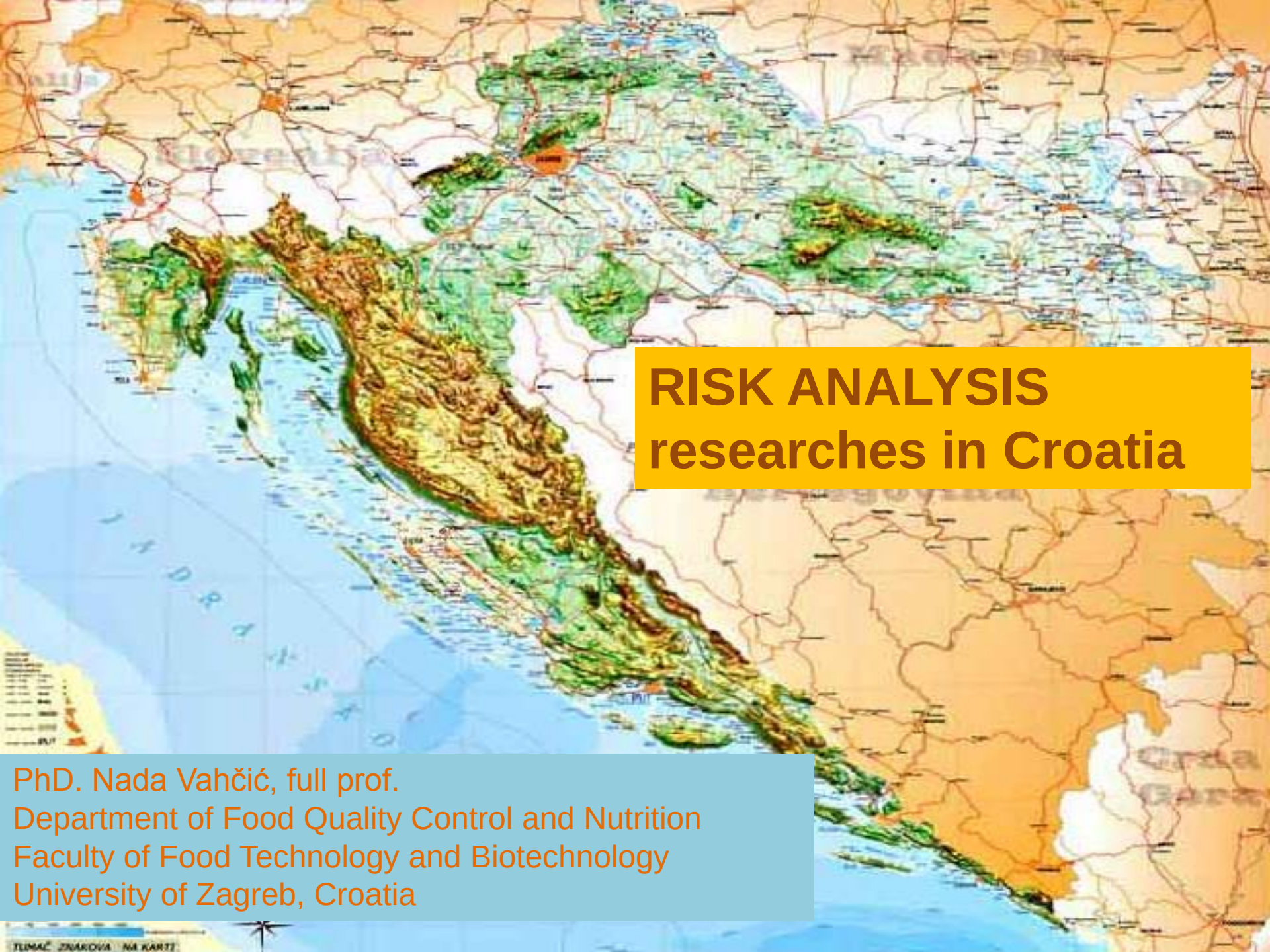

RISK ANALYSIS researches in Croatia

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Department of Food Quality Control and Nutrition
Faculty of Food Technology and Biotechnology
University of Zagreb, Croatia

Content

- Introduction
  - Risk analysis
    - Risk assessment
- Review
  - Science in world
    - USA
    - EU
    - Croatia
  - Risk assessment in world
    - FAO/WHO
    - EFSA
    - CFA
    - Scientific projects/researches as a part of risk assessment
- Instead of conclusions

Risk analysis

Risk analysis comprises the three tasks as shown

Risk analysis

- The tasks are functionally separate, but conceptually of equal importance. There is some overlap among the tasks at times.
- A risk analysis begins and ends with risk management. The risk managers pose questions of scientific substance for the risk assessors to answer in the course of their assessment.
- Communication among assessors and managers dominates the early stages of an analysis and is eventually replaced by communication between the team and stakeholders.

Risk assessment

- The Codex Alimentarius Commission defines risk assessment as:

  "A scientifically based process consisting of the following steps:
  - hazard identification,
  - hazard characterization,
  - exposure assessment, and
  - risk characterization."
- The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties.

Risk assessment

Risk assessment can be defined informally as the work required in asking and answering the following questions:

- What can go wrong?
- How can it happen?
- How likely is it?
- What are the consequences?

Risk management

- The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Risk management

- the work required in asking and answering the following questions:
  - What questions do we want risk assessment to answer?
  - What can be done to reduce the impact of the risk described?
  - What can be done to reduce the likelihood of the risk described?
  - What are the trade-offs of the available options?
  - What is the best way to address the described risk?

