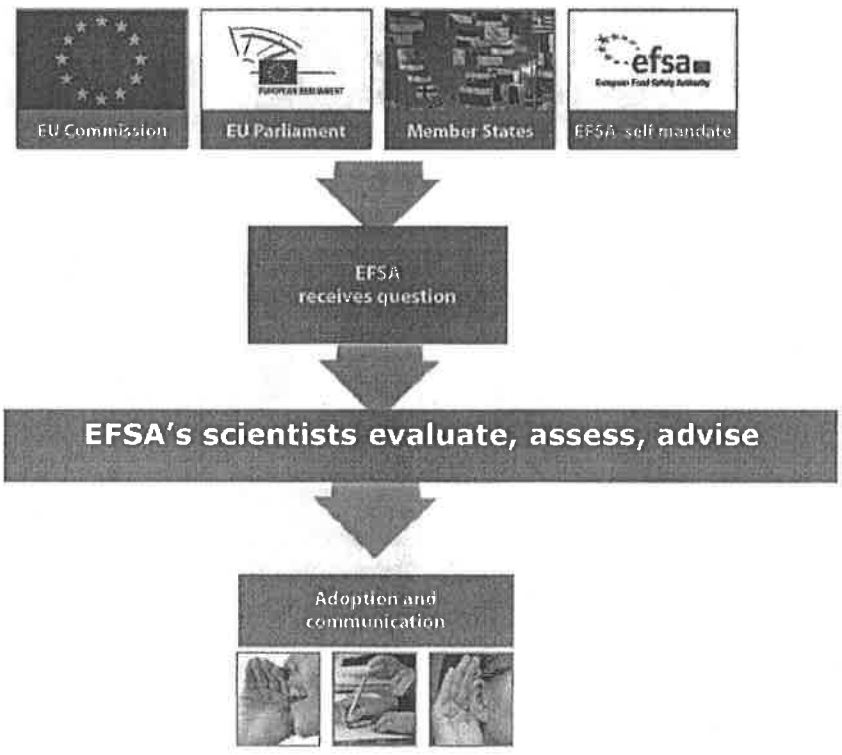
... SCIENTIFIC EXCELLENCE IN RISK ASSESSMENT

- > 3,300 outputs
  - > 2,330 opinions
  - 500th opinion: 2007
  - 1000th opinion: 2009
  - 2000th opinion: 2012
- Scientific expertise across Europe
- Impartiality of scientific advice



- EFSA Journal, Scientific Colloquia, international cooperation...

... THROUGHOUT THE WORKFLOW



EFSA HAS A ROBUST GOVERNANCE...

15 EU member ~~States~~, 聘任 D.G of EFSA 設定 work pla. budget

Management Board + Advisory Forum

28 Members + Iceland + Nor

+ +

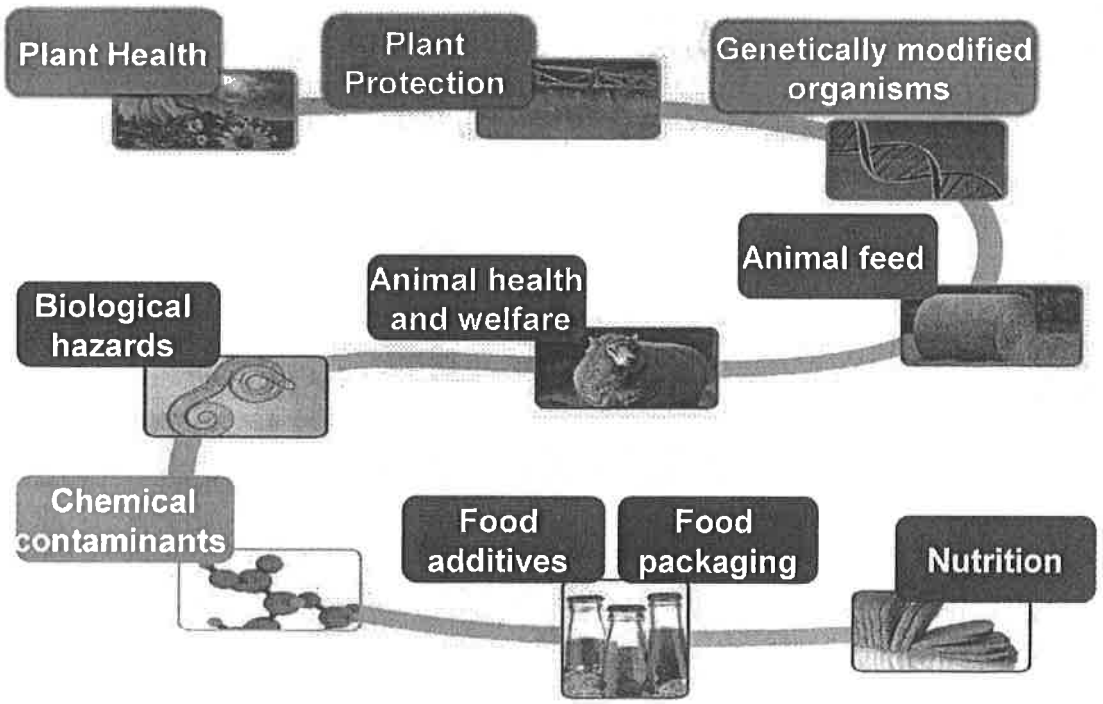
EFSA Staff

Scientific Committee and Panels → conduct R3K assess

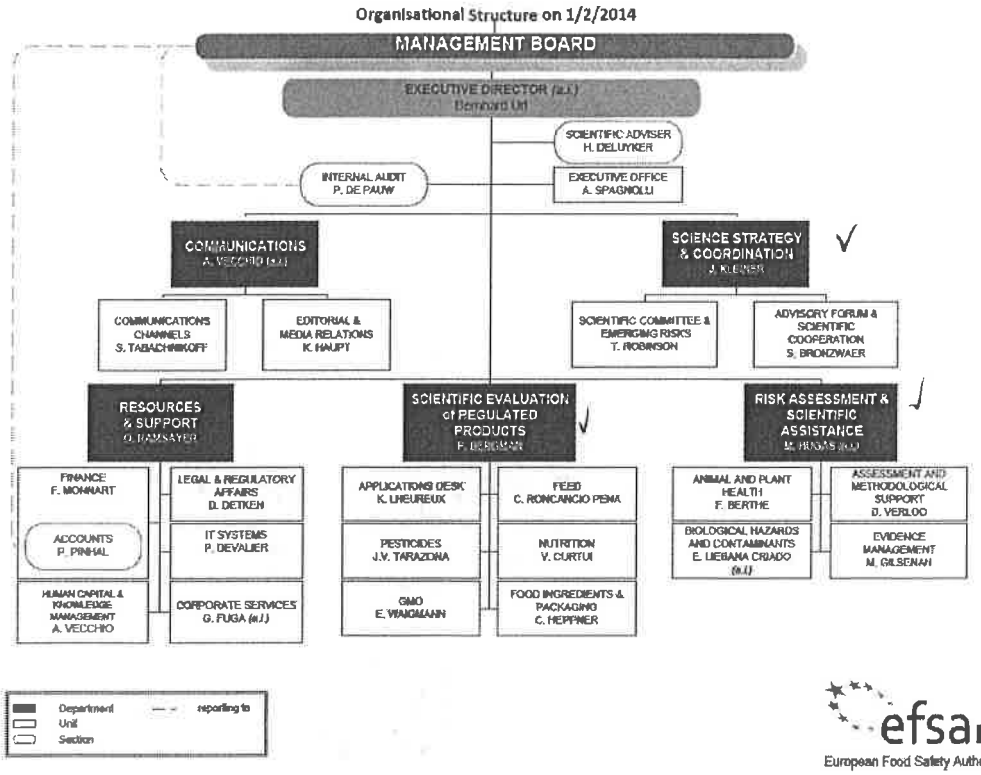
有11個 Committee

= efsa European Food Safety Authority

... WHOSE ROLE IS TO PROVIDE SCIENTIFIC ADVICE FROM FARM TO FORK



... AS WELL AS TALENTED STAFF



European Food Safety Authority

...WITH DIFFERENT ROLES

Panels

- Owners of scientific opinions

Scientific Committee

- Ensures consistency
- Issues guidance
- Assess emerging risks

Staff

- Support panel work
- Produce scientific and technical advice
- Communication

Risk communication is the core activity of EFSA

RISK COMMUNICATIONS IS

EUROBAROMETER

... TO RESPOND TO FUTURE CHALLENGES

Improve mid-term planning

Integrated multi-disciplinary advice

Reinforce risk assessment capacity (scientific cooperation)

