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IHCP Mission
As part of the European Commission’s Directorate General Joint Research Centre (DG JRC), the Institute for Health and Consumer Protection (IHCP) fulfils the JRC’s mission in providing scientific support to policies related to health and consumer protection.
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Dear Readers,

I have pleasure in presenting the 2006 Annual Report of the Institute for Health and Consumer Protection (IHCP) which is one of the seven scientific Institutes of the European Commission's Directorate General Joint Research Centre (JRC).

Since taking up the post of IHCP Director in July 2006, I have come to appreciate the full extent of the manifold activities of the IHCP. These activities stretch across all the areas of expertise of the Institute and directly impact on many contemporary issues related to health and consumer protection.

This report highlights the IHCP's achievements during 2006, which also happened to be the closing year of the EU's sixth Framework Programme for Research and Technological Development. Some notable milestones reached in the course of the year included the inauguration of the Institute's second European Community Reference Laboratory (CRL for Food Contact Materials), the final adoption of the new Chemicals legislation REACH in which the IHCP played a significant role, and the 15th anniversary of the Institute's European Centre for Alternative Methods (ECVAM).

The dedication and flexibility of the IHCP staff have been the predominant factors in achieving these milestones as well as in the handling of emergency situations such as the non-authorised import of genetically-modified rice (LL601) in August. I am proud to manage with my team of IHCP Unit Heads such highly motivated Staff Members.

Serving European consumers is our main concern and in our capacity as a European scientific research Institute, the IHCP is ideally positioned to provide support for policies related to health and consumer protection. The IHCP also participates actively in networks with other European and international scientific institutions as well as National Authorities.

It goes without saying that we will continue to take care of the needs of our stakeholders and of the European consumer in general. The scientific results and findings of the IHCP aim to serve as an impartial orientation for EU policy makers and help fulfil our motto: Science for a healthier life!

I would like to acknowledge the support of all Staff at the IHCP (the majority of who are pictured in this report) in delivering our commitments with a high degree of scientific quality. I look forward to intensifying our relationships with stakeholders and to raising the profile of the quality of our scientific service in the future.

Enjoy your reading!

Elke ANKLAM
Director, Institute for Health and Consumer Protection

Message from the Director

The Institute's Directorate office incorporates both the IHCP secretariat and the IHCP projects office. The latter is responsible for the IHCP overall programme management and oversees the execution of the Institute's annual work plan.
Mission Statement

As part of the European Commission's Directorate General Joint Research Centre (DG JRC), the Institute for Health and Consumer Protection (IHCP) fulfils the JRC's mission in providing scientific support to policies related to health and consumer protection.

Introduction

The Institute for Health and Consumer Protection (IHCP) is one of the seven scientific institutes of the JRC. IHCP is located on the Ispra site in Northern Italy and employs around 300 multidisciplinary researchers.

History

The Institute was established in October 1998 after a reorganisation of existing expertise and structures within the JRC Institutes related to the area of health and consumer protection.

Skills base

The Institute draws from a wide spectrum of disciplines which derive from branches of all three of the biological, chemical, and physical sciences. The competences comprising the main focus of the Institute’s work include toxicology, computational chemistry, genetics, in-vitro analysis, molecular imaging, surface science and nanotechnology. The synergies arising from such a wealth of scientific backgrounds contribute significantly to the overall JRC mission of providing scientific and technical support to the development and implementation of EU policies.

The IHCP also actively contributes to shaping the European Research Area (ERA) through extensive networking, participation in collaborative research projects, shared infrastructure and training of scientists from the Member States and Candidate Countries.
Main Working Area

- Chemicals (REACH) and Biocides
- Genetically-Modified Organisms (GMOs)
- Cosmetics and Alternative Testing
- Consumer Products
- Food and Food-Contact Materials
- Health and Environment
- Nanotechnology

The Institute is currently mainly engaged in two broad categories of activity:

1. **Exposure and risk assessment**
   - With particular emphasis on:
     - chemicals
     - biocides
     - volatile organic compounds
     - noise
     - nanomaterials and nanoparticles
     - QSARs (Quantitative Structure - Activity Relationships)

2. **Method development and validation for harmonisation at EU level**
   - This includes:
     - alternatives to animal testing
     - sampling and analysis of GMOs
     - migration of substances from consumer products
     - and high-throughput automated *in-vitro* test assays
     - food contact materials and wine

Scientific Organisation

The work performed at the IHCP is divided into the following five scientific Units which address a number of distinct areas related to health and consumer protection:

1. **Biotechnology & GMOs**
   - B&GMOs Unit

2. **Biomedical Materials and Systems**
   - NMI Unit

3. **European Centre for the Validation of Alternative Testing Methods**
   - ECVAM Unit

4. **Physical and Chemical Exposure**
   - PCE Unit

5. **Toxicology and Chemical Substances**
   - TCS Unit; ECB

During 2006, the Units were further broken down into 16 defined working areas (Actions). The IHCP Units and their associated Actions are further described in the following pages.

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1. In 2007 the Unit was re-named as “Nanotechnology and Molecular Imaging (NMI)”.
2. An Action is a defined part of the JRC’s Multi-Annual Work Programme and associated Annual Work Programmes with its own clearly identifiable set of objectives and associated resources. Each Action has an appointed Action Leader, responsible to his / her Unit Head for the management of the work and for its successful implementation in accordance with the approved Action Work Plan.
Biotechnology and Genetically-Modified Organisms
History

As early as 1990, the JRC started to provide scientific and technical support to various EC policy services responsible for GM legislation (mainly the Directorate Generals of Health and Consumer Protection, Environment, and Agriculture). Since that time, it has received all summary notifications of deliberate field trials required under the environmental Directive and has served as a general information source to the public. On the basis of this work, the JRC became a nominated expert in the development of an operational Biosafety Clearing House under the Cartagena protocol and was given the associated role of EU focal point. Since 1997 the JRC is active in the validation of analytical methods for GMO testing in food.

In 2002, a consortium of national enforcement laboratories was established as the European Network of GMO Laboratories (ENGL). Today, the Network comprises members from more than 100 laboratories (representing all 27 EU Member States as well as Norway and Switzerland). In addition, laboratories from other countries (e.g. China, Turkey, and Tunisia) participate in the Network as observers.

In 2003, based upon its expertise and its pan-European networking, the B&GMOs Unit was given the mandate of Community Reference Laboratory for GM Food and Feed (CRL-GMFF) with the principal mandate to validate detection methods for food and feed products submitted for marketing. It also plays a key role in the implementation of emergency measures in case illegal GMOs are introduced in the EU market.

B&GMOs works closely with European standardisation bodies and Agencies such as the European Committee for Standardisation (CEN), the European Food Safety Authority (EFSA) and Codex Alimentarius.

Role

The European Commission has developed a broad legislative framework to ensure that Genetically Modified Organisms (GMOs) and GMO-derived products meet the highest standards of safety for the environment, as well as for human and animal health.

Regulation needs to be enforced uniformly and effectively across the EU and the process of implementation requires critical measures such as access to validated methods and technical guidance for detection and sampling.

As the Community Reference Laboratory for GM Food and Feed (CRL-GMFF), the B&GMOs Unit has the mandate to provide scientific support for the development and implementation of the EU biotechnology regulations and is playing a leading role in the harmonisation of technical GM-issues.

Further information
http://bgmo.jrc.ec.europa.eu
In 2006 the work of the B&GMO Unit was divided into 3 areas of activity (summarised in the following pages):

**Scientific and technical support for the implementation of GMO legislation (GMO support)**

**Community Reference Laboratory for GMOs in food and feed (CRL-GMFF)**

**GMO Data processing, analysis, exchange and dissemination** (GMO-DAPX)

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**Skills base**

The Unit has established a sound level expertise in the field of molecular biology which it supports by advanced facilities, mainly devoted to the development and the validation of methods for GMO detection and quantification. It devotes significant efforts to the understanding of sampling problems related to GM detection and quantification in food and raw materials.

As a complementary activity to its work as CRL, B&GMOs has developed skills in the molecular characterisation of GMOs and in the development of high-throughput detection technology. Being a member of the EMBLnet, it is also the JRC reference for bioinformatics.

In addition, the Unit is active in sharing its expertise and facilities via the provision of various training programmes.