Risk communication

- The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Risk communication

- The work required in asking and answering the following questions:
  - Why are we communicating?
  - Who is our audience?
  - What do our audiences want to know?
  - What do we want to get across?
  - How will we communicate?
  - How will we listen?
  - How will we respond?

Risk assessment

- Microbiological
- Chemical
- Pest
- Foods derived from GM animals
- Nutrients

Microbiological Risk Assessment

- The "Principles and guidelines for the conduct of microbiological risk assessment," CAC/GL-30 was published in 1999 and provide an outline of the elements of a Microbiological Risk Assessment.
- The general list of tasks includes the following:
  - General Considerations
  - Statement Of Purpose Of Risk Assessment
  - Hazard Identification
  - Exposure Assessment
  - Hazard Characterization
  - Risk Characterization
  - Documentation
  - Reassessment

Chemical risk assessment
Generic risk assessment model for insecticides

THE HUMAN HEALTH RISK ASSESSMENT MODEL

- Hazard assessment (hazard identification and hazard characterization)
- Human exposure assessment
- Risk characterization

THE ENVIRONMENTAL RISK ASSESSMENT MODEL

- Environmental exposure assessment
  (air, soil, surface water and aquatic sediment)
- Effects
  (aquatic organisms, soil organisms and soil function, non-target terrestrial arthropods including honeybees, terrestrial vertebrates, higher terrestrial plants)

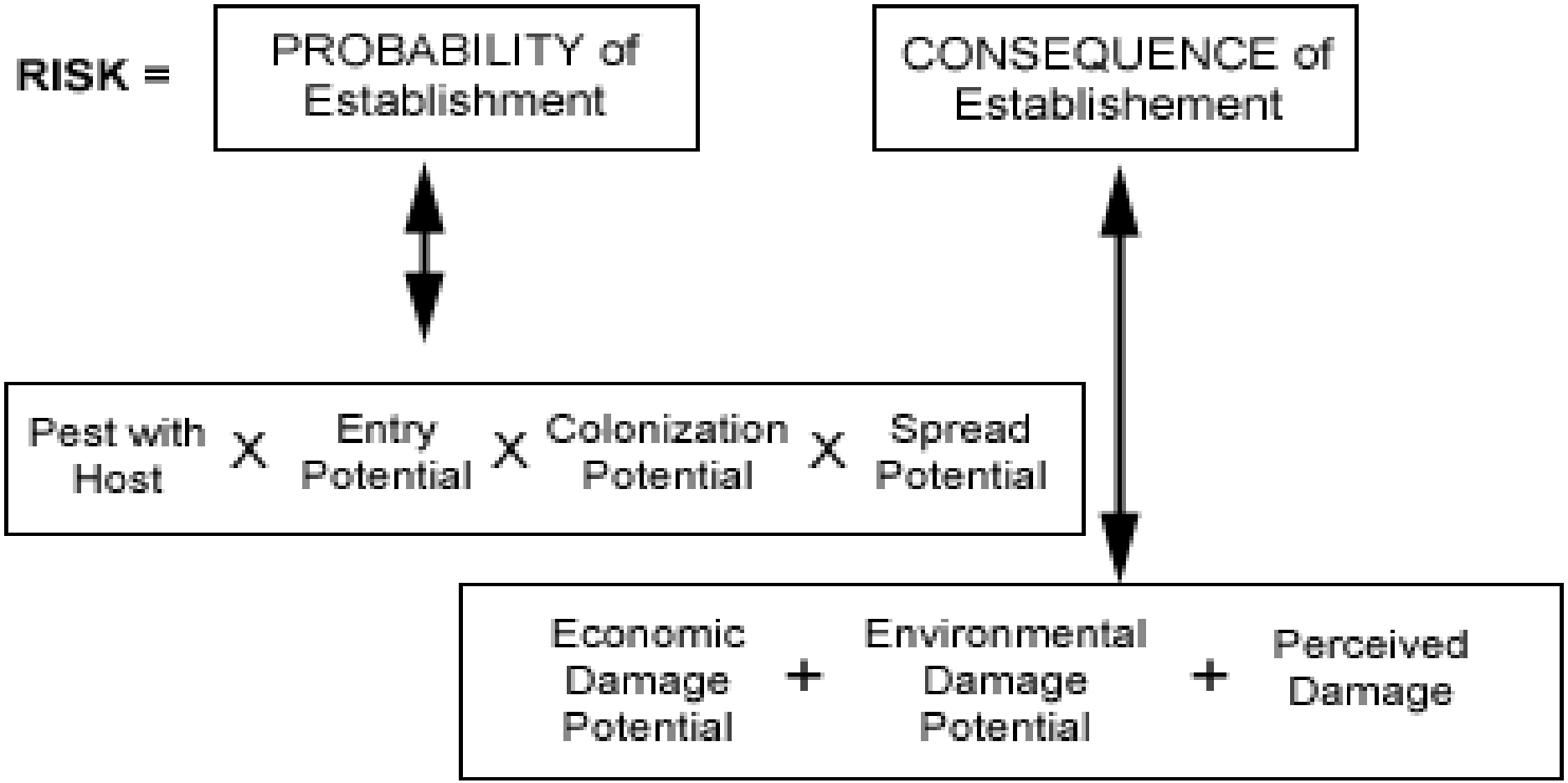
Food Additive Safety Assessment

Although different organizations might describe the steps a little differently they are essentially these:

- Identify the substance of potential concern
- Undertake toxicity studies of substance if needed
- Determine "No Observed Adverse Effect Level" (NOAEL)
- Select safety factor or uncertainty factor to extrapolate results from animals to humans
- Calculate Acceptable Daily Intake (ADI)
- Calculate Estimated Daily Intake (EDI) of substance
- Compare EDI and ADI

Pest Risk Assessment

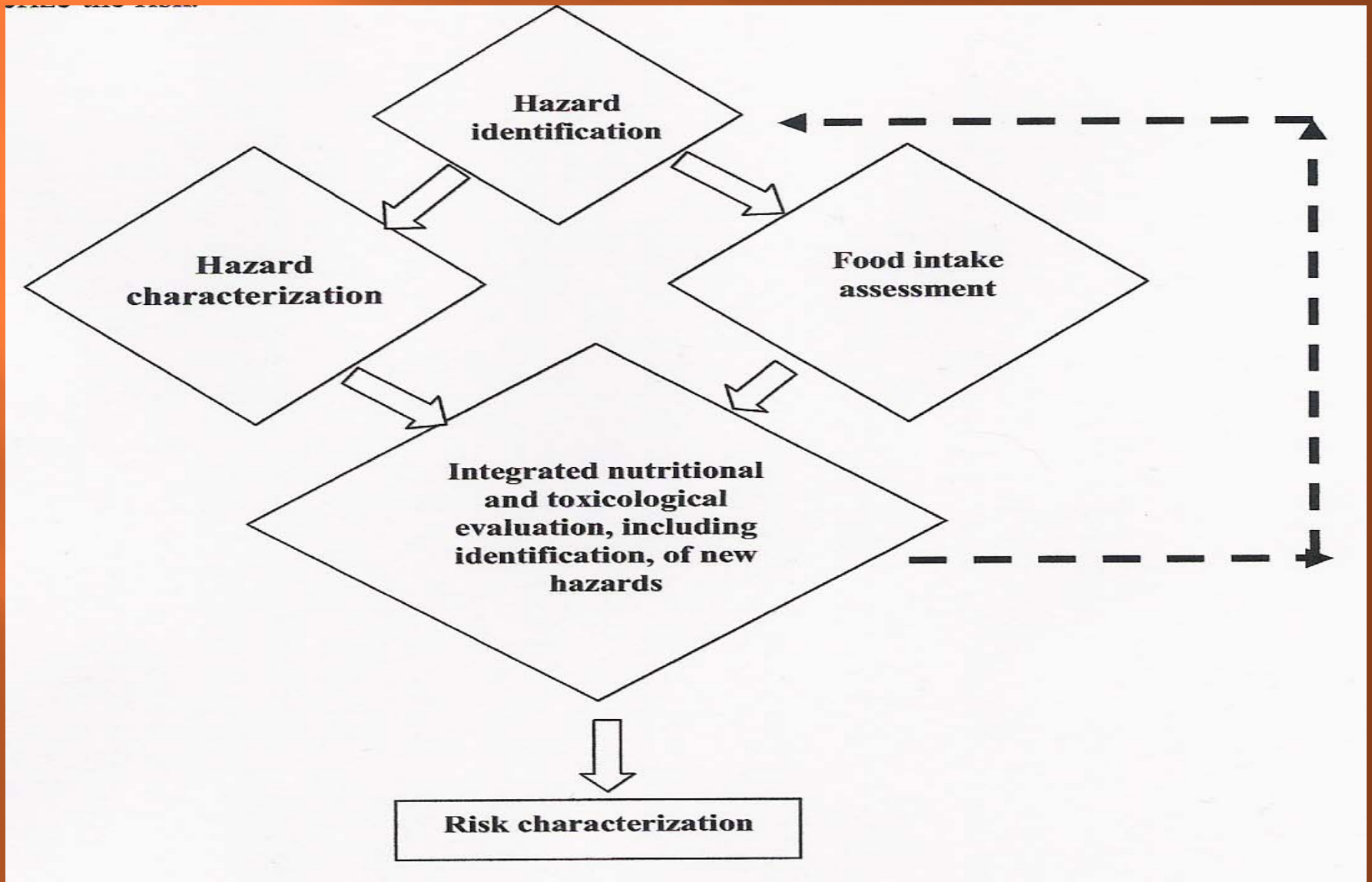
Pest Risk Assessment Model



Safety assessment of foods derived from GM animals

- Comparative safety assessment
- Hazard identification and characterization
  - Molecular characterization
  - Safety of the gene product
  - Allergenicity
  - Gene transfer
  - Unintended effects
- Food intake assessment
- Integrated toxicological evaluation
- Integrated nutritional evaluation
- Risk characterization