Development of **harmonised methodologies**

Optimise **internal scientific expertise**

Collection and analysis of **high-quality data**

Risk assessment **training**

Proactive approach to **emerging risks**

II. INTERNATIONAL SCIENTIFIC COOPERATION

Challenges & opportunities

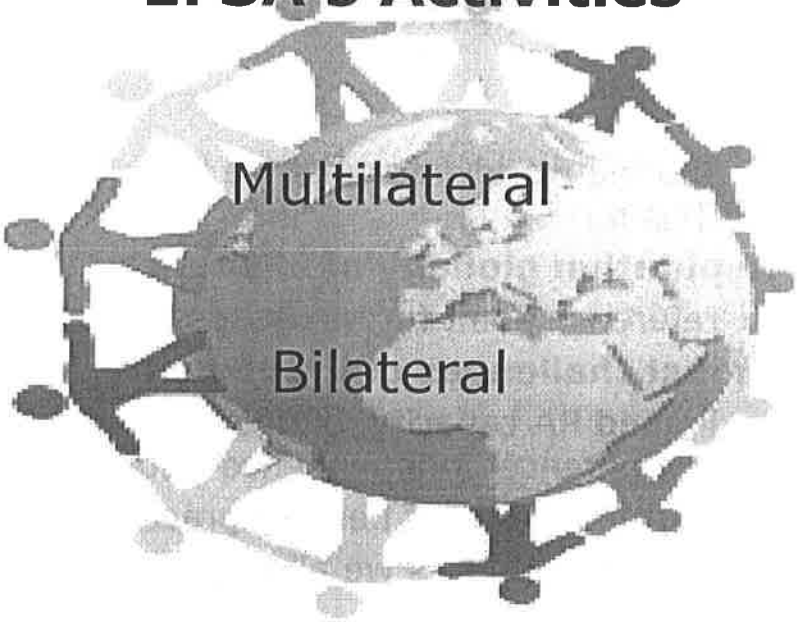
- **EU visibility**
  - sharing worldwide what we have built in the EU thus far
- **Reputation globally of EFSA as**
  - reference point for risk assessment
- **Global challenges of RA bodies:**
  - limited RA capacity, budget constraints, scientific competence, independence issues
  - Harmonisation of best RA practices is key
  - work together as we all face similar challenges

KEY OBJECTIVES

- Support of EU in its international commitments
- Support the key objectives defined in **Science Strategy**:
  a. **Optimisation** of the use of **RA capacity** in EU/Internationally
  b. Development and **harmonisation** of **RA methodologies** and approaches
  c. Strengthening the **scientific evidence** for RA and risk monitoring
- Promote of coherence in risk communication and building awareness of EFSA's activities at international level

INTERNATIONAL SCIENTIFIC COOPERATION

EFSA's Activities



EFSA's MULTILATERAL COOPERATION

To support EU in international commitments

- Enhance EFSA's support to Codex Alimentarius activities
- Improve collaboration with Joint FAO/WHO Expert Committees
- Strengthen cooperation with EU agencies in areas of international relevance (e.g. emerging issues, consistency in RA, joint efforts in developing harmonised RA tools)

To develop a more extensive work programme with WHO and FAO, e.g.

- risk assessment approaches, risk communication guidance, joint evaluation of specific substances of priority, emerging risks

To continue EFSA's activities with

- international organisations (e.g. IPPC/EPPO, OECD, OIE)
- multilateral liaison group (food chemical safety and microbial food safety and currently health claims)

EFSA's BILATERAL COOPERATION

Target: international harmonisation, standardisation of best RA practices / mapping research activities / improving access to data

To continue

- the cooperation with the US agencies through an annual physical meeting and regular cluster meetings on dedicated areas of mutual interest.
- the existing cooperation with risk assessment bodies in Australia, Canada, Japan, New Zealand and United States

To develop bilateral relations with third countries

- case by case in consultation with DG SANCO
- Priority to countries with signed agreement with the EU
- a planning for meetings with delegations from risk assessment bodies in third countries

II. International Scientific Cooperation

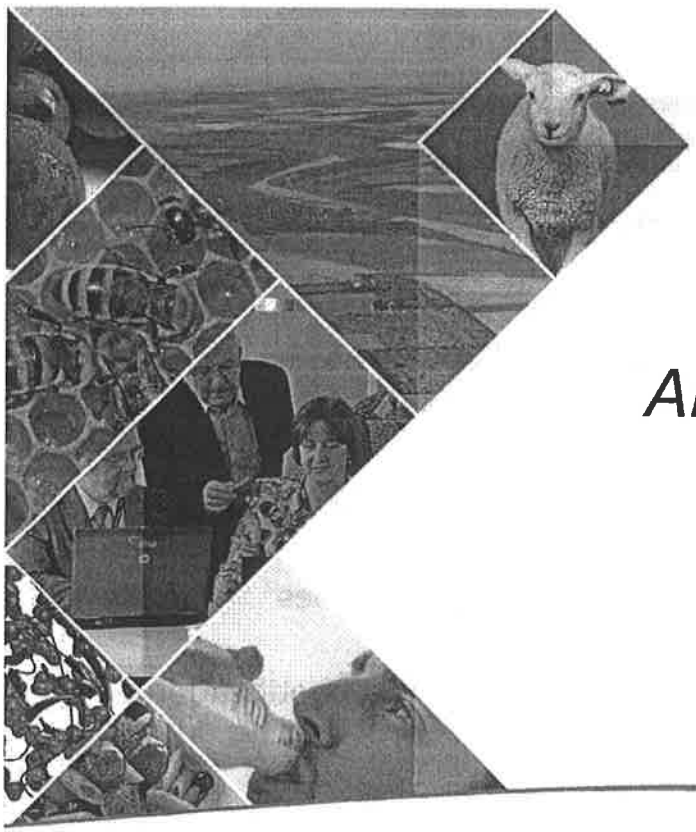
COHERENCE IN RISK COMMUNICATION WORLD WIDE

To build further on the existing risk communication activities

- **To establish an international platform to ensure coherence in Risk Communication for:**
  - Exchanging information and experiences
  - Developing common practices and guidelines
  - Building on existing practice including prenotification on specific (emerging) issues and early warning on key public announcements
  - Building on existing communication activities linked to RA

MECHANISMS FOR INTERNATIONAL SCIENTIFIC COOPERATION

- Harmonisation with international RA bodies (e.g. WHO, FAO, OIE)
  - Specific topics in risk assessment & data collection (e.g. TTC, weight of evidence, risk communication guidance, exchanging exposure assessment data)
- Thematic events: international workshop/seminars e.g. on
  - trends and developments in risk assessment (EXPO 2015) ✓
  - best practices in risk communication → 2016 on best practice in risk communication
- Knowledge transfer:
  - visits of third country delegations ✓
  - Scientists visiting EFSA ✓ → visit to Codex, Jecfa meeting
- EFSA's experts/staff assigned for short-medium tasks
  - Scientific support to EU delegation at Codex
  - Participating in JECFA/JMPR meetings



Any questions?

European Food Safety Authority

EFSA Journal 2012;10(10):s1002

SPECIAL ISSUE

The role of EFSA in assessing and promoting animal health and welfare

Franck Berthe, Philippe Vannier, Per Have, Jordi Serratosa, Eleonora Bastino, Donald Maurice Broom, Jörg Hartung, James Michael Sharp[1, 2]

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Received: 05 June 2012

ABSTRACT

This paper describes the overall achievements of the Animal Health and Welfare (AHAW) Panel of EFSA and its support unit since 2003. The AHAW Panel deals with animal health and animal welfare issues, primarily related to food-producing animals, at the human–animal–environment interface. Scientific opinions adopted by the AHAW Panel are comprehensive scientific reviews and risk assessments and provide the scientific grounds for the identification of control options, most of them being reflected in European Union legislation on animal health and welfare. Between 2004 and 2012, the AHAW Panel delivered 47 scientific opinions related to animal health and 38 scientific opinions on animal welfare on a wide variety of issues. The welfare of animals is a matter of much public concern and has an overall impact on the condition of the animals, with consequences for productivity, disease and food safety. A major achievement of the AHAW Panel has been to establish a unique multidisciplinary capacity, combining expertise in addressing animal health and welfare issues. The AHAW Panel has also demonstrated its capacity to respond rapidly to urgent requests, thus becoming a prominent partner of risk managers in response to crises. Over time, the AHAW Panel has become internationally recognised as a leader in risk assessment in the field of animal health and welfare, based on EFSA core values of scientific excellence, independence and transparency. The development of robust methodological frameworks for the assessment of risks related to animal health and welfare is a continuing process for the AHAW Panel. Over the past ten years, EFSA has achieved greater participation from the scientific community, stakeholders and interested parties, and fostered cooperation with relevant organisations in the EU Member States in the area of animal health and welfare. The AHAW Panel has demonstrated that evaluating health and welfare and assessing risk in animal populations serves to protect public health, the environment and the economic benefit we derive from animals.