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**Policies Supported**

- Directive for the deliberate release into the environment of GMOs - 18/2001/EC
- Food Safety and Environment
- Cartagena Protocol and Regulation on transboundary movements of GMOs - 1991/2003
- Regulation on traceability and labelling - 1830/2003/EC
- Recommendation on technical guidance for sampling and detection of genetically modified organisms - 2004/787/EC
- Regulation 641/2004/EC on detailed rules for the implementation of Regulation 1829/2003/EC

**Customers**

- DG Health and Consumer Protection
- DG Environment
- DG TRADE
- EU Member States
- International Organisations

**Main Research Partners**

- Laboratoire de Phytopathologie et de méthodologies de la détection (INRA Versailles)
  Versailles Cedex, France
- Scientific Institute of Public Health (IPH)
  Brussels, Belgium
- Institute for Agricultural and Fisheries Research (ILVO)
  Meise, Belgium
- AgroBioInstitute (ABI)
  Sofia, Bulgaria
- School of Life Science and Biotechnology, Shanghai Jiaotong University
  P.R. China
- National Veterinary Institute
  Oslo, Norway
- Federal Institute for Risk Assessment (BfR)
  Berlin, Germany
- University of Namur,
  Unit on Cellular Biology
  Namur, Belgium

**Sample weighing for DNA extraction**
Milestones

The Unit achieved the following milestones during the course of 2006:

Support to the emergency measures adopted for the import control of unapproved LLRice 601
CRL-GMFF verified in-house the detection method for genetically-modified LLRice 601 within the same month that the Commission was alerted to the unauthorised release into the EU market.

Dossiers for validation of detection methods
Over fifty dossiers were processed for the validation of specific GMO detection methods.

International networking and management of the European Network of GMO Laboratories
In its several plenary and working group meetings, the ENGL network discussed effectiveness of sampling approaches and analytical testing for approved and non-approved GMOs and produced reference documents on expressing GM percentage. It also strengthened its collaborations with European biotechnology companies, as well as with the international seed testing association and with non-EU member states such as Morocco, Tunisia, the Black Sea countries, Malaysia and China.

Final report on the analysis of the molecular structure of maize Bt-10
The report providing the analysis of the molecular structure of maize Bt-10, which illegally entered the EU market in 2005, was completed and presented to Member States.

Quality assurance
In 2006, the CRL-GMFF was additionally awarded ISO 9001:200 certification and accreditation according to ISO 17025.

Cartagena Protocol on Biosafety
Members of the Unit were involved in the negotiations concerning the implementing measures of the Cartagena Protocol on Biosafety. Long-awaited agreement was finally obtained on an important article which establishes the documentation requirements for GMO shipments. Significant progress has been made with respect to the management of the role as EU focal point and with the implementation of the Biosafety Clearing House.

Support to the EU neighbouring countries
The Unit provided a training course on the analysis of food and feed samples for the detection of GMOs to the University of Tunis. The purpose was to promote the diffusion of harmonised approaches in GMO detection in Maghreb Region laboratories and to facilitate their alignment with the European approach and requirements on GMOs.

Key Publications in 2006*


Community Reference Laboratory for GM-food and feed. Various validation reports, see http://gmo-crl.jrc.it/statusofdoss.htm

* Full list of publications in peer-reviewed journals in 2006 included under page 64 and ff.

Guy Van den Eede, Unit Head

Career Résumé Guy Van den Eede obtained his degree in agricultural engineering from the University of Leuven and went to the State University Ghent for specialisation in plant molecular biology where he stayed as assistant until he joined the European Commission in 1990. Since the beginning he has been responsible for S/T support for the implementation of the EU GMO regulation. When the Biotechnology and GMOs Unit was created in 2002, he took up the position of Unit Head.

Nationality Belgian

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S/T Support

for the implementation of GMO legislation (Molecular characterisation of GM-products and related analytes)

Website
http://bgmo.jrc.ec.europa.eu
General objective

Research and development in areas related to the analysis of genetically modified organisms (GMOs) in support to the Community Reference Laboratory for GM food and feed (CRL-GMFF), the European Network of GMO Laboratories (ENGL) and to Commission services. Analytical methods for the detection and quantification of GMOs in food and feed samples, identification and molecular characterisation studies, assessment of reference analytes, training activities to enforcement laboratories in GMO testing and support in capacity building.

Main outputs in 2006

- Technical support for the definition of sampling plans and analytical experimental design for the detection of Rice LL601 as support to Commission Decision 2006/578/EC of 23 August 2006 on emergency measures regarding the non-authorised genetically modified organism LL RICE 601.

- Scientific expertise and support to the mandate of the CRL-GMFF in the conception and preparation of appropriate control samples for the CRL-GMFF validated methods.

- Support regarding the Bt-10 maize emergency via the provision of appropriate control samples and molecular characterisation for this non-authorised event.

- Further extension to the study of the molecular characterisation of genomic modifications in GMOs in support to ENGL, to Commission services and to the CRL-GMFF.

- Development of two innovative multi-target protein based methods for the detection and quantification of GMO related proteins and corresponding delivery as peer reviewed publications.

- Two specialised scientific and technical training courses for officials of the Food and Veterinary Office (FVO) of DG SANCO. This training was an essential contribution for the official monitoring of the proper implementation of EU policy on GMOs in EU Member States official laboratories.

- One specific training course for a Romanian delegation entitled “Technical guidance for sampling and detection of GMOs and material from GMOs” at JRC-Ispra.

- One specific training course on GMO detection for North African Countries organised in September 2006 in Tunisia to promote the diffusion of harmonised approaches in GMO detection in Maghreb Region laboratories and to facilitate their alignment with European approaches and requirements on GMOs.

Maddalena Querci, Action Leader

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“Robust analytical tools facilitate assessment of GM labelling to give consumers trust.”
CRL-GMFF

Community Reference Laboratory for Genetically Modified Food and feed

Website
http://bgmo.jrc.ec.europa.eu
General objective

The Community Reference Laboratory for Genetically Modified Food and Feed (CRL-GMFF) was established in 2004. The principle duties and functions of the CRL lie within the validation of detection methods and provision of appropriate control samples as part of the official EU authorisation procedure for GMOs. Central focus is placed upon direct policy support with on-going support to emergency measures to help prevent unauthorised GMOs entering the EU food/feed chain.

The CRL is assisted by a consortium of national reference laboratories, the European Network of GMO Laboratories (ENGL), chaired by the Biotechnology and GMOs Unit.

Main outputs in 2006

- Validation of ten detection methods by the CRL (including DNA extraction procedures for sugar beet, cotton and rice), reports of which are published on the CRL website; additional six international collaborative studies for method validation carried out in collaboration with the ENGL.
- Support to emergency measures via the validation of detection procedures regarding the unauthorised rice LL Rice 601, preparation and distribution to National Reference Laboratories of control samples for LL Rice 601.
- Support to DG SANCO and Member States in the context of illegal import of Bt63 rice from China; assessment and testing of two detection methods, full support to the ENGL through provision of scientific advice on detection methods and distribution of control samples; liaise with Chinese Authorities through established collaboration between the ENGL and China.
- Scientific and technical involvement in the validation of an innovative multiparametric detection tool based on micro-array technology (GMO-Chips).
- ISO 9001:2000 Certification awarded regarding the internal quality management system underpinning the operations and procedures within the CRL.
- ISO 17025:2005 Accreditation achieved in support of the overall implementation of specific tasks and duties as defined under Regulation (EC) No 1829/2003.
- Two Plenary and Steering Committee meetings of the European Network of GMO Laboratories (ENGL) were organised and hosted at JRC-Ispra in March and October 2006. The network has been further developed and now has more than 100 members and international observers, including China.

Key Words

Genetically modified organisms (GMOs)
Biotechnology
Notifications
Method validation
European Network of GMO Laboratories (ENGL)
Control samples
Molecular biology
Emergency measures

Validation Report of the CRL-GMFF

Stephen Langrell, Action Leader
[Since March 2007 employed at the JRC’s Institute for Prospective Technological Studies, Seville]

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“Validated analytical methods are crucial for harmonised GM measurement in Europe.”
GMO-DAPX

GMO Data processing, analysis, exchange and dissemination

Website
http://bgmo.jrc.ec.europa.eu
General objective

To develop and implement the data and information processing measures necessary to support the regulatory requirements in the authorisation process of genetically modified organisms. The work comprises three main areas: Biometrics which includes all the data analysis activities associated with methods validation and sampling; Bioinformatics which includes the data processing activities associated with the management of DNA sequences, and Regulatory information systems which includes all the activities related to the information exchange and dissemination requested by legislation.