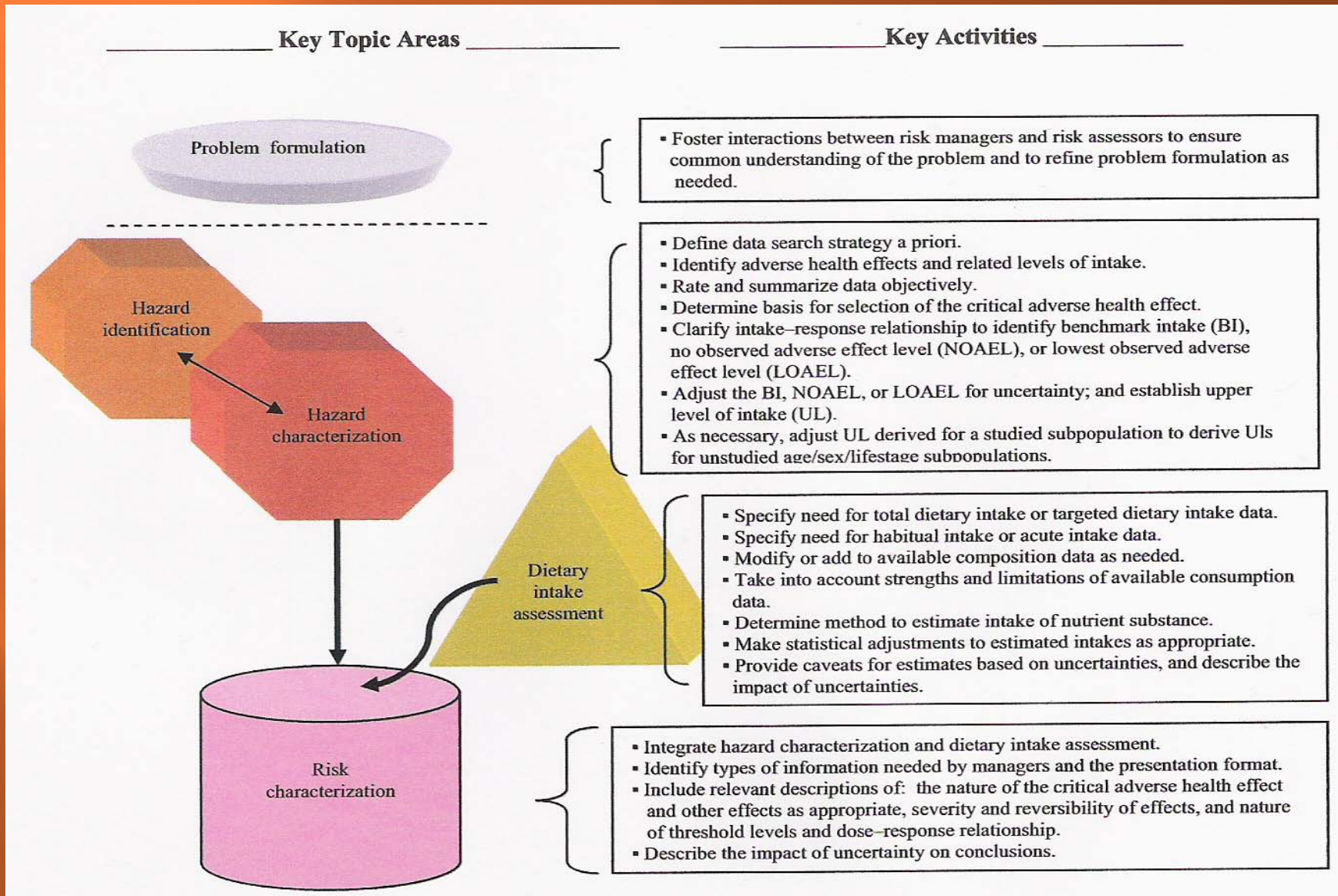
Safety assessment of foods derived from GM animals



Nutrient risk assessment

- Nutrient hazard identification and characterization
  - identify adverse health effects associated with intake
  - select the critical adverse health effect
  - establish ULs after taking into account uncertainties
  - characterize the hazard and identify vulnerable subgroups
- Dietary intake assessment
  - specifying the type of dietary intake assessment
  - using composition data
  - using consumption data
  - estimating intake
  - dealing with uncertainties
  - reporting the dietary intake assessment
- Nutrient risk characterization