KEY WORDS

Animal health, animal welfare, risk assessment

[1] Correspondence: ahaw@efsa.europa.eu

[2] Acknowledgement: The authors wish to thank the members of the AHAW Panel (2009–2012), Anette Bøtner, Linda Keeling, Frank Koenen, Simon More, David Morton, Pascal Oltenacu, Fulvio Salati, Mo Salman, Moez Sanaa, Jan Arend Stegeman, Endre Szücs, Hans-Hermann Thulke, John Webster, Marcus Doherr, Mariano Domingo and Martin Wierup, for the stimulating discussions during the preparation of this paper.

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INTRODUCTION

In the Risk Assessment and Scientific Assistance (RASA) Directorate, the Panel on Animal Health and Welfare (AHAW Panel) provides scientific advice on all aspects of animal health and welfare, including those that have implications for human health, in order to support the science-based development of animal health and welfare standards within the European Union. It epitomises the EU approach to food safety: "from the farm to the fork". The work of the AHAW Panel is relevant to food safety but also to food security.

In recent years, there has been increased public concern about the sustainability of systems such as those for producing human food; concepts of food quality have been refined. Human health but also animal health and welfare are among the components of sustainable systems and good-quality food. Safeguarding animal health is a public good that benefits all segments of society; animal welfare is another dimension of this public good. The core activity of the AHAW Panel and its support unit is to assess all aspects of health and welfare pertaining to animal production systems and practices that are applied in the EU, as well as conditions resulting from animals interacting with wildlife and the risks arising at the human–animal–environment interface.

Ethical, socioeconomic, cultural and religious aspects are outside the remit of the AHAW Panel.

Since 2003 the AHAW Panel has been actively engaged in providing independent scientific advice to EU and Member States decision makers (i.e. risk managers) and consumers on questions relating to animal health and welfare, primarily in food-producing animals. An integral part of this work has been the development of technical guidance documents and methodological approaches in order to ensure that EFSA's approaches to risk assessment related to animal health and welfare are transparent.

This paper describes the main achievements of the AHAW Panel and its support unit since 2003.

SCIENTIFIC ADVICE ON QUESTIONS RELATED TO ANIMAL HEALTH AND WELFARE

Between 2004 and 2012, the AHAW Panel has delivered more than 47 scientific opinions related to animal health and 38 scientific opinions on animal welfare, providing scientific advice and technical support to risk managers on a wide variety of issues. The division between animal health and animal welfare is, however, arbitrary as almost all are relevant to animal welfare and most are relevant to animal health. The number of scientific opinions adopted by the AHAW Panel, as well as statements, guidance, external scientific reports and technical reports, between 2004 and 2012 is presented in Table 1.

The type of questions received by the AHAW Panel generally relate to: (i) reviewing the scientific basis of existing EU legislation (e.g. Council Directives 91/629/EEC and 97/2/EC on the welfare of calves (EFSA, 2006a), Commission Regulation (EC) No 1266/2007 on bluetongue (EFSA Panel on Animal Health and Welfare (AHAW), 2011a), Council Directive 95/29/EC and Council Regulation (EC) No 411/98 and Council Regulation (EC) No 1/2005 on animal welfare during transport (EFSA, 2004a,b; EFSA Panel on Animal Health and Welfare (AHAW), 2011b)); (ii) considering possible new legislation (e.g. risks of importing wild birds other than poultry into the EU (EFSA, 2006b), and the welfare of dairy cows (EFSA, 2009a)); (iii) performing post-event scientific assessments (e.g. Q-fever (EFSA Panel on Animal Health and Welfare (AHAW), 2010a), novel swine influenza (EFSA Panel on Animal Health and Welfare (AHAW), 2010b and 2011c), foot and mouth disease (EFSA Panel on Animal Health and Welfare (AHAW), 2012a)); (iv) addressing new, arising concerns (e.g. oyster mortality (EFSA Panel on Animal Health and Welfare (AHAW), 2010c), epizootic ulcerative syndrome (EFSA Panel on Animal Health and Welfare (AHAW), 2011d)); and (v) contributing to the implementation of the EU Animal Health Strategy 2007–2013 (EC, 2007, e.g. disease categorisation, risk factors and surveillance) and the Animal Welfare Strategy 2012–2015 (EC, 2012), e.g. outcome-based indicators (EFSA Panel on Animal Health and Welfare (AHAW), 2012a,b).

Table 1: Scientific outputs by the AHAW Panel between 2004 and 2012, as well as external scientific reports with breakdown into questions related to animal health and welfare

	AHAW Scientific Opinions[a]									
	Opinions[a]		Statements[a]		Guidances[a]		External scientific reports[b]		Technical reports[b]	
	AH	AW	AH	AW	AH	AW	AH	AW	AH	AW
2004	1	4								
2005	3	4								
2006	6	2	1							
2007	12	4						1	2	
2008	6	5								
2009	4	13		1	1		8	1	1	
2010	7	2	1				2	3		2
2011	6	1					1	3	1	
2012[c]	2	3		1		1	3	1	4	1

[a] Available online: www.efsa.europa.eu/efsajournal
[b] Available online: www.efsa.europa.eu/publications
[c] Before June 2012.

AH, animal health; AW, animal welfare.

All the opinions listed above illustrate the impact of scientific assessment by the AHAW Panel on European legislation. For example, Council Regulation (EC) No 1/2005[3] on the protection of animals during transport is essentially based on the conclusions and recommendations of the 2004 EFSA scientific opinion on the welfare of animals during transport. This opinion has recently been updated (EFSA Panel on Animal Health and Welfare (AHAW), 2011b) and has contributed to a report from the European Commission to the European Parliament and the Council proposing additional management options for the enforcement of Regulation (EC) No 1/2005. Similarly, EFSA opinions on the welfare aspects of the main systems of stunning and killing (EFSA, 2004a) led to Council Regulation (EC) No 1099/2009[4] on the protection of animals at the time of killing. Further to this, stunning and killing of fish has been addressed by seven species-specific scientific opinions adopted in 2009, which are expected to support the development of legislative measures for the protection of fish at the time of killing (EFSA, 2009b–h).

Over the past ten years, requests received from the European Commission have evolved from very broad questions on various issues (probably because of the need to establish the broad context for performing risk assessment within the area of animal health and animal welfare) to more focused and specific questions (e.g. the electrical requirements for waterbath stunning (EFSA Panel on Animal Health and Welfare (AHAW), 2012c)).

Frequently, questions that initially appear to be animal health specific also cover aspects related to animal welfare. An example of this is the recent publication of the report on the impact of the Schmallenberg virus (EFSA Panel on Animal Health and Welfare (AHAW), 2012b). Similarly, animal welfare questions also cover aspects related to animal health such as, for example, the scientific opinion on the impact on welfare of genetic selection in commercial broilers (EFSA Panel on Animal Health and Welfare (AHAW), 2010d). The combining of animal health and welfare expertise into a single panel gives EFSA a unique capacity to address such complex, interactive issues.

[3] Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97. OJ L 3, 5.1.2005, pp. 1–44.

[4] Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing. OJ L 303, 18.11.2009, pp. 1–30.

While most questions have concerned animals used for food production, the AHAW Panel has also adopted scientific opinions on laboratory animals (e.g. the welfare of experimental animals (EFSA, 2005a)) and wild animals (e.g. the welfare aspects of killing and skinning seals (EFSA, 2007a)).

Three successive panels (2003–2006,[5] 2006–2009[6] and 2009–2012[7]) have contributed to this production of scientific outputs. Members of the Panel come from different backgrounds, expertise and experience to address the spectrum of questions on animal health and welfare. One-third of the members of the AHAW Panel are experts in animal health, mainly infectious diseases, one-third are experts in animal welfare, including behaviour, and one-third are experts in methodologies, i.e. risk assessment, modelling and epidemiology.

The AHAW Panel also benefits greatly from access to a wide network of world-class experts and cooperation with other national agencies and international organisations operating in the field of animal health and animal welfare. Every year, more than a hundred experts are invited to participate in working groups of the Panel

Often, the multifaceted questions addressed by the AHAW Panel call for cooperation with other EFSA panels and units and other EU agencies such as the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC). Many examples illustrate this interagency cooperation (e.g. the H1N1 influenza virus, Q fever, arthropod-borne diseases). The World Organisation for Animal Health (OIE) and the Food and Agriculture Organization of the United Nations (FAO) are two international organisations that are relevant for the AHAW Panel, and their representatives are regular observers at plenary meetings of the AHAW Panel.