Main outputs in 2006

- Full implementation, testing and delivery of the GMOREGEX system (a register of the authorised GMOs in the EU). This system automates the workflow, document and data exchange and tracking system for the mutual recognition authorisation process under Directive 2001/18/EC.
- Operation of the European Community Biosafety Clearing-House (EC BCH) Focal Point. The BCH is an information exchange mechanism established by the Cartagena Protocol on Biosafety to assist parties to implement its provisions and to facilitate the exchange of information and experiences with living modified organisms (LMOs).
- Re-design of the GMO Detection Methods Database application. This database provides public, searchable list of methods for the detection of, identification and quantification of transgenic events published in literature. The purpose of the re-design is to make its usage more user-friendly and information retrieval more effective.
- Promotion of the AMPE (Analytical Method Performance Evaluation) software developed to harmonise data processing for methods validation within partnerships and to external parties.
- GMO Core sequence database containing stored sequence data from CRL dossiers and EMBnet specialised node.

Antonia Rana, Action Leader

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“Data analysis and information dissemination are critical tools in supporting the GM legislative process.”
**Biomedical Materials and Systems**

* Since 2007 re-named as the Nanotechnology and Molecular Imaging Unit (NMI)
History

The BMS Unit has been an integral part of the IHCP since its foundation in 1998. Building on its expertise in materials science, surface technology, photonics, and cyclotron applications in health, the Unit has developed new core competences in the rapidly developing field of nanotechnology (NT). Due to its pervasiveness in many different fields of science, NT has particular significance for the policy maker with regard to environmental concerns, as well as health and safety (EHS) effects. The Unit’s activities focus today on nanotoxicology and bio-sensors development. These activities are complemented by the development of automated toxicity assays integrating advanced molecular-imaging techniques. A research activity on medical radioisotope production has been established at the cyclotron in combination with a major commercial activity in this field. To reflect the evolution of its activities into Nanotechnology, the title of the Unit will become “Nanotechnology and Molecular Imaging” in 2007.

Role

The BMS Unit provides an important horizontal support function to the work of the Institute. It has a slightly different “flavour” to the other IHCP Units in that its staff derives mostly from the physical sciences / engineering backgrounds, which provides a healthy mix to the otherwise predominantly biology- and chemistry-based scientific background of the Institute.

In particular, the BMS Unit provides scientific support in JRC priority areas related to environment and health, alternative methods, exposure monitoring, and security.

Drawing on the extensive experience and expertise of the field of surface engineering and bio-photonics, the Unit is actively engaged in research related to nanotechnology and develops new bio-interfaces and bio-sensors for specific applications in toxicology, and exposure monitoring.

BMS worked particularly closely with ECVAM throughout 2006 to develop an automatic in-vitro testing platform that should not only minimise the variability typically present in manual tests but will also provide a stream of valuable data to support the reliability assessment of candidate assays.

The Unit also houses a variable-energy multi-particle cyclotron (of the order of 10-40 MeV). The cyclotron supports research in different fields such as nuclear medicine, biomaterials testing and bio-kinetics, and includes daily radioisotope production for cancer diagnosis with positron emission tomography (PET).

Further information
http://nmi.jrc.ec.europa.eu
Scientific Organisation

During 2006, the work of the BMS was divided into 3 areas of activity (summarised in the following pages):

NanoBioTechnology for Health Applications (Nanobiotech)

In-vitro testing technologies and assay automation (InvITech)

Cyclotron Applications in Health and Environment (CYCLOTRON)

Skills base

The technical skills base of BMS cover a range of disciplines, predominantly in the physical sciences, but with particular expertise in optics, materials science, nuclear physics, nanotechnology, and image processing.

The Unit houses an impressive array of advanced and specialised instrumentation for its main research themes in optical metrology, bio-interfaces and sensors, nuclear medicine, molecular imaging and nanotechnology.
**Milestones**

Installation and Commissioning of robotic testing platform and host-laboratories in the sister Unit ECVAM
This is the first time *in-vitro* toxicity assays have been run in an automated fashion at the JRC. The technique promises to increase the throughput and quality/reliability of test assessment.

NanoBiotech Clean Room facility installed and operational
A new clean room was installed towards the end of the year and will soon be functional. It will provide BMS with state-of-the-art facilities for further developing its activities in nanotechnology and nanotoxicology.

**Development of High sensitivity biosensors based on nanostructured surfaces**
The Unit developed a new type of immuno-sensor platform based on nanostructured surfaces. The sensors present enhanced sensitivity compared to homogenous surfaces and open up new routes for signal amplification. The detection can be applied to different targets (in particular food contaminants, and cytokines) for the analysis of food products and cell metabolites in *in-vitro* tests.

**Workshop on Physics of sensors and detection systems: 6-7 December**
The workshop assembled over 100 participants from 18 countries. Invited speakers gave an overview on the state of the art development of nanotechnologies and their applications in the field of sensors and detection. Applications presented were mostly in the field of health and environment monitoring, and security.

**Key Publications in 2006***


* Full list of publications in peer-reviewed journals in 2006 included under page 64 and ff.

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**Hermann Stamm**, Unit Head

**Career Résumé** Hermann Stamm obtained his degree in physics in 1978 and PhD in 1981 in solid state physics from the University of Stuttgart (D). From 1981 to 1987 he held a position as research scientist and group leader at the Research Centre Karlsruhe. In 1987 he joined the Advanced Materials Institute of the JRC where he was responsible for several projects in the field of materials reliability and became Head of Sector in 1995. In 2000 he was nominated Head of the BMS Unit, in which a major nanobiotechnology project was set up.

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Nano-Biotech

Nano biotechnologies for health application

Website
http://nmi.jrc.ec.europa.eu
General objective

Development of a nanotechnology platform for support of applications in the field of health and environmental monitoring. Applications include development of (bio) sensors, monitoring and detection system, cell surface interface mechanisms for in-vitro testing, and nanotoxicology.

Main outputs in 2006

- Development of a high-sensitivity biosensor for cytokines (which provide the mechanism for inter-cellular communication) for integration in an in-vitro test system. The sensor is based on an immuno reaction with antibodies of IL1b and nanostructured surfaces which act as an amplifier of the signal in a ELISA reaction. This process allows a detection in the range of 100 nM.

- Development of an electrochemical sensor for lactic acid. The measurement of lactic acid is particularly relevant for applications in the food industry, as well as in clinical diagnostics and this sensor will provide a valuable tool for monitoring cells during toxicology testing. The potentiometric sensor developed is based on nanostructured electrodes and has a detection limit of 0.02 μM.

- Development of an Interdigitated Electrode detection sensor for testing cell adhesion. The complete microfabrication of the sensor has been developed for on-line monitoring of cell toxicity and allows collection of real-time information on cell metabolism which dramatically reduces the time inefficiencies of traditional measurements.

- Development of an Atomic Force Microscopy model for cell nanoparticle interaction. The model, in good agreement with experimental results, highlights the influence of the nanoparticle physico chemical properties on the translocation phenomena and gives an indication on the probability of penetration of nanoparticles into a cell dependent upon the size and surface energy of the particle.

François Rossi, Action Leader

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“At the crossroads of physics, biology and chemistry, nanobiotechnology opens up many exciting new possibilities in application to the life sciences.”
InViTech

*In-vitro* testing technologies and assay automation

Website
http://nmi.jrc.ec.europa.eu
General objective

To operate a state-of-the-art automated testing facility where various in-vitro bioassays can be implemented in high-throughput and high-content formats. Through the combination of automation technology with advances in photonics, microelectronics and nanobiotechnology, InViTech also offers exclusive access to next-generation bioassay technologies in response to the ever growing demand for more sophisticated in-vitro methods.

Main outputs in 2006

- Installation and Commissioning of a state-of-the art automated testing. This will allow the JRC to run complex in-vitro toxicity assays in an automated fashion.
- Design and implementation of a method to run a cytotoxicity assay based on rodent fibroblast (3T3) cells and their ability to incorporate the neutral red dye when viable. This assay is an alternative-method candidate for reduction of animal testing related to acute systemic toxicity assessment of chemicals.
- Demonstration of automated imaging systems for image-based endpoints in toxicity assays. The systems developed allow more precise quantitative measurement of the biological endpoints of Colony Forming Efficiency (CFE), counting colonies in 2D and 3D matrices and cardiomyocyte-beating.
- Partial completion of InViTech testing labs. Once operational (in early 2007), these laboratories will enhance the in-vitro testing capabilities of the Institute.