Nutrient risk assessment

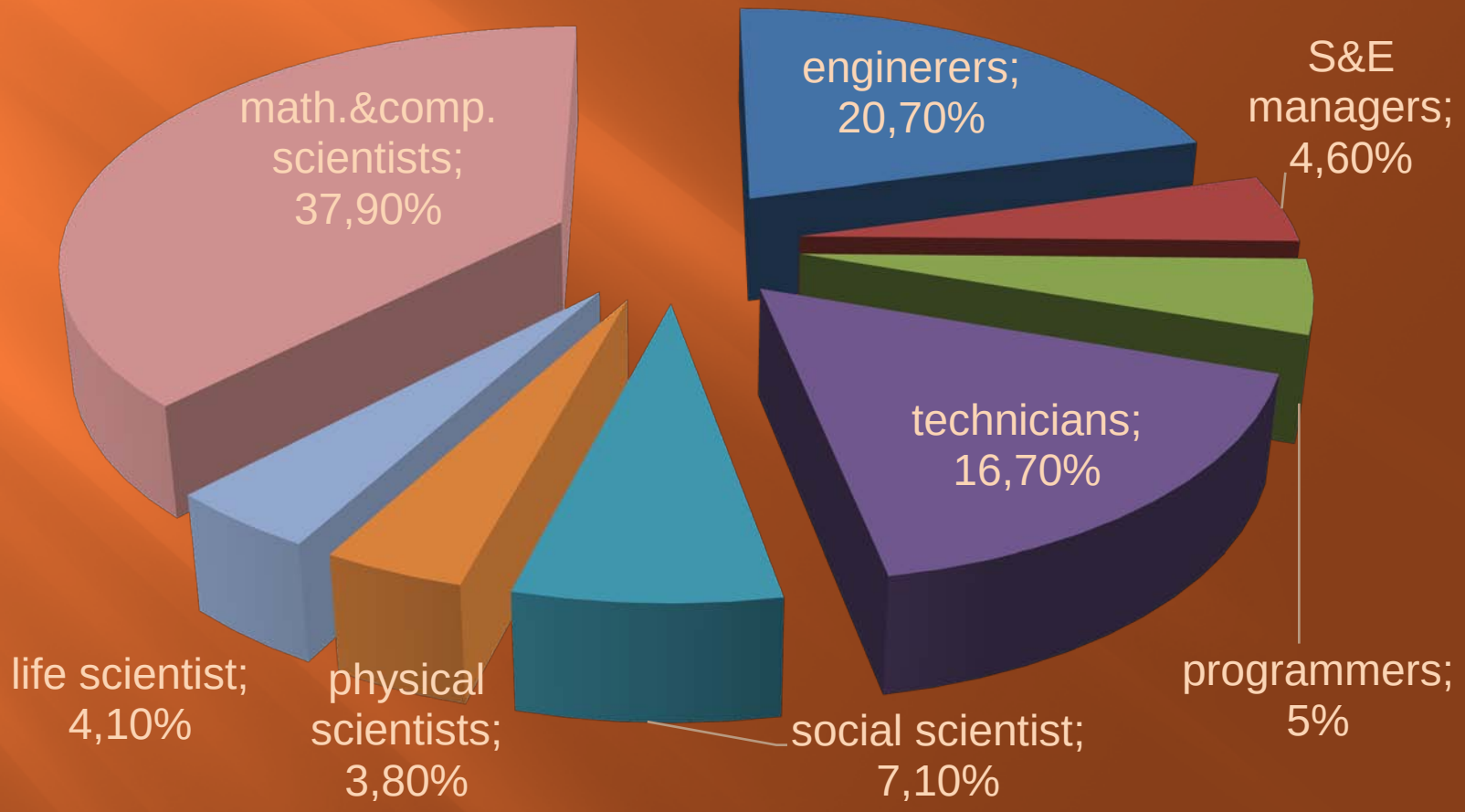


World science

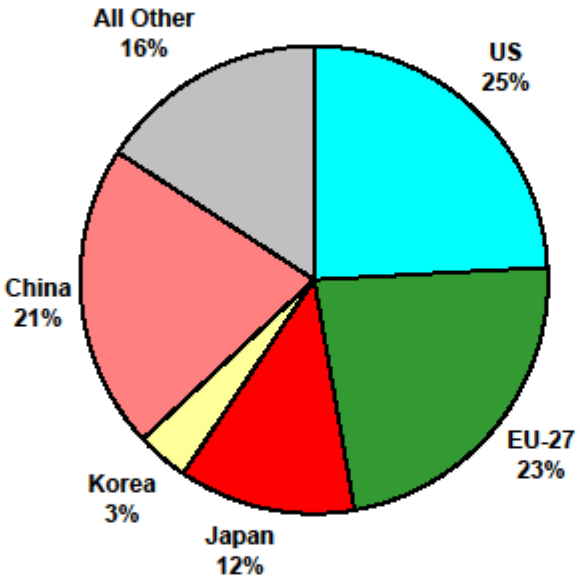
Science/United States

Employment in Science & Engineering occupations in the United States reached an estimated 5,781,000 by May 2008.

Employment distribution across science and technology occupations: 2008



Shares of World* S&E Researchers, 2006



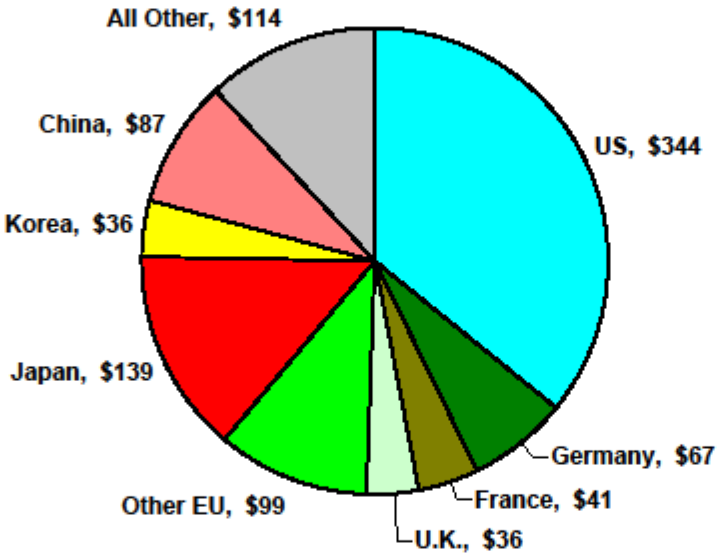
Total World * S&E Researchers (FTEs) = 5.8 million **

* World = OECD members plus Argentina, China, Romania, Russia, Singapore, Slovenia, South Africa, Taiwan. Does not include India.

Source: OECD, Main Science and Technology Indicators, 2008.
2006 data or latest year available.
* *- calculated using full-time equivalents.