The scientific activities within animal health and welfare are further supported by the EFSA Scientific Network for Risk Assessment in Animal Health and Welfare (hereafter the AHAW Network). The terms of reference of the AHAW Network are to (i) facilitate the harmonisation of animal health and welfare assessment practices and methodologies; (ii) enhance the exchange of information and data between EFSA and Member States; and (iii) achieve synergies in animal health and welfare risk assessment activities. Organisations from the 27 EU Member States participate, while Switzerland, Iceland and Norway are also part of the AHAW Network as observers.

The AHAW Network held its first meeting in November 2010 and since then several technical meetings and workshops were held for the members of the Network. These included the use of models in risk assessment for animal health, the implementation of risk assessment in animal welfare, and the data needs and specification and sharing and accessing of data. The Network has also provided opportunities to conduct retrospective comparative analyses of EFSA scientific opinions and those of national agencies on specific issues (e.g. echinococcosis, oyster mortality, Q fever). The exchange of information pertaining to ongoing activities within the Network has fostered cooperation between members of the Network on topics addressed at national and EU levels (e.g. bovine tuberculosis, Schmallenberg virus).

In delivering scientific opinions and providing independent scientific advice to risk managers on questions related to animal health and welfare, the AHAW Panel has also promoted scientific

[5] Bo Algers, Harry J. Blokhuis, Donald Maurice Broom, Ilaria Capua, Stefano Cinotti, Michael Gunn, Jörg Hartung, Per Have, Xavier Manteca Vilanova, David B. Morton, Michel Pépin, Dirk Udo Pfeiffer, Ronald John Roberts, José Manuel Sánchez Vizcaino, Alejandro Schudel, James Michael Sharp, Georgios Theodoropoulos, Philippe Vannier, Marina Verga, Martin Wierup and Marion Wooldridge

[6] Bo Algers, Harry J. Blokhuis, Donald M. Broom, Anette Bøtner, Patrizia Costa, Mariano Domingo, Mathias Greiner, Daniel Guemene, Jörg Hartung, Trevor Hastings, Per Have, Frank Koenen, Christine Müller-Graf, David B. Morton, Albert Osterhaus, Dirk U. Pfeiffer, Ron John Roberts, Moez Sanaa, Mo Salman, J. Michael Sharp, Philippe Vannier, Martin Wierup and Marion Wooldridge

[7] Anette Bøtner, Don Broom, Jörg Hartung, Linda Keeling, Frank Koenen, Simon More, David Morton, Pascal Oltenacu, Albert Osterhaus (2009–2010), Fulvio Salati, Mo Salman, Moez Sanaa, Mike Sharp, Jan Arend Stegeman, Endre Szücs, Hans-Hermann Thulke, Philippe Vannier, John Webster, Marcus Doherr, Mariano Domingo and Martin Wierup.

communication, the exchange of information and data, networking to avoid duplication of effort and improved efficiency.

THE METHODOLOGY OF RISK ASSESSMENT IN ANIMAL HEALTH AND WELFARE

The quality of risk assessment depends on the appropriate formulation of the questions, a clear understanding of their background, the best use of scientific data and expert opinion, and the application of advanced risk assessment methodology to address the questions posed.

When looking at all the scientific opinions adopted by the AHAW Panel over the past ten years, it can be seen that the methodologies have evolved in two directions. One of these has already been mentioned above: initially broad requests dealing with many concepts for various species lately becoming more targeted in terms of their questions and objectives and therefore enabling more in-depth analysis. The second direction taken through the scientific opinions of the AHAW Panel is the shift from purely qualitative to more quantitative risk assessment.

In 2010, the AHAW Panel developed a guidance document on good practice in conducting scientific assessments of animal health using modelling (EFSA Panel on Animal Health and Welfare (AHAW), 2009). The guidance takes account of previous opinions on animal health, two-thirds of which used some kind of modelling and on average every third opinion was supported by a quantitative model. These models range from simple to complex and apply a combination of scientific, economic, and socioeconomic data. The guidance document provides a detailed workflow enabling modelling to be integrated transparently and consistently in risk assessment. The workflow is divided into several phases combining EFSA standard operating procedures with the modelling process. The phasing approach has been gradually implemented by the AHAW Panel.

Following the recommendations of the AHAW Panel, a dynamic wiki-like web-based glossary for the terminology used in modelling was developed. This glossary, maintained and continuously reviewed by EFSA experts, supports and facilitates the consistent use of terminology in the wide range of outputs on animal health or welfare.

The AHAW Panel is also developing risk assessment methodologies for animal welfare. Building on its unique experience, the AHAW Panel has adopted the guidance on risk assessment for animal welfare (EFSA Panel on Animal Health and Welfare (AHAW), 2012d). This document provides methodological guidance to assess risks in animal welfare, considering the various husbandry systems and management procedures and the different animal welfare issues. The terminology for the risk assessment of animal welfare is described. The major components of problem formulation are the description of the exposure scenario, the target population and the conceptual model, linking the relevant factors of concern in animal welfare. The formal risk assessment consists of three components: exposure assessment, consequence characterisation and risk characterisation. The systematic evaluation of the various aspects and components of the assessment procedure aims to ensure its consistency. All assumptions used in problem formulation and risk assessment need to be clear. This also applies to the assessment of uncertainty and variability in the various steps of the risk assessment. The choice of qualitative, semi-qualitative or quantitative approaches is based on the purpose or the type of questions to be answered and data and resource availability for a specific risk assessment. Quantitative data should be used whenever possible. Positive effects on welfare can be handled within the framework of risk assessment if the analysis considers factors having both positive and negative effects on animal welfare. The guidance also provides details of the main components of risk assessment documentation. This guidance document puts EFSA at the forefront of the development of risk assessment methodology for animal welfare.

It is anticipated that more guidance documents will be issued in the near future. For example, the AHAW Panel has gained experience in assessing the role of wildlife in the maintenance of infectious diseases (e.g. African swine fever (EFSA Panel on Animal Health and Welfare (AHAW), 2010e), foot and mouth disease (EFSA Panel on Animal Health and Welfare (AHAW), 2012a). This is a recurrent

need for risk managers (e.g. bovine tuberculosis), although it is likely to be highly dependent on local factors. The AHAW Panel can provide valuable technical guidance on how to perform such an assessment. Similarly, the increased need for data, data specification and data collection will require technical guidance from the Panel.

Considering the broad diversity of issues addressed by the AHAW Panel, data collection constitutes one of the most important and time-consuming activities of the AHAW Unit. Literature searches are usually the primary activity. The AHAW Panel implements the EFSA guidance on systematic literature reviews. Such literature reviews allow for a transparent and reproducible search of the available information and harmonised data collection. The AHAW unit has outsourced systematic literature reviews (e.g. Lefebvre et al., 2010) and conducted some in-house (e.g. bluetongue (EFSA Panel on Animal Health and Welfare (AHAW), 2011e)). Data have also been collected via public calls for data (e.g. call for data on the harvesting of feathers (EFSA Panel on Animal Health and Welfare (AHAW), 2010f) and consultation with Member States or stakeholders and interested parties. The European Commission and Member States have been involved in data collection both through the network of EU reference laboratories,[8] established by the European Commission (e.g. oyster mortality (EFSA Panel on Animal Health and Welfare (AHAW), 2010c), and directly through requests to the Scientific Committee of the Food Chain on Animal Health[9] (e.g. data on Q-fever (EFSA Panel on Animal Health and Welfare (AHAW), 2010a) or the impact of the Schmallenberg virus (EFSA Panel on Animal Health and Welfare (AHAW), 2012b)).

Most of the outputs of the AHAW Panel, however, mention gaps in data and poor-quality data as a major source of uncertainty. As the development of harmonised terminologies and standards for data collection can improve the data quality in support of the risk assessment process, a project was granted (under the provisions of Article 36 of EFSA's Founding Regulation (EC) No 178/2002[10]) to (i) develop a methodology for data collection including the definition of metadata standards for outcome values to support data validation and quality assessment; and (ii) establish a methodological framework for the use of data in a scientific assessment to address questions relevant to animal diseases. The outcome of this scientific cooperation and the ongoing self-mandate to review the Community Summary Report (EFSA, 2009i; EFSA Panel on Animal Health and Welfare (AHAW), 2011f) will contribute to addressing the risk assessment needs for data in the field of animal health.