Maurice Whelan, Action Leader

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“Automation of complex in-vitro methods will greatly facilitate the increased testing demands for risk assessment.”
CYCLOTRON

Cyclotron Applications in Health and Environment

Website
http://nmi.jrc.ec.europa.eu
General objective

To improve production technology and radioisotope availability for the support of research into new diagnostic and therapeutic applications in Nuclear Medicine. In addition, to develop and apply radiotracers for material and radiobiological studies with Thin Layer Activation (TLA) and Charged Particle Activation Analysis (CPAA).

Main outputs in 2006

- A new production route was implemented for Cu-64 which is a highly promising isotope for medical applications.
- Construction and successful testing of a new cyclotron target system for the production of Th-226, a promising alpha ‘nanogenerator’ for cancer treatment using alpha-immunotherapy (in collaboration with the JRC Institute for Transuranium Elements).
- Refurbishment and alignment of one of the Cyclotron beamlines for the installation of a novel Adiabatic Resonance Crossing (ARC) target system. ARC is a method of activating materials using moderated neutrons produced at a cyclotron facility.

Neil Gibson, Action Leader

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“Our Cyclotron contributes directly to scientific advances in health care.”
European Centre for the Validation of Alternative Methods
History

ECVAM was created by a Communication from the Commission to the Council and the Parliament in October 1991, pointing to a requirement in Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes, which requires that the Commission and the Member States should actively support the development, validation and acceptance of methods which could reduce, refine or replace the use of laboratory animals. The stated objectives of ECVAM are:

- To coordinate the validation of alternative test methods at the European Union level
- To act as a focal point for the exchange of information on the development of alternative test methods
- To set up, maintain and manage a database on alternative procedures
- To promote dialogue between legislators, industries, biomedical scientists, consumer organisations and animal welfare groups, with a view to the development, validation and international recognition of alternative test methods.

Over the years, ECVAM has established a wide international network of collaborators. It also works in close collaboration with other Commission services, such as DG Environment, DG Enterprise, DG Research and DG Health and Consumer Protection.

Role

The Unit serves as an international reference centre, one of whose main tasks is to develop and validate alternative testing methods which do not rely on the use of animals. Where animal tests cannot entirely be replaced, ECVAM seeks to refine the tests such that animal suffering is minimised and the overall number of required animals is reduced. The principle is commonly referred to as the 3Rs (Replacement, Reduction, and Refinement).

ECVAM is primarily concerned with animal tests in the field of toxicological assessment. As well as coordinating international validation studies, the Unit plays an active role in the pre-normative research activities of the JRC.

Further information
http://ecvam.jrc.ec.europa.eu/
In 2006 the work of ECVAM consisted of 14 key-areas, with the support of various working groups with participation of stakeholders and international experts, directly targeting the animal tests to be replaced.

These key-areas of ECVAM were divided into 3 areas of activity (summarised in the following pages):

1. Validation of alternative tests for the chemicals and cosmetics legislation (VALTEST)
2. Validation of emerging areas and enabling technologies (VALEMAR)
3. Database Service on Alternative Methods (DBALM)

Due to the political sensitivity of its duties, ECVAM has its own Scientific Advisory Committee (ESAC) with participation of: all Member States, relevant industrial associations, academic toxicology, the animal welfare movement, and other Commission services with an interest in the alternatives area.

**Skills base**

ECVAM's work is focused on the development and evaluation of *in-vitro* methods (e.g. cell and tissue cultures), the validation of animal tests reducing animal use and suffering as well as of computer modelling based on structure-activity relationships, and on physiological and biokinetic modelling. In furtherance of an evidence-based toxicology paradigm which challenges unconsidered acceptance of non-validated traditional test methods, ECVAM contributes to the definition and validation of integrated test strategies.

ECVAM staff comprises biologists, (bio)chemists, toxicologists, physicians, veterinarians, statisticians, engineers and informatics specialists.
Milestones

Public access via Internet to the ECVAM database service

ECVAM celebrated its 15th anniversary towards the end of the year, and used the occasion for launching a public database service on alternative methods to animal experimentation, DB-ALM. After 10 years of preparation this factual database of quality-controlled information was made generally available (http://ecvam-dbalm.jrc.cec.eu.int/).

Endorsement of nine alternative methods

ECVAM finalised the validation of nine alternative in-vitro methods (used for testing for skin corrosion, chemotherapeutic drugs, aquatic toxicity testing, and bacterial contamination of pharmaceuticals) that were endorsed by the ECVAM Scientific Advisory Committee. The validations related to skin corrosion tests are particularly pertinent for the phasing out of animal testing for cosmetics ingredients.

Second “Europe Goes Alternative” conference

The importance of ECVAM’s work, in particular its coordinating role of the toxicity test strategy development for REACH, was made highly visible at the second conference of the European partnership for alternative approaches to animal testing (EPAA) in December.

Key Publications in 2006*


* Full list of publications in peer-reviewed journals in 2006 included under page 64 and ff.

Thomas Hartung, Unit Head

**Career Résumé**  Thomas Hartung obtained degrees in biochemistry and medicine from the Universities of Tuebingen and Freiburg and gained a PhD in pharmacology from the University of Konstanz as well as an MD from the University of Tuebingen. He worked for several years as associate professor and CEO of a technology transfer centre. In 2002 he joined the Commission as Head of Unit, responsible for ECVAM and became honorary full professor of the University of Konstanz in 2003.

**Nationality**  German  
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VALTEST
Validation of Alternative Tests for the Chemicals and Cosmetics Legislations

Website
http://ecvam.jrc.ec.europa.eu
General objective

To provide support to the existing and upcoming Chemicals Policy (REACH) and the Cosmetics Directive through the development, validation and promotion of non-animal methods, especially those designed for the testing of chemical substances and products (including cosmetics and biocides). The toxicological areas of concern are acute and chronic systemic toxicity, topical toxicity (skin and eye irritation/corrosion, skin penetration, phototoxicity), sensitisation (skin and respiratory), carcinogenicity and mutagenicity/genotoxicity and reproductive toxicity.

Main outputs in 2006

- Validation of the Episkin and EpiDerm assays for the prediction of acute skin irritation.
- Validation of cell transformation assays in-vitro for carcinogenicity testing.
- Retrospective validation of the micronucleus test in-vitro for genotoxicity testing.
- Retrospective validation of cytotoxicity/cell-function assays for the prediction of eye irritation.
- Collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) for the retrospective validation of organotypic assays for the prediction of severe eye irritants.
- Statement on the application of the Colony Forming Unit-Granulocyte/Macrophage (CFU-GM) assay for predicting acute neutropenia in humans.
- Validation of in-vitro cytotoxicity test methods for estimating starting doses for acute oral systemic toxicity testing.
- RIP 3.3 –2 Technical guidance documents to industries for the endpoints on skin and eye irritation/corrosion, respiratory irritation; skin and respiratory sensitisation; reproductive toxicology; acute and chronic toxicity; carcinogenicity/mutagenicity in the framework of REACH.

Valérie Zuang , Action Leader

Nationality  Luxembourgish
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“Our work continues to ensure the safety of cosmetics and chemicals whilst reducing the dependence on animal testing.”
VALEMAR

Validation of emerging areas and enabling technologies

Website
http://ecvam.jrc.ec.europa.eu
**General objective**

To contribute to the development, validation and acceptance of methods which could reduce, refine or replace the use of laboratory animals as required by Council Directive 86/609/EEC. The work covers validation activities for emerging areas (pharmaceuticals including biologicals, food, ecotoxicology, *in-vitro* nanotoxicology, etc), cross-cutting areas as kinetics and supports all of ECVAM’s validation activities by providing sophisticated methods for biostatistical analysis, Good Laboratory Practice, Good Cell Culture Practice and enabling technologies.