AAAS

Shares of Total World R&D, 2007*



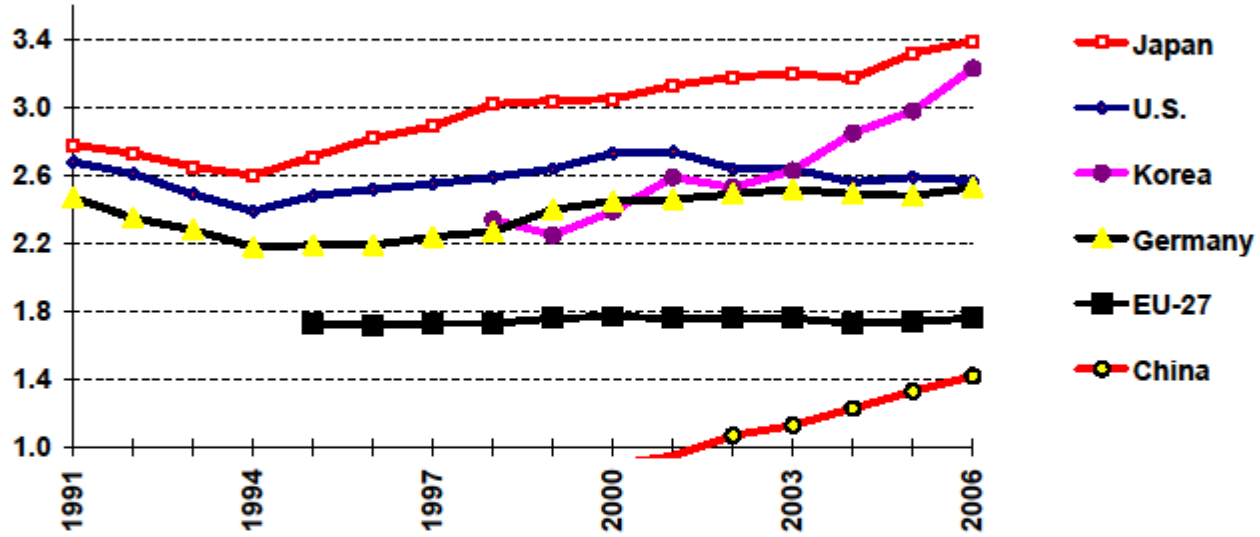
Total World R&D = U.S. $962 billion**

* World = OECD members plus Argentina, China, Romania, Israel, Russia, Singapore, Slovenia, South Africa, Taiwan. 2007 or most recent year available.

Source: OECD, Main Science and Technology Indicators, 2008.
2007 data or latest year available.
* *- calculated using purchasing power parities.

AAAS

Total National R&D as % of GDP, 1991-2006



Source: National Science Foundation, National Patterns of R&D Resources and OECD, Main Science and Technology Indicators. Data not available for all nations for all years. AUGUST '08 © 2008 AAAS

AAAS

Science/EU

- 1992: The Maastricht Treaty enlarges the EU's role in promoting research and technological development.
- 2000: Lisbon Summit in March; European Union should aim to become the world's most competitive and dinamic knowledge-based economy by 2010.
- The competition is tough: at present, the United States and Japan each spend more on R&D than the EU and its member states.
- Research and new technologies have a vital role to play in achieving this goal and in guaranteeing the future prosperity of Europeans.
- Research is an investment in our future well-being.
- Creation of a European research area (ERA)

Science/EU

- As early as 1992, it funded over 3 200 projects worth €93 million to ensure that their valuable scientific potential and expertise did not suffer.
- European Union's involvement in research:
  - the sixth framework programme
    - It runs from 2002 to 2006 and has a budget of €17.5 billion over the full period
  - The seventh framework programme
    - It runs from 2007 to 2013 with funding to around of €53 billion (up to €54 billion)