For animal welfare, the AHAW Panel has undertaken work on animal-based measures for the welfare of animals (EFSA Panel on Animal Health and Welfare (AHAW), 2012e,f). This aspect of the AHAW Panel's work reflects a shift in the way in which scientists and policy makers in Europe are considering animal welfare assessment. This is a move away from a system that measures aspects of the environment the animal lives in towards one that measures the way in which the animal itself responds to this environment. It will pave the way for the collection of data from Member States and future quantitative risk and benefit assessment. The AHAW Panel has also issued a statement (EFSA Panel on Animal Health and Welfare (AHAW), 2012g) that clarifies some common issues of terminology, provides for the integration of concepts, and presents some essential characteristics of animal-based measures to ensure that they are 'fit for purpose'. It highlights the fact that more information is needed about the direction and strength of the various links between input factors and animal-based measures of welfare outcomes. The statement also highlights the importance of the systematic collection of standardised field data on animal-based measures and their subsequent availability in well-defined databases. Targeted analysis of such data will help in selecting the most appropriate measure, or combination of measures, according to the specific purpose of the welfare assessment. The development, validation and practical implementation of welfare indicators will offer new opportunities to collect epidemiological data and information on the welfare status of food-producing animals in Europe.

[8] Available from http://ec.europa.eu/food/animal/diseases/laboratories/index_en.htm
[9] Available from http://ec.europa.eu/food/committees/regulatory/scfcah/animal_health/index_en.htm
[10] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, pp. 1–24.

CONCLUSIONS

The work of the AHAW Panel has changed greatly over the past ten years, adapting to new scientific knowledge and methodologies. The AHAW Panel has also established a constructive and interactive dialogue with decision makers, while maintaining the formal scientific independence foreseen in EFSA's Founding Regulation (EC) No 178/2002. It has achieved greater participation of the scientific community, stakeholders and interested parties and fostered cooperation with relevant organisations in the EU Member States. This is a major achievement because the quality of risk assessments depends on the appropriate formulation of questions and terms of reference, a clear understanding of their background, the best use of scientific data and expert opinion, and the application of advanced risk assessment methodology to address the question posed.

The development of robust methodological frameworks for the assessment of risks related to animal health and welfare is a major achievement of the AHAW Panel. However, it remains one of the continuing, long-term tasks of the Panel to improve the methodological approach to risk assessment applied to animal welfare. In particular, the questions of repeated exposure to, and the interaction of, welfare hazards need to be addressed.

Over the past ten years, the AHAW Panel has assumed an internationally recognised leading role as risk assessor in the field of animal health and welfare, based on EFSA's core values of scientific excellence, independence and transparency.

The majority of human infectious diseases have originated through the cross-species transmission of pathogens from animals to humans (Wolfe et al., 2007). About 70 % of human diseases have evolved from those of animals (Schneider et al., 2011). The scientific opinions from the AHAW Panel have demonstrated that assessing the risks to the health and welfare of animal populations may also serve to protect public health, the environment and the economic benefit we derive from those animal populations. In particular, what is meant by animal welfare is not just restricted to the protection and well-being of animals. The welfare of animals has an overall impact on the condition of the animals, including possible implications for animal health and food safety. These aspects have been considered in many of EFSA's scientific opinions on animal welfare. For example, tail biting in pigs is a major welfare issue and also a risk factor for increased frequency of abscesses and infections in carcasses (EFSA, 2007b). On the other hand, the risk of contamination with *Salmonella enteritidis* might be higher when eggs are produced in non-cage-based systems because of the greater exposure of laying hens and their eggs to environmental contamination (EFSA, 2005b).

Within EFSA, the AHAW Panel deals with animal health and welfare questions, primarily related to food-producing animals, at the human–animal–environment interface. Scientific opinions adopted by the AHAW Panel have shown that this interface is not only relevant for foodborne zoonoses and biological hazards in food. Non-foodborne zoonoses, including arthropod-borne diseases, have become more prominent at the human–animal interface. It is important to note that the involvement of EFSA and the AHAW Panel in these questions has been achieved by developing good relationships with relevant EU partners such as the ECDC. The AHAW Panel has also demonstrated its capacity to respond rapidly to urgent requests, thus becoming a prominent partner of decision makers in response to crises (e.g. Q fever, Schmallenberg virus, influenza virus).

Overall, and not least, the major achievement of the AHAW Panel has been the establishment of a unique multidisciplinary capacity, blending expertise in addressing animal health and welfare issues.

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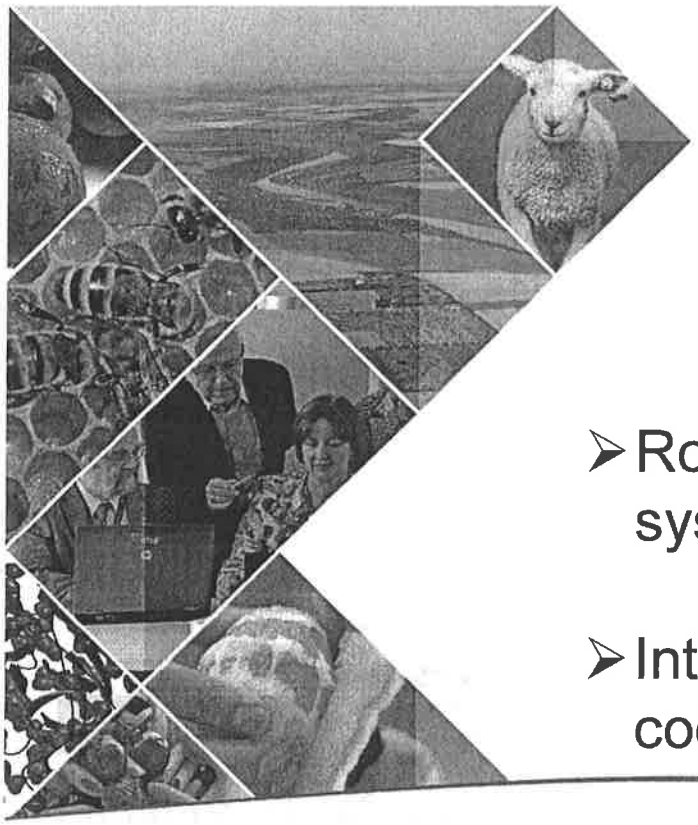


EFSA today

- Role on food safety system
- International scientific cooperation

efsa
European Food Safety Authority

www.efsa.europa.eu

EFSA WAS SET UP IN JANUARY 2002 AS

- an independent source of scientific advice and communication on risks associated with the food chain
- part of a comprehensive programme to:
  - improve EU food safety system
  - help ensure a high level of consumer protection
  - restore and maintain confidence in the EU food supply
  - clearly separating risk assessment and risk management functions

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

EFSA IS TASKED TO

- Provide independent scientific advice and support for EU law/policies on food and feed safety
- Provide independent, timely risk communication
- Promote scientific cooperation

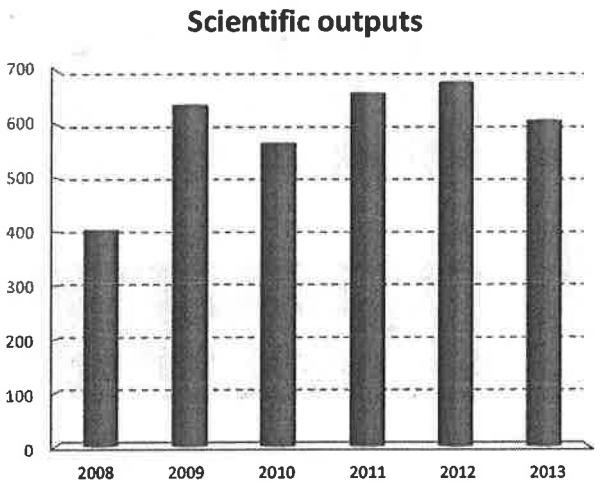
European Food Safety Authority

...WITH HEADQUARTERS IN PARMA

- 2003: scientific work starts
- 2005: moved to Parma from Brussels
- Since 2003 more than 3,300 scientific outputs including 2,330 scientific opinions
- Budget 2014: EUR 79.6 million
- Over 450 staff, 60% engaged in the production of scientific advice