**Main outputs in 2006**

- Scientific validity statements on five *in-vitro* methods for pyrogenicity testing of pharmaceuticals for parental use (regulatory acceptance in progress). A positive outcome would contribute to worldwide reduction of animal tests (replacement of the test in rabbits).
- Scientific validity statement on the threshold approach for acute toxicity testing in fish (regulatory acceptance in progress). Potential to reduce the number of fish used for acute aquatic toxicity by 50%.
- Launch of several new validation studies in the areas of kinetics, ecotoxicology and vaccine testing.
- Collaborative activities (new and ongoing) with research institutes, industrial laboratories and universities worldwide (leading to international harmonisation of guidelines, mutual acceptance, and creates awareness of the 3Rs).
- REACH Implementation Project 3.3.2: Contribution to endpoint working groups acute aquatic toxicity, bioaccumulation/bioconcentration and toxicokinetics.
- *In-vitro* Nanotoxicology: Exploratory research project investigating the evaluation of toxic effects using standardised *in-vitro* methods.

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**Marlies Halder, Action Leader**

**Nationality** German  
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“Our tests contribute to the safety of consumer products and pharmaceuticals and provide proven alternatives to the traditional animal tests.”
DB-ALM

ECVAM DataBase service on Alternative Methods to animal experimentation

Websites
http://ecvam.jrc.ec.europa.eu
http://ecvam-dbalm.jrc.ec.europa.eu
General objective

DB-ALM was established in 1996 to achieve a principal objective of ECVAM, as required by the European Commission and Parliament, to establish, maintain and manage a database on alternative procedures to animal experiments. The DB-ALM provides ready-to-use information on various aspects of animal alternatives, at any stage of development and/or validation, as evaluated data sheets. The DB-ALM focuses on in-vitro techniques for toxicology assessments of chemicals and formulations.

Furthermore, based on the competencies and experiences gained in setting up DB-ALM, two complementary projects have been assigned to it, namely the establishment of the ECVAM Thesaurus and the ECVAM website. The thesaurus includes a systematically ordered collection of harmonised terms most commonly used by scientists active in the animal alternatives area and was developed as a result of the coordination of the international ECVAM Task Force on Alternatives Databases. The ECVAM website is the main portal to all activities of the entire ECVAM Unit.

Main outputs in 2006

- In 2006, the entire DB-ALM was launched via the Internet for public access. The online access was announced in an official ceremony of the Institute by the Director on the occasion of the 15th anniversary of ECVAM on 29th October 2006 and represents the fulfilment of an institutional duty of the institute set by the Commission.

  After the launch of DB-ALM, the service could record a ca. 20 new weekly registrations from 37 countries by the end of 2006.

- In parallel to the preparation of the public launch of DB-ALM big efforts have been made to ensure a continuous increase/updating of the information content. Towards the end of 2006 the principal data content of the DB-ALM included 207 method descriptions, 59 study descriptions, 6432 test descriptions with their results for 2209 test compounds and 3901 bibliographic citations. This represents an increase in the total information content of more than 20% compared to 2005.

Annett Janusch-Roi, Action Leader

Nationality  German

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“Evaluated, accessible information on alternative methods to animal testing serves to support both research and legislation.”
Physical and Chemical Exposure
History

The PCE Unit was originally part of IHCP’s sister Institute IES (Institute for Environment and Sustainability) but was transferred to IHCP with its staff and instrumentation in 2002 as part of the JRC restructuring for the sixth framework programme.

Consequent to the transfer of the PCE Unit to IHCP and the transfer of main activities on food and feed safety and quality from the IHCP to the JRC’s Institute for Reference Materials and Measurements (IRMM), two further laboratories were integrated into its work, namely: the Food Contact Materials Laboratory (now a Community Reference Laboratory); and BEVABS (European Office for Wine, Alcohol, and Spirits). In addition, the toxicogenomics laboratory was formed to enrich the potential of PCE in assessing health-related responses to human exposure to chemical and physical stressors.

The total human exposure to in-door and out-door environmental stressors remains very much the focus of the PCE Unit. In addition, the Unit is progressing its work in the field of the metabolic profiling of biofluids (biomonitoring) as well as in the exploration of advanced -omics technologies for assessment of exposure and health effects.

Role

The work of the PCE Unit is concerned with public health risk assessment and the evaluation and quantification of human exposure to health stressors through the environment and consumer products, such as chemicals, UV radiation and noise. Investigation into the biological effects of these types of stressors is extremely complex due to the multiplicity of potential variables. It is not always straight-forward to separate one type of stressor from another and “cocktail” effects of more than one type of stressor can have further secondary effects.

Furthermore, there is convincing evidence that human exposure data represent a major bottleneck in the risk assessment process. This has been recognised by the EU Environment Council, which has since requested the Commission to undertake action for eliminating deficiencies in the data. To respond to this challenge, PCE is developing harmonised tools and reference data in support of exposure assessment procedures for the implementation of key policy instruments.

Further information
http://www.jrc.ec.europa.eu/pce/
Scientific Organisation

In 2006, the Unit’s scientific activities were reviewed in preparation for the new EU Seventh Framework Programme (2007-2013) and in response to the research needs of the Commission’s Strategy on Environment and Health and Health and Consumer Policy; activities were organised under the following three areas of activity (summarised in the following pages):

- Human exposure to environmental stressors and health effects (EXPO-Health) including the CRL on Food Contact Materials
- Integrated exposure assessment and modelling (EXPO-Model)
- European Office for Wine, Alcohol and Spirit Drinks (BEVABS)

Skills base

PCE has competencies primarily in the chemical and biological sciences although the Unit also has a number of physicists who are involved in the modelling aspects of the work.

The emphasis of PCE’s work is in exposure assessment to chemical and physical stressors with core research activities in: determination of exposure sources and routes, consumer exposure modelling, biology-based toxicokinetic / dynamic modelling, in-vivo / in-vitro evaluation of effects using advanced genomic technologies, modelling of noise propagation, and UV radiation.
Milestones

Inauguration of the Community Reference Laboratory on Food Contact Materials

The Community Reference Laboratory on Food Contact Materials was officially inaugurated in December 2006. The CRL is responsible for providing national control laboratories with harmonised analytical tools, and will co-ordinate the Network of National Reference Laboratories for the primary purposes of information exchange, capacity building and the provision of training.

European Exposure Assessment Toolbox Report

The Unit provided the first results concerning the application of the “European Exposure Assessment Toolbox” on exposure assessments of chemicals released from consumer products and articles (including toys and textiles).

Experimental Exposure and Health Effect Activities

PCE provided validated methods for the quantitative analysis of certain new fibre mixtures in textiles, and measured the release of volatile organic compounds (VOCs) from carpets and building materials in its specialised Indoortron facility. Whole genome DNA-microarrays were also used to compare early events in biological responses of human cells exposed to different chemical mixtures relevant for indoor environments.

Measuring campaigns

PCE carried out measuring campaigns in kindergartens and public buildings in various European cities to evaluate indoor/outdoor relationships and personal exposure concentrations of priority pollutants.

Training

The Unit provided training on analytical methods for the European Wine databank to official laboratories from the new EU Member States.

Key Publications in 2006*


* Full list of publications in peer-reviewed journals in 2006 included under page 64 and ff.

Dimitrios Kotzias, Unit Head

Career Résumé  Dimitrios Kotzias obtained a degree in Chemistry in 1972 from the University of Bonn from where he also gained a PhD in 1974. He joined the Commission in 1986 after working for several years as head of the “Laboratory for Organic Chemical Analysis” in the Institute of Ecological Chemistry at the National Centre of Environmental Sciences (GSF), Munich. Since 1998 he was Head of the Air Quality Unit of the IES and due to re-organisation part of this unit went to the IHCP in 2002. From March 2005 to July 2006, he was the Acting Director of the IHCP. He is author or co-author of more than 200 scientific papers.

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EXPO-Health

Human Exposure to Environmental Stressors and Health Effects

Websites
http://www.jrc.ec.europa.eu/pce
http://crl-fcm.jrc.it/
General objective

To develop and assess novel methodologies in the field of environmental health science. In particular, the integration of toxicogenomics, computational techniques for biology-based modelling and data analysis, and advanced analytical chemistry to enable an inter and multidisciplinary approach for assessing the relationship between chronic low dose exposure to environmental stressors across the human life span from foetus to adulthood and the associated effects on human health. In this context, to act as Community Reference Laboratory on Food Contact Materials.