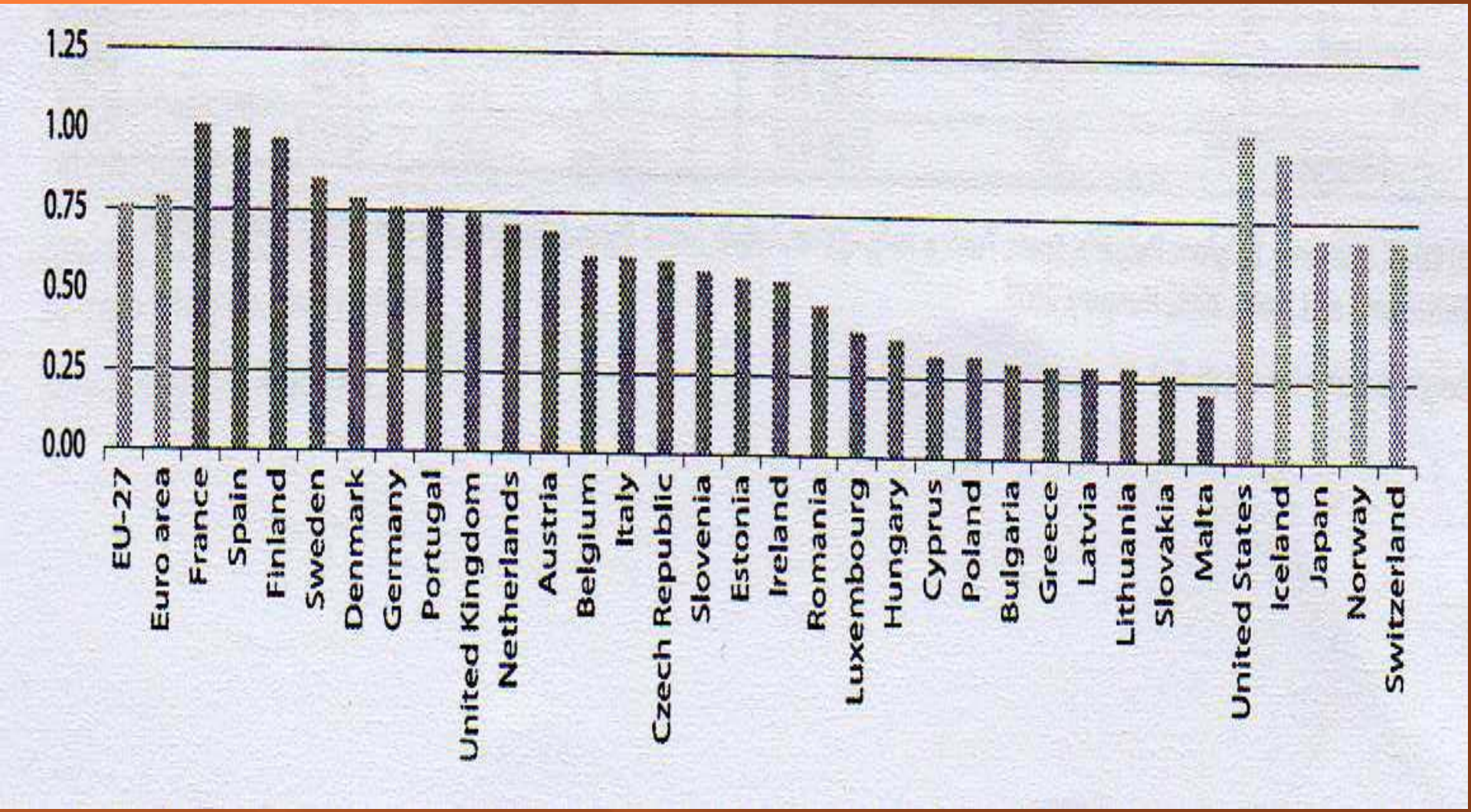
EUROSTAT YEARBOOK 2009

- Education is seen as a key to developing an innovation-orientated society
- Students studying in secondary and post-secondary non-tertiary education (2006) (EU-27: 3.282.000)
- Students studying creative or innovative subjects in tertiary education (2006) (EU-27: 18.775.000)