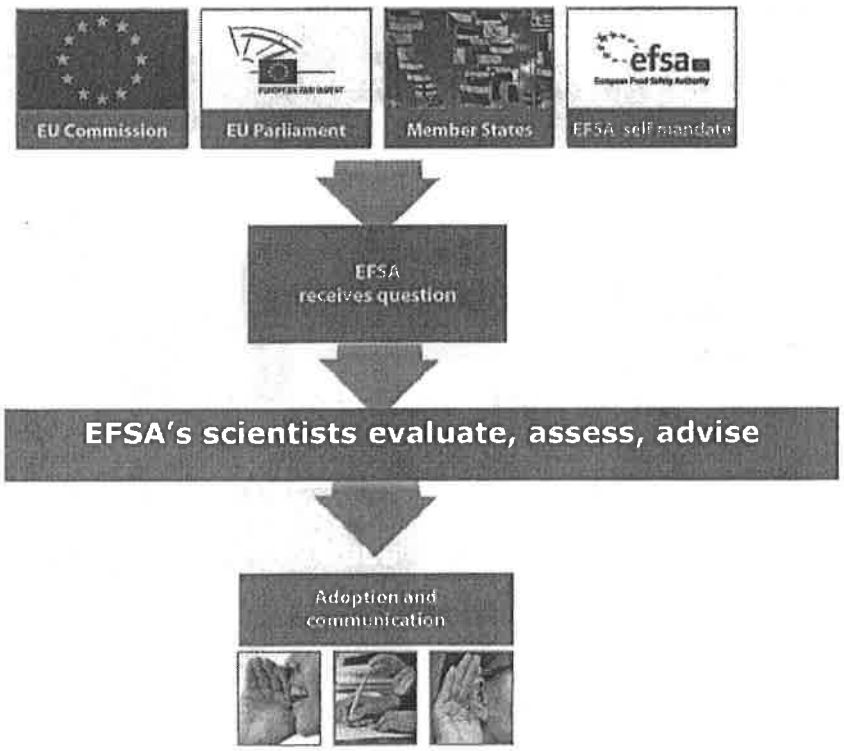
... SCIENTIFIC EXCELLENCE IN RISK ASSESSMENT

- > 3,300 outputs
  - > 2,330 opinions
  - 500th opinion: 2007
  - 1000th opinion: 2009
  - 2000th opinion: 2012
- Scientific expertise across Europe
- Impartiality of scientific advice
- EFSA Journal, Scientific Colloquia, international cooperation...



EFSA today

... THROUGHOUT THE WORKFLOW



EFSA HAS A ROBUST GOVERNANCE...

15 EU member, 聘任 D.G of EFSA 設定 work plan budget

Management Board + **Advisory Forum** (28 Members + Iceland + Norway)

\+ \+

EFSA Staff + **Scientific Committee and Panels** → conduct R3K assessm.

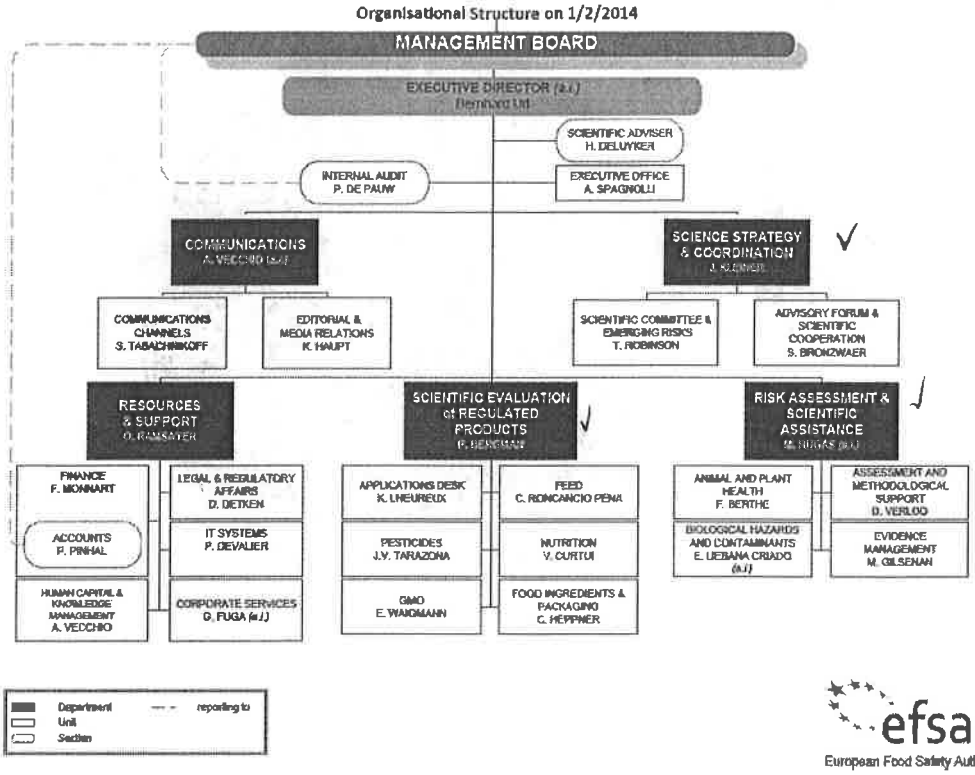
↓ 有11個 Committee

= efsa European Food Safety Authority

... WHOSE ROLE IS TO PROVIDE SCIENTIFIC ADVICE FROM FARM TO FORK

- Plant Health
- Plant Protection
- Genetically modified organisms
- Animal feed
- Animal health and welfare
- Biological hazards
- Chemical contaminants
- Food additives
- Food packaging
- Nutrition

... AS WELL AS TALENTED STAFF



European Food Safety Authority

...WITH DIFFERENT ROLES

Panels

- Owners of scientific opinions

Scientific Committee

- Ensures consistency
- Issues guidance
- Assess emerging risks

Staff

- Support panel work
- Produce scientific and technical advice
- Communication

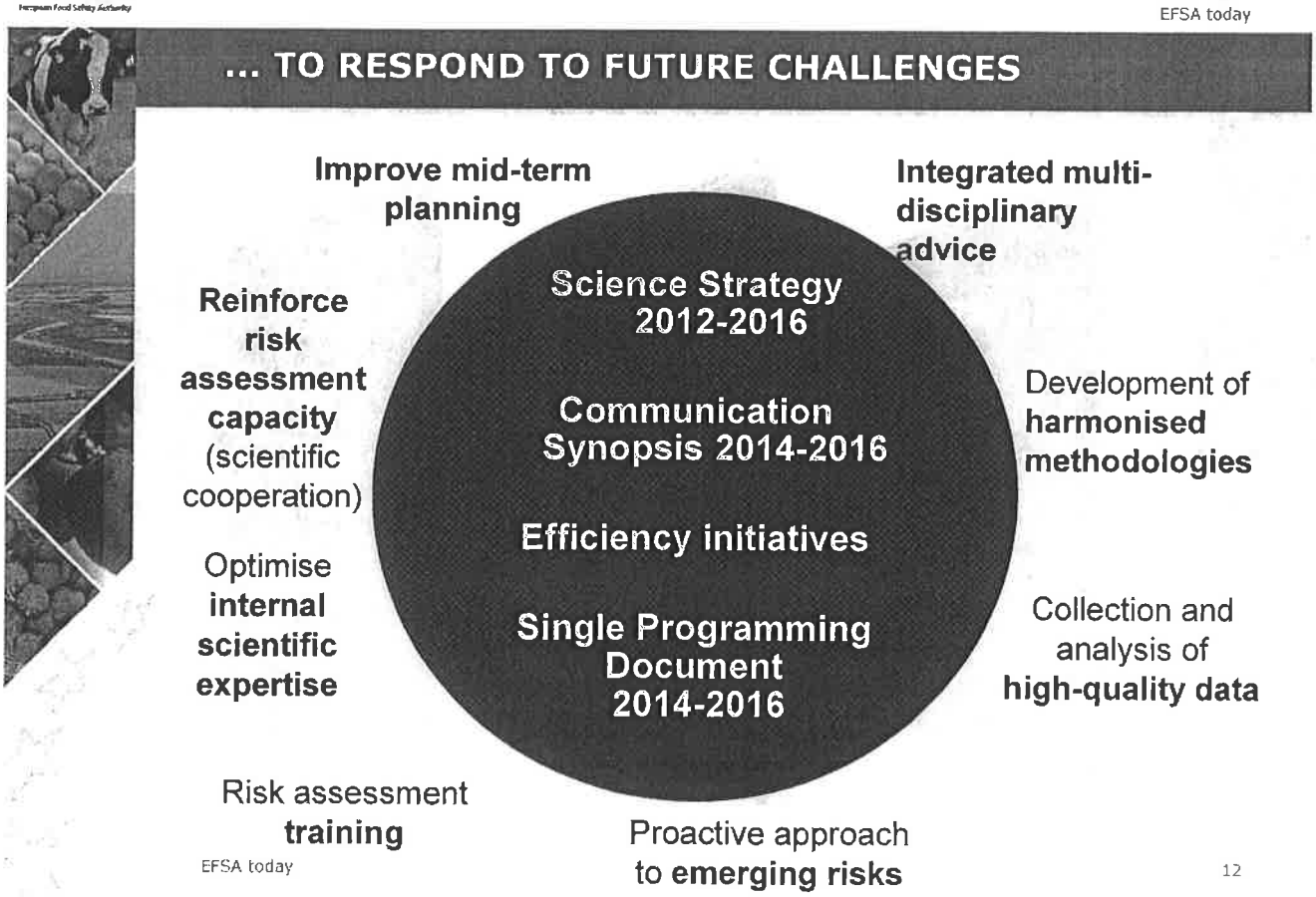
Risk Communication is the core activity of EFSA