Main outputs in 2006

- Establishment and operation of the Community Reference Laboratory on Food Contact Materials (CRL-FCM).
- Exposure assessment for plasticizers in sauces and condiments.
- Completion of outdoor / indoor / personal exposure campaigns to volatile organic compounds (VOCs) in Arnhem, Nijmegen, Thessaloniki and Leipzig.
- Completion of a project on investigating the degradation of atmospheric pollutants by photocatalytic materials.
- Harmonisation of methods for testing carpet emissions.
- Training activities:
  Organisation and delivery of a training course on migration modelling from food contact materials for new Member States and candidate countries. Specialised training of colleagues from DG Health and Consumer Protection (Food and Veterinary Office inspectors) at the CRL-FCM.

Dimosthenis Sarigiannis, Action Leader

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“Our science contributes to a better understanding of exposure and health effects from consumer products and via the environment.”
EXPO-Model

Integrated Exposure Assessment and Modelling

Website
http://www.jrc.ec.europa.eu/pce
**General objective**

To develop an integrated toolbox to host methods, assessment procedures, reference data and guidance for harmonised exposure assessment in the EU. The ultimate aim of EXPO-Model is to develop and validate source models for consumer products and help establish a generic consumer exposure modelling framework by building up a complete taxonomy of sources and source models. The area of work supports Commission services providing scientific understanding and assessment tools for policies relevant to the impact of chemicals and physical agents (noise, electro-magnetic fields (EMF), ultra-violet (UV)) on humans.

**Key Words**

- Human exposure
- Chemicals
- Exposure models
- European exposure assessment toolbox
- Consumer products / articles
- Indoor air quality
- UV mapping and human exposure
- Noise modelling and noise / chemicals interactions

**Main outputs in 2006**

- Report on maintenance and operation of a toolbox in view of its implementation for the General Products Safety Directive (GPSD) and potentially for the New Chemicals Policy (REACH). By using a single reference system/tool with harmonised exposure assessment methodologies support to the implementation of the consumer policy is provided.

- Co-ordination of the Global Net on “Consumer Exposure Modelling” - a consortium of expert model developers and users from Europe, America, Canada and Asia, aiming at harmonising and validating existing consumer exposure models on the basis of common procedures and protocols.

- Noise night time guidelines development.

- Working paper on EMF communication and risk perception in the EU.


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**Dimitrios Kotzias, Action Leader**

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“Understanding the real risks from exposure is a first essential step towards safeguarding health and quality of life.”
European Office for Wine, Alcohol and Spirit Drinks

Website
http://www.jrc.ec.europa.eu/pce
General objective

The office addresses major fraud in the wine industry and manages the European Union Wine Databank on authentic European wines. The office also co-ordinates the network of official Member States laboratories involved in Isotopic Ratio Mass Spectrometry (IRMS) and Nuclear Magnetic Resonance (NMR) measurements required for the databank. These analytical techniques are also applied to anti-fraud and authenticity of agro-food products in support to Commission services. Biomonitoring and exposure studies pertaining to European policies in Environment and Health issues are carried out in collaboration with other IHCP and JRC activities. Research results from initiatives in NMR and MS fingerprinting (Metabonomics) are also being assessed and validated.

Main outputs in 2006

• Control and improvement of the sampling plan for the EU Wine Databank in Cyprus. Scientific and technical help to the Cyprus State General Laboratory (SGL) for implementation and quality control in isotopic techniques. SGL obtained the accreditation for the SNIF-NMR method applied for the EU wine databank.

• In support to Enlargement and Integration policy a training course on the EU Wine Databank was provided for eleven experts from six New Member States. The participants were trained in the use of Informatic tools (WINE DB 1.3 and EXTRAWINE of the EU Wine isotopic Databank) and official access was provided.

• Delivery of a three day training course on isotopic ratio mass spectrometry applications for anti-fraud and authenticity controls in agro-food sectors to seven scientists and technicians from new member states and candidate countries.

• General co-ordination of the EU Wine Databank and information update.

Claude Guillou, Action Leader

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“We help ensure that the wine in your glass is what the label on the bottle says it is.”
Toxicology and Chemical Substances
History

The European Chemicals Bureau was established within the JRC in 1993 by a communication to the European Council and Parliament (93/C 1/02).

The principal task of the Bureau was to carry out and coordinate the scientific/technical work required for the implementation of EU chemicals legislation (directives, regulations), in particular: concerning Directive 92/32/EEC on classification and labelling; Council regulation (93/793/EC) on the evaluation and control of existing chemical substances; and Council regulation EEC Nr. 2455/92 concerning the export and import of certain dangerous chemicals.

In subsequent agreements with the Commission's Environment Directorate General, new tasks were added including: support to the notification of new substances (92/32/EEC); drafting and revision of the risk assessments as laid down in Directive 93/67/EEC; and authorisation of active substances as laid down in the Biocidal Products Directive (98/8/EC).

Role

The Toxicology and Chemical Substances Unit (TCS), commonly referred to as the European Chemical Bureau (ECB), is the JRC’s centre of excellence in science – policy linkages to EU chemicals legislation. The chemicals industry forms a large and highly important economic sector of the European Union. EU chemicals legislation aims to ensure a high level of protection for workers, consumers, and the environment against dangerous chemicals whilst supporting the efficient functioning of the internal market on chemicals.

The new Chemicals legislation – REACH (Registration, Evaluation, and Authorisation of Chemicals) was adopted by the European Council and European Parliament at the end of 2006, will come into force in 2007, and will become operational on 1 June 2008.

REACH will have far-reaching implications on the Chemicals industry and the TCS Unit has been working closely with the various stake-holders to prepare technical guidance for industry for its implementation. In particular, TCS has been responsible, in close cooperation with the chemicals industry and the Organisation for Economic Cooperation and Development (OECD), for designing and managing the development of the informatics tools (IUCLID 5 registration tool and the REACH-IT system for the Agency) which will play a central role in implementing the legislation. The tools will be used by industry as well as the future European agency on chemicals which is due to be established in Helsinki in the course of 2007.

The Unit website which has become one of the most visited sites of Chemical Information in Europe as well as globally, is a portal of information to the European Chemical Substances Information System (ESIS) and contains updated information on the progress of Reach Implementation Projects, EU Risk Assessment Reports on Chemicals, chemical databases, training courses and workshops.

Further information
http://ecb.jrc.ec.europa.eu/
**Scientific Organisation**

During 2006 the work of the TCS Unit was divided into four areas of activity (summarised in the following pages):

**Assessment of Chemicals**

**REACH Support**

IT tools for REACH and Informatics or in short **REACH IT**

**Computational Toxicology (QSARs)**

**Customers**

- DG Environment
- DG Enterprise and Industry
- DG Employment and Social Affairs
- DG Health and Consumer Protection
- DG Taxation and Customs Union
- DG Research
- Competent Authorities
- Chemicals Industry
- Organisation for Economic Co-operation and Development (OECD)
- National Environmental Protection Agencies
- Non Governmental Organisations (NGOs)
- Member States
- Scientific Community
- United Nations Environment Programme (UNEP)
- United States Environmental Protection Agency (US-EPA)
- World Health Organisation (WHO)
- World Trade Organisation (WTO)

**Main Research Partners**

- Helmholtz Centre for Environmental Research – (UFZ), Department of Ecological Chemistry Leipzig, Germany
- Istituto di Ricerche Farmacologiche “Mario Negri”, Laboratory of Environmental Chemistry and Toxicology Milan, Italy
- The European Chemical Industry Council (CEFIC) Brussels, Belgium
- UK Environment Agency London, United Kingdom
- Organisation for Economic Co-Operation and Development (OECD), Chemical Safety Paris, France
- RIVM, Research for Man and Environment, Environment and Chemicals Bilthoven, The Netherlands
- INERIS, French National Institute for Industrial Environment and Risks Paris, France

**Policies Supported**

- New Chemicals Legislation (REACH)
- Directive relating to the notification of new industrial substances 67/548/EC
- Directive relating the risk assessment of new notified substances 93/67/EC
- Directive concerning the placing of biocidal products on the market 98/8/EC
- Directive on the restriction on marketing and use 76/769/EC
- Directive on placing plant protection products on the market 91/444/EC
- Regulation concerning the evaluation and control of existing substances (EC) No 793/93
- Regulation on the risk assessment existing substances (EC) No 1488/94
- Regulation concerning Export / Import (EEC) 304/03

**Skills base**

The Unit has strong competences in chemistry (environmental, molecular), risk assessment, chemical engineering, toxicology, and informatics. In relation to its work with EU chemicals and biocide legislation, TCS plays an active part in achieving consensus in the various stake-holder groups as well as providing the necessary support tools (IT, classification dossiers, EU Risk Assessment Reports of Chemicals, etc.).