RISK COMMUNICATIONS IS

EUROBAROMETER

EFSA today

... TO RESPOND TO FUTURE CHALLENGES



II. INTERNATIONAL SCIENTIFIC COOPERATION

Challenges & opportunities

- **EU visibility**
  - sharing worldwide what we have built in the EU thus far
- **Reputation globally of EFSA as**
  - reference point for risk assessment
- **Global challenges of RA bodies:**
  - limited RA capacity, budget constraints, scientific competence, independence issues
  - Harmonisation of best RA practices is key
  - work together as we all face similar challenges

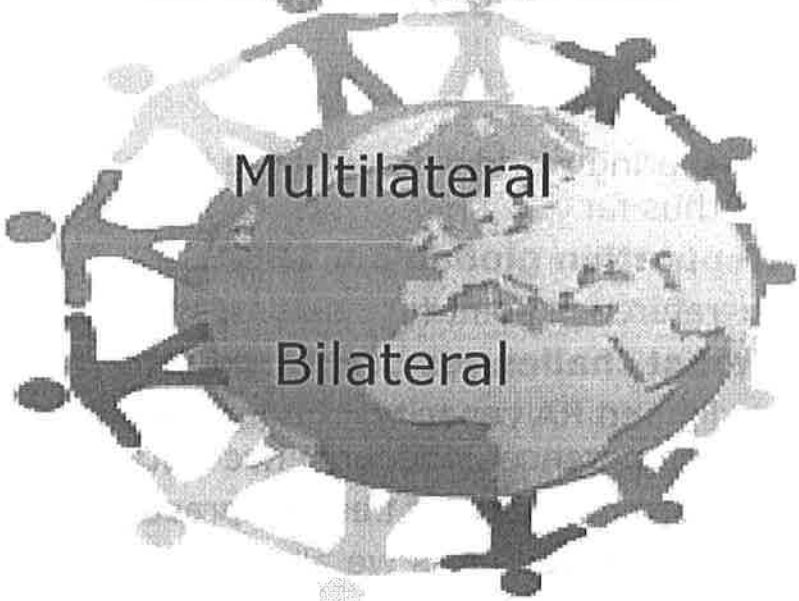
II. International Scientific Cooperation

KEY OBJECTIVES

- Support of EU in its international commitments
- Support the key objectives defined in **Science Strategy**:
  a. **Optimisation** of the use of **RA capacity** in EU/Internationally
  b. Development and **harmonisation** of **RA methodologies** and approaches
  c. Strengthening the **scientific evidence** for RA and risk monitoring
- Promote of coherence in risk communication and building awareness of EFSA's activities at international level

INTERNATIONAL SCIENTIFIC COOPERATION

EFSA's Activities



EFSA's MULTILATERAL COOPERATION

To support EU in international commitments

- Enhance EFSA's support to Codex Alimentarius activities
- Improve collaboration with Joint FAO/WHO Expert Committees
- Strengthen cooperation with EU agencies in areas of international relevance (e.g. emerging issues, consistency in RA, joint efforts in developing harmonised RA tools)

To develop a more extensive work programme with WHO and FAO, e.g.

- risk assessment approaches, risk communication guidance, joint evaluation of specific substances of priority, emerging risks

To continue EFSA's activities with

- international organisations (e.g. IPPC/EPPO, OECD, OIE)
- multilateral liaison group (food chemical safety and microbial food safety and currently health claims)

EFSA's BILATERAL COOPERATION

Target: international harmonisation, standardisation of best RA practices / mapping research activities / improving access to data

To continue

- the cooperation with the US agencies through an annual physical meeting and regular cluster meetings on dedicated areas of mutual interest.
- the existing cooperation with risk assessment bodies in Australia, Canada, Japan, New Zealand and United States

To develop bilateral relations with third countries

- case by case in consultation with DG SANCO
- Priority to countries with signed agreement with the EU
- a planning for meetings with delegations from risk assessment bodies in third countries

II. International Scientific Cooperation

COHERENCE IN RISK COMMUNICATION WORLD WIDE

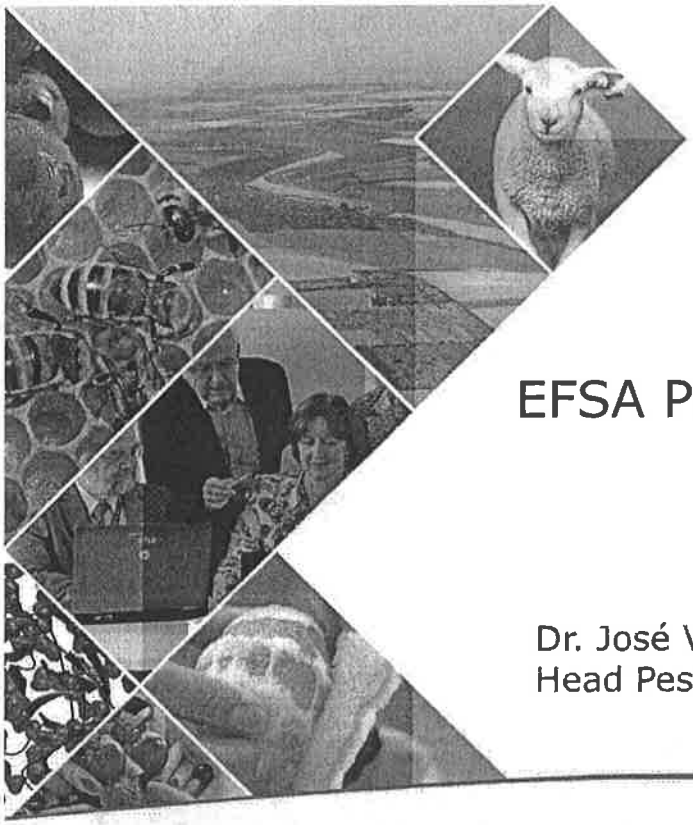
To build further on the existing risk communication activities

- **To establish an international platform to ensure coherence in Risk Communication for:**
  - Exchanging information and experiences
  - Developing common practices and guidelines
  - Building on existing practice including prenotification on specific (emerging) issues and early warning on key public announcements
  - Building on existing communication activities linked to RA

MECHANISMS FOR INTERNATIONAL SCIENTIFIC COOPERATION

- Harmonisation with international RA bodies (e.g. WHO, FAO, OIE)
  - Specific topics in risk assessment & data collection (e.g. TTC, weight of evidence, risk communication guidance, exchanging exposure assessment data)
- Thematic events: international workshop/seminars e.g. on
  - trends and developments in risk assessment (EXPO 2015) ✓
  - best practices in risk communication → 2016 on best practice on risk communication
- Knowledge transfer:
  - visits of third country delegations ✓
  - Scientists visiting EFSA ✓ → to visit to Codex, Jecfa meeting
- EFSA's experts/staff assigned for short-medium tasks
  - Scientific support to EU delegation at Codex
  - Participating in JECFA/JMPR meetings

Any questions?



EFSA Pesticides Unit

Dr. José V. Tarazona
Head Pesticides Unit

efsa
European Food Safety Authority

www.efsa.europa.eu

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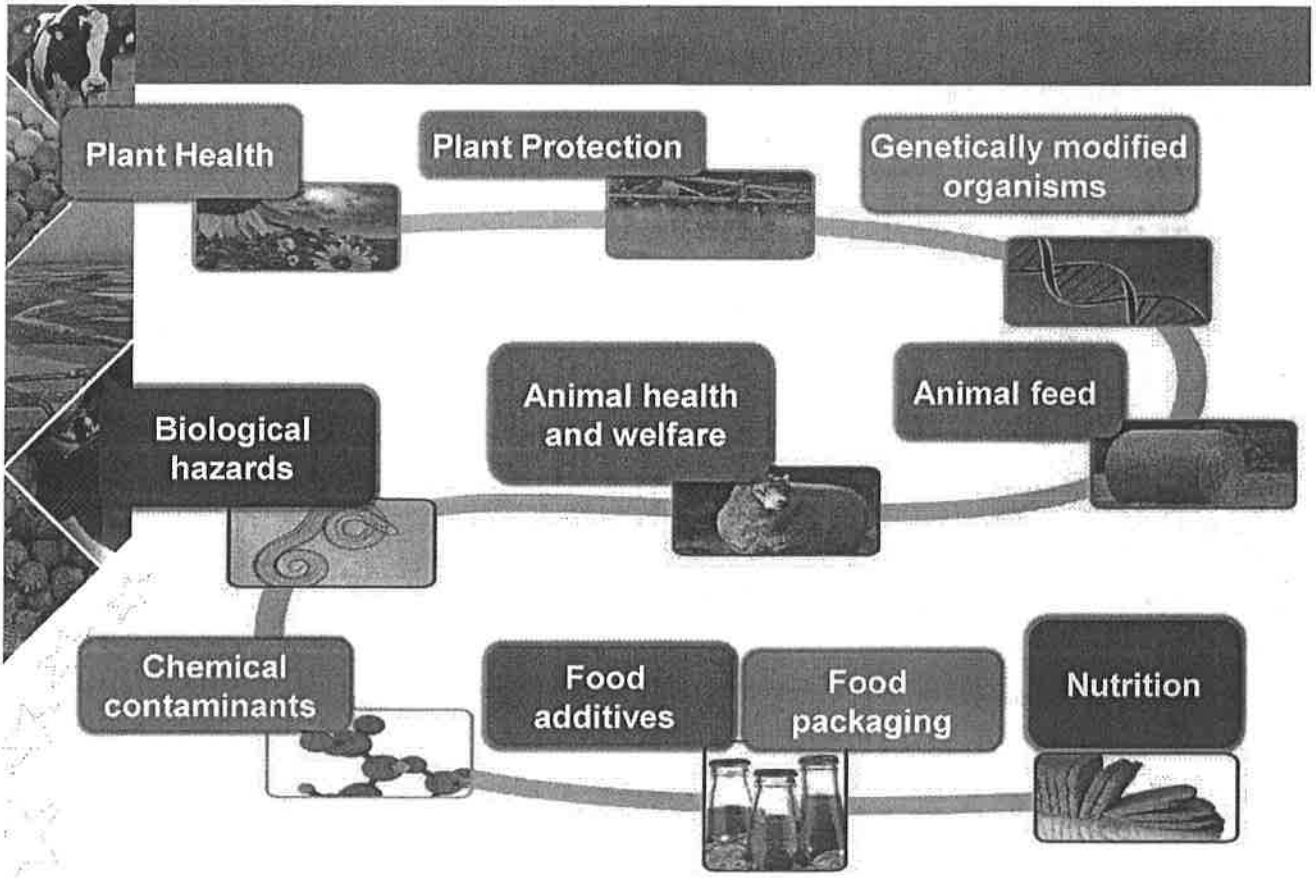
What is EFSA?

- **E**uropean • The European reference body
- **F**ood • Covers the entire food chain
- **S**afety • Assess, advise, communicate
- **A**uthority • Independent, trusted, based on sound science



KEY VALUES

EFSA's activities are guided by a set of key values:

- Openness and transparency
  - EFSA listens to the views of outside parties, particularly its stakeholders.
  - Stakeholder Consultative Platform and an annual Stakeholder Conference.
  - Info-sessions and other activities.
  - New policy on transparency under development.
- Excellence in science
- Independence
- Responsiveness

Pesticides Unit activities

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

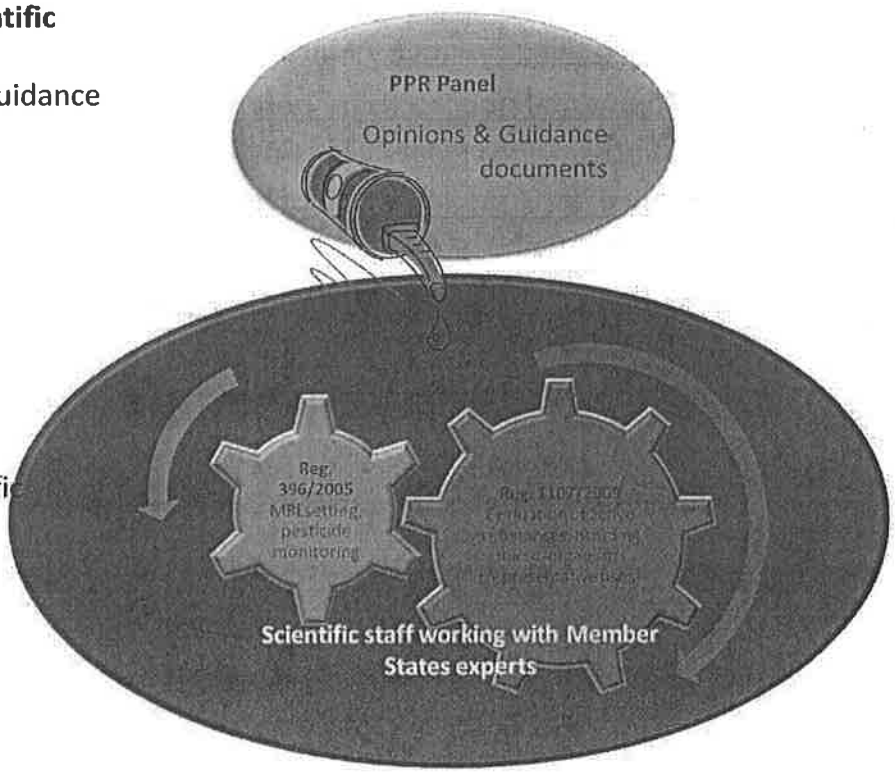
Coordinates the Peer Review of active substances → Provides **Conclusions** for single active substances to support the EU decision-makers

Maximum Residue Levels MRLs → ➢ **Reasoned Opinions** ➢ **Annual report**

Scientific consistency

General Scientific assessment:
Opinions & Guidance

Dossier specific assessment:
Conclusion



work through working groups

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PPR PANEL EXPERTISE

Twenty-one independent scientific experts, covering:

- *Chemical active substances*
- *Microbiological active substances*
- *Physical-chemical properties of pesticides*
- *Methods of analysis* of pesticides
- *Toxicology and regulatory toxicology*
- *Non dietary exposure and risk assessment* of pesticides
- *Dietary exposure and risk assessment of pesticides residues in food and feed*
- *Environmental fate and behaviour* of pesticides
- *Ecotoxicology*
- *Ecology and population dynamics*
- *Ecological/Environmental exposure and risk assessment.*

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PPR outputs 2013-

- Good modelling practice 7 March 2014 Scientific Opinion PPR Panel
- Developmental neurotoxicity potential of acetamiprid and imidacloprid 17 December 2013 Scientific Opinion PPR Panel
- Relevance of dissimilar mode of action 3 December 2013 Scientific Opinion PPR Panel
- Guidance on tiered risk assessment for edge-of-field surface water 18 July 2013 Guidance PPR Panel
- Cumulative Assessment Groups for Pesticides 12 July 2013 Scientific Opinion PPR Panel
- FOCUS groundwater: Assessment of Higher Tiers 28 June 2013 Scientific Opinion PPR Panel
- FOCUS groundwater: Assessment of Lower Tiers 27 February 2013 Scientific Opinion PPR Panel

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PPR ongoing opinions

- Opinion addressing the state of the science on risk assessment for **non-target arthropods**
- Opinion addressing the state of the science on **in-soil risk assessment**
- Opinion addressing the state of the science on risk-assessment for **non-target terrestrial plants**
- Opinion addressing the state of the science on risk assessment for **amphibians and reptiles**
- Opinion on the FERA guidance proposal "Guidance on how **aged sorption studies** for pesticides should be conducted, analysed and used in regulatory assessments" (FERA, 2012)
- ...

risk for aquatic animals

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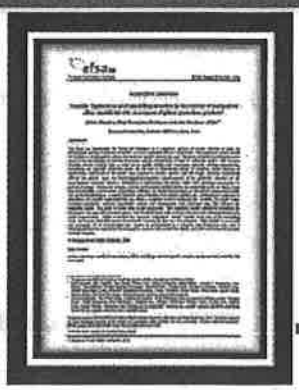
Needs for scientific coordination/alignement



- Scientific opinions: as starting point for further guidance

PPR Guidance

EFSA Guidance

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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

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The Peer-Review Process

Dossier submission

DAR
Draft Assessment Report

EFSA

PEER REVIEW

EFSA,
RapporteurMS,
other MSs,
EU Commission,
Notifier, Public

1. **Commenting phase**
2. **Evaluation of comments**
3. **Expert's consultation**
4. **Conclusion**

Commission
Standing Committee on the Food Chain and Animal Health (SCoFCAH = EC +MSs)

Approval/Non Approval

DOSSIER CONTENT (REG.1107/2009)

- Summary dossier
- Complete dossier
  - with full text of individual tests and study reports (studies involving deliberate administration to humans are not accepted)
  - In line with the data requirements
- Scientific peer-reviewed open literature over the last 10 years (active substance & metabolites)

SUMMARY DOSSIER (REG.1107/2009)

- Representative uses
- Summaries and results of tests and studies for each data requirement
- Vertebrate studies: justification on steps for avoiding animal testing and duplications
- Checklist demonstrating completeness
- When relevant copy of an Maximum Residue Levels (MRL) application
- Assessment of the information submitted