The Unit also contains a group specialised in computational toxicology which is particularly active in developing the field of quantitative structure-activity relationships (QSARs), and alternative methodologies to obtain critical toxicological information using chemical categories, read across and waiving.

**Samples of chemical solutions for analysis**
Milestones

REACH Implementation Project meetings
A large number of draft guidance documents for REACH processes have been written during the REACH Implementation Project (RIP) involving many meetings with the stakeholder community. The success of this work has been widely acknowledged by European Industry, the COM and MS, and the methodology employed to reach compromises on important issues has been endorsed by all stakeholders.

Completion phase of the IUCLID5 chemical dossier software tool
IUCLID5 is a complex database tool (containing over 8,000 data fields) for collecting and disseminating information concerning properties (physical-chemical, toxicological) of chemicals and hazard data. All data requirements and core functionality necessary to prepare a REACH registration dossier were implemented and the application, testing by an extensive stakeholder group exercise, will be rolled out in mid 2007.

OECD adoption of harmonised templates
The OECD formally adopted 90 harmonised templates (an international standard format for reporting properties of chemicals and hazard data) developed with the JRC. These harmonised templates will greatly assist industry in complying with REACH legislation and will facilitate data sharing between organisations.

Notification of New Chemical Substances
In the first three quarters of the year, 416 notification dossiers for new substances (299 new dossiers, 117 updates) and related follow-up correspondence and classification & labelling files received, handled and distributed to all Member States, Norway and Iceland.

Training and capacity building workshops
The Unit organised a number of training courses and workshops on risk assessment under current legislation and how to implement REACH. Training courses on current chemicals legislation for candidate countries were given in both Croatia and Turkey. Extensive training on site over 1 year was also given to the new staff that will form the nucleus of the European Chemicals Agency which will be established in June 2007 in Helsinki.

Key Publications in 2006*


* Full list of publications in peer-reviewed journals in 2006 included under page 64 and ff.

Steven Eisenreich, Unit Head

Career Résumé  Steven J. Eisenreich obtained degrees in Chemistry and Analytical Chemistry in 1969 and 1972, respectively, and obtained his PhD in 1975 all from the University of Wisconsin. He was professor of environmental chemistry at the University of Minnesota (1975-1995) and Rutgers University (1995 to 2001). In July 2001 he joined the Commission as Head of Unit responsible for inland and marine waters, and in 2005 became head of the European Chemicals Bureau. He has been recognised for his scientific work in environmental organic chemistry through a series of major international awards.

Nationality  Greek and American            E-mail  steven.eisenreich@ec.europa.eu
Assessment of Chemicals

Website
http://ecb.jrc.ec.europa.eu/
General objective

To provide scientific support to the implementation of EU policies related to the safe use of chemicals, ensuring through the development of methodologies a systematic and harmonised approach to assessment of risks. The aim of the legislation is to ensure a high level of protection for workers, consumers and the environment against dangerous chemicals and to ensure the efficient functioning of the internal market on chemicals under the current Community legislation. A science-based consistent approach to the assessments requires development and application of methodologies, at a harmonised level between Member States and different regulatory frameworks.

Main outputs in 2006

- **Existing Substances and Notification of New Substances**
  Finalisation of risk assessments on 16 priority existing substances and submission to the Scientific Committee for Health and Environmental Risks (SCHER) for independent peer review. Publication of a further 15 on the ECB website following the SCHER peer review. Processing of 585 notification dossiers for new substances and 207 classification and labelling files. Publication of the updated European List of Notified Chemical Substances (ELINCS).

- **Biocidal Products Directive**
  Finalisation and agreement of scientific and technical discussions for 5 substances. Input to legislative text provided for the 4th review regulation.

- **Import / Export (PIC) Regulation and Rotterdam Convention**
  Processing of 1414 export notifications and 81 import notifications

- **Training**
  In support to Enlargement and Integration, a training course on Capacity Building for REACH was organised in Cyprus and courses on current chemicals’ control legislation for candidate countries were organised in Croatia and Turkey. Additionally, training courses on risk assessment under current legislation and REACH were held in Bilthoven (NL) and Ispra.

**Sharon Munn, Action Leader**

**Nationality** British

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“Transparent and robust risk assessment of chemicals is based on sound science.”
REACH Support

Support to the future chemicals legislation

Website

http://ecb.jrc.ec.europa.eu/
General objective

To provide the necessary scientific and technical support to policy makers during the adoption and implementation process of REACH (Registration, Evaluation and Authorisation of Chemicals) and to the new regulation implementing the globally harmonised system for classification and labelling. The activities focus particularly on the development of the Technical Guidance Documents (TGDs) required for industry and authorities through the execution of the Reach Implementation Projects (RIPs).

This work is carried out in close collaboration with other stakeholders in the implementation of REACH (including Member States, Industry and Non Governmental Organisations (NGOs)).

Main outputs in 2006

- Development of a number of (draft) guidance documents for REACH processes and discussion of these with the stakeholder community.
- Extensive support to the development of the draft EU regulation implementing the GHS system for classification and labelling.
- Dissemination of the REACH ‘philosophy’ and of the results of the REACH Implementation Projects through lectures, papers, press releases and the ECB website.
- Support to the preparations for setting up the European Chemicals Agency (EChA) to be established in 2007 in Helsinki. In particular extensive training on REACH and RIP processes to 20 staff the majority of whom will form the nucleus of the Agency.

Jack de Bruijn, Action Leader

Nationality Dutch
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“The JRC has helped make REACH possible and REACH will ensure a healthier environment for us all.”
REACH IT

IT tools for REACH and Informatics

Website
http://ecb.jrc.ec.europa.eu/
General objective

To provide IT-related support concerning the preparation of the new European Chemicals Agency (ECHA) so that it can begin its tasks immediately at entry into operation of the REACH regulation and develop IT systems to be used by industry in order to fulfil its legal obligations.

Main outputs in 2006

- **Development of the IUCLID5**
  Software application to manage and report to the regulatory authorities information on properties and hazards of chemicals. All data requirements and core functionality necessary to prepare a REACH registration dossier were implemented. The application was subject to testing by an extensive stakeholder group.

- **REACH-IT system**
  The analysis and design of the central IT system of the European Chemicals Agency (ECHA) was entirely reviewed to take into consideration changes in the final version of the REACH regulation and fully completed.

- **OECD harmonised templates**
  Standard formats for reporting summaries of results of tests performed on chemicals to determine their properties or effects on human health and the environment were completed for ninety properties and effects and endorsed by the OECD member countries.

- **Global Portal to information on chemical substances**
  The first development phase, which consists of cross-linking the ECB information system (ESIS) to databases from government and international organisations was designed and the prototype presented and validated.

- **European Customs Inventory of Chemical Substances (ECICS database)**
  The update and upgrade of the database was completed regarding the Pharmaceutical Agreement, the Chemical Weapons Convention and EC 304/2003.

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**Christel Schilliger-Musset, Action Leader**

**Nationality** French  
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“Our development of robust IT systems to ensure accessible information on dangerous properties of chemicals is fundamental to REACH.”
Computational Toxicology

(including quantitative structure-activity relationships (QSARs))

Website
http://ecb.jrc.ec.europa.eu/
General objective

To promote the availability of reliable, computer-based estimation methods for the regulatory assessment of chemicals, with particular emphasis on quantitative structure-activity relationships (QSARs) and grouping methods, through the development, assessment, implementation and acceptance of these non-testing methods.

Main outputs in 2006

- REACH Implementation process concerning chemical categories and regulatory applicability of QSAR models.
- Training and capacity building among regulators and industry via the organisation of:
  1 training course
  2 meetings of the EU QSAR Working Group
  1 meeting of OECD QSAR Group
  3 scientific workshops (on chemometrics, bioaccumulation and carcinogenicity modelling).
- Implementation and dissemination of web-based tools including the QSAR Database and Toxtree, a tool for predicting different types of toxic hazard.
- Development, beta testing and regulatory acceptance of QSAR Model Reporting Formats.
- Development, assessment and implementation of novel methods for chemometric ranking.

Andrew Worth, Action Leader

Nationality British
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“Computational chemistry augments our understanding of risks posed by chemicals.”
Role

The Management Support Unit of the IHCP provides the necessary administrative and general support for assisting the Institute’s Scientific Units to execute their part of the work programme. It is responsible, amongst other things, for budget preparation/management, purchasing and contracting orders, procurement procedures, human resource management (including recruitment and training), communications and public relations, infrastructure and buildings management and safety.

Visits to the Institute

As well as being responsible for the IHCP’s PR material, the Communications and PR sector organises the large number of visitors which the Institute receives on an annual basis. Visitors range from VIPs to, university students. In 2006 examples of VIP visitors included: Member of the European Parliament, Paulo Casaca; Maltese Minister for Rural Affairs and the Environment, George Pullicino; Ambassador of Finland in Rome, Pauli Mäkelä; Austrian Secretary of State, Eduard Mainoni; Swiss State Secretary for Education and Research, Charles Kleiber; the EC Spokesperson for Science and Research, Antonia Mochan as well as high-level delegations from Turkey and Slovenia.

Raymond Crandon, Unit Head

Career Résumé  Raymond Crandon studied with the Chartered Institute for Secretaries and Administrators in the UK before starting a career in a building society where he became a branch manager in 1980. In 1984 he joined the European Commission, at DG REGIO. In 1987 he transferred to the JRC at Ispra. With the creation of the institutes in 1989, he became the assistant to the Director of the Institute for Remote Sensing Applications, later to become the Space Applications Institute. In 2000 he transferred to the Directorate for Resources as assistant to the Director. On the 1st January 2004 he was appointed head of the IHCP-MSU.

Nationality  British  E-mail  raymond.crandon@ec.europa.eu

Communications and PR team
Support to Enlargement and Integration

The Enlargement and Integration Action of the JRC consists of a number of integrated activities aimed at stimulating scientific and technical collaboration, including hosting of temporary staff at the JRC Institutes, organisation of workshops and training courses and provision of JRC information days within the Enlargement Countries.

During 2006 the IHCP provided 8 specialist workshops and training events on specific topics involving more than 300 participants.

Examples of IHCP Enlargement and Integration activities in 2006 include:

- GMO detection in North African Countries training course (held in Tunisia).
- Capacity building for REACH: Future role of EU Member States (held in Cyprus).
- Physics of Sensors and Detection Systems workshop (held in Ispra).
- Cyclotron Networking Workshop (held in Ispra).

In addition, a number of specific study tours and visits (relating in particular to chemicals management and detection of GMOs) were organised for delegations from Turkey, Croatia and Romania.

The Institute hosted 9 non-statutory staff from the New Member States and Candidate Countries within the framework of the work of the Institute's Scientific Units.

Exploratory Research Activities

Exploratory research is an annual programme which is funded from a small proportion (up to 6%) of the available Institute's funds. The programme allows the JRC Institutes to embark on less applied research and helps develop new competences and expertise for the development of future work programmes.

Selection of Exploratory Research projects is made by the IHCP Director in consultation with the IHCP Scientific Committee based on the submission of proposals from the Scientific Units.

In 2006, the Institute funded the following 7 Exploratory Research projects:

- A feasibility study to explore the strategic combinations of in-silico and in-vitro methods to assess skin irritation potential of chemicals.
- Investigation of Computational Approaches for the Ranking Of Chemicals according to their Environmental and Toxicological Concern.
- Nanoparticles-cells interaction by Atomic Force Microscopy.
- Synthesis of single radiolabelled nano-Co\[^{57}\]CoFe\(_2\)O\(_4\).
- The use of signalling pathways as toxicological endpoint for developmental toxicity testing.
- Uncertainty assessment in health risk assessment.
IHCP Scientific Committee

The Institute holds a Scientific Committee which is chaired by the Institute Director and consists of a small and equal number of nominated and elected members from the Scientific Units. The primary objective of the IHCP Scientific Committee is to provide support to the Director on technical and scientific matters related to the work of the Institute and the JRC work programme.

The Committee provides a discussion platform among the scientific staff of the Institute and serves as an important communication channel between the scientific staff of the Institute and the Director.

Elections for the new (2006-2009) Scientific Committee of the IHCP were held in April 2006.

Institute Excellence Awards

Each year the Scientific Committee evaluates the nominations proposed by the IHCP Scientific Units for the annual Institute excellence awards. The purpose of the awards is to provide recognition of particular achievement in the different categories.

In 2006 the Committee selected the following nominations for each of the categories:

Best Young Scientist

Ondrej Kylián of the BMS Unit, for the particularly high number of recent peer-reviewed publications in 2006 and the field of plasma techniques (a new area of specialty for the JRC) which he has been active in establishing.

Support to EU Policy

The ECB team involved in the preparation of the REACH legislation were selected for their widely recognised and acclaimed contribution to the formulation and implementation process.

Best peer reviewed scientific paper

The paper entitled “Selective Immobilization of Protein Clusters on Polymeric Nanocraters” (Advanced Functional Materials), selected due to the scientific quality of the journal and the high impact factor of the journal.
Staff

Core staff
Of the total core staff of the JRC (which amounted to 1717 end of year 2006), the IHCP employs 176 core staff members.

Visiting staff
In addition to its core staff the Institute has 133 visiting staff members (including trainees, post-doctoral grant holders, seconded national experts, auxiliaries and contractual agents).

The division between M-male and F-female staff members are indicated in the table below.

Of the total staff approximately 85% are working on scientific projects and 15% are doing administrative or support work.

<table>
<thead>
<tr>
<th></th>
<th>M</th>
<th>F</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core staff (Officials &amp; Temporary Agents)</td>
<td>102</td>
<td>74</td>
<td>176</td>
</tr>
<tr>
<td>Visiting staff</td>
<td>58</td>
<td>75</td>
<td>133</td>
</tr>
<tr>
<td>Total IHCP</td>
<td>160</td>
<td>149</td>
<td>309</td>
</tr>
</tbody>
</table>

IHCP Staff distribution (end-of-year situation) 2006

Budget

The IHCP budget is mainly divided into staff costs and research credits, with a budget in 2006 amounting to approximately 43 million Euro. Most of this budget is made available through the EU Research Frame Work Programme and relates to the Institutional work of the Institute.

Competitive Activities

In addition an increasing portion of the IHCP’s income comes from participation in competitive activities. In 2006 income from competitive activities amounted to approximately 3.4 million Euro.

The competitive work has three main components: participation in FP6 indirect actions, performing additional work upon request for other Commission services, and contract work undertaken for third parties such as regional authorities or industry.

Publications registered in 2006

<table>
<thead>
<tr>
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<th>Total</th>
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<tbody>
<tr>
<td>Monographs &amp; articles*</td>
<td>96</td>
</tr>
<tr>
<td>Technical EUR reports</td>
<td>46</td>
</tr>
<tr>
<td>Contributions published in conferences proceedings</td>
<td>21</td>
</tr>
<tr>
<td>Other documents &amp; publications</td>
<td>3</td>
</tr>
<tr>
<td>Total Publications</td>
<td>166</td>
</tr>
</tbody>
</table>

* The full list of publications in peer reviewed journals in 2006 included under page 64 and ff.
IHCP
Organisational Chart

1. D. Kotzias served as Acting Director from 16th March 2005 until July 2006
2. Since 2007 re-named as Nanotechnology and Molecular Imaging (NMI)
IHCP Publications

Full list of publications in peer-reviewed journals in 2006

GENETICALLY MODIFIED ORGANISMS


NANOTECHNOLOGY, BIOMATERIALS and BIOSENSORS


**ALTERNATIVE TEST METHODS**


**CHEMICAL & PHYSICAL EXPOSURE ASSESSMENT (CONSUMER PRODUCTS, ENVIRONMENT, FOOD)**


**TOXICOLOGY OF CHEMICAL SUBSTANCES**


Abstract
Report on the activities, accomplishments and resources related to the JRC work carried out in 2006. An overview is given of the mission and its implementation, the scientific activities and the relations with the outside world.
The mission of the JRC is to provide customer-driven scientific and technical support for the conception, development, implementation and monitoring of EU policies. As a service of the European Commission, the JRC functions as a reference centre of science and technology for the Union. Close to the policy-making process, it serves the common interest of the Member States, while being independent of special interests, whether private or national.