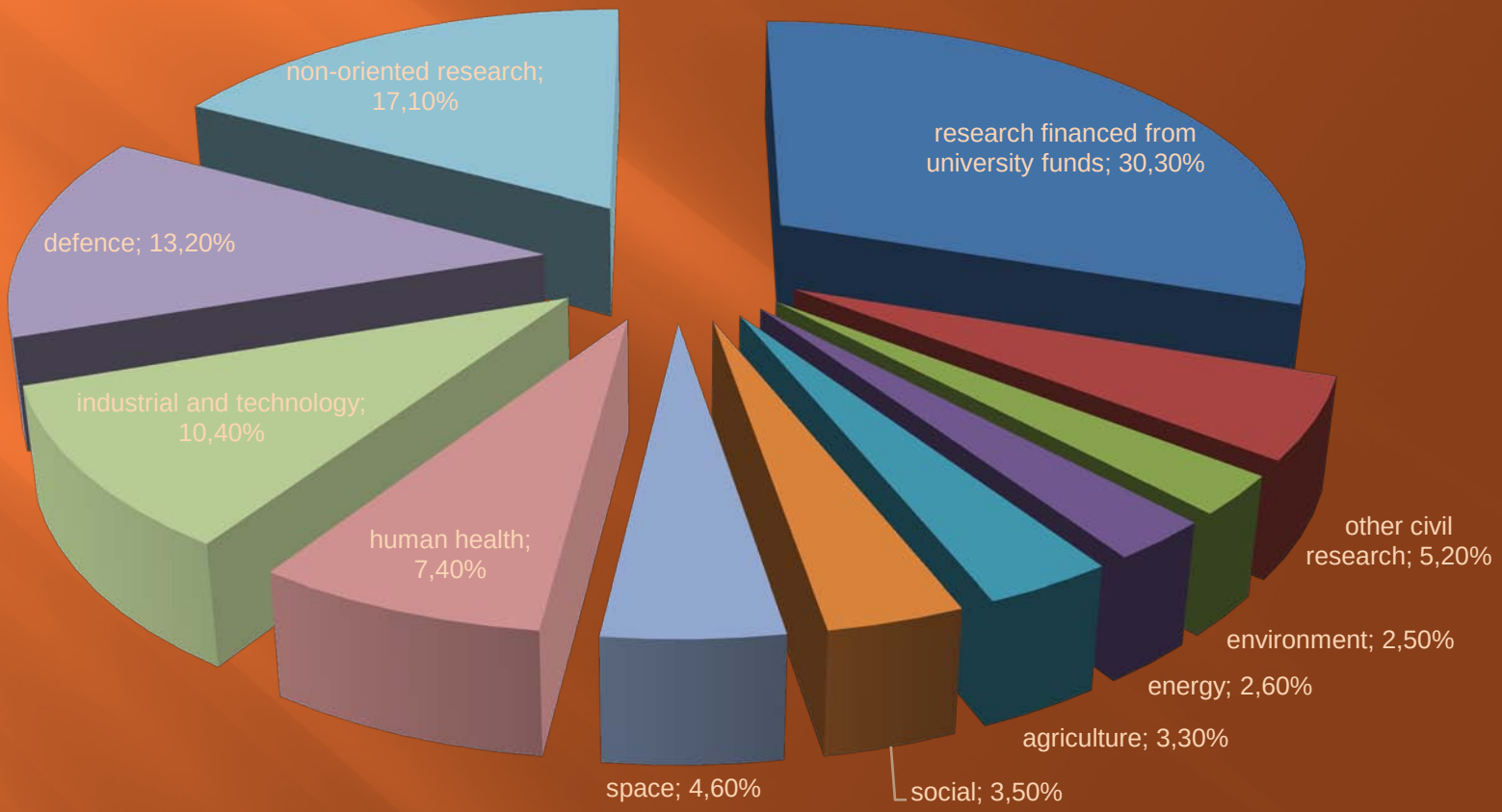
EUROSTAT YEARBOOK 2009

- Research and development
- Increased levels of research and development
- (R & D) expenditure are seen as one means to achieve the goals set out in 2000 by the European Council in Lisbon: in 2002 a target that investment in R & D should reach 3 % of GDP by 2010 was set.
- Government budget appropriations or outlays for research and development (EU-27: 87.840 mil.;178,2 € per inhabitant)(2007)
- Research and development expenditure, (EU-27: 213.127 € mil.;432,3 € per inhabitant)(2006)

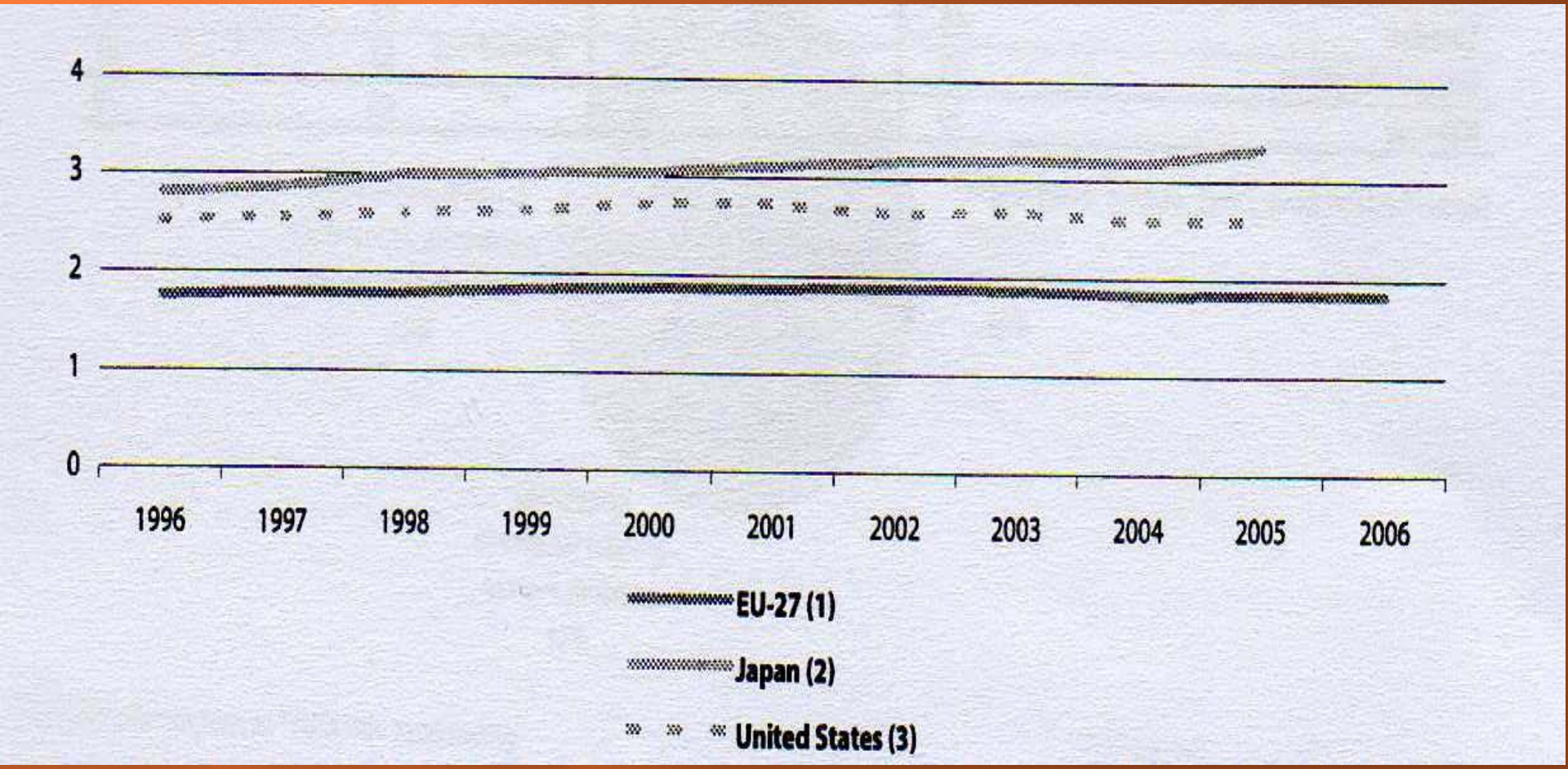
Government budget appropriations or outlays for research and development, 2007 (% share of GDP)



Socio-economic objectives of government budget appropriations or outlays for research and development, EU-27, 2006 (% share of total)



Gross domestic expenditure on research and development (% share of GDP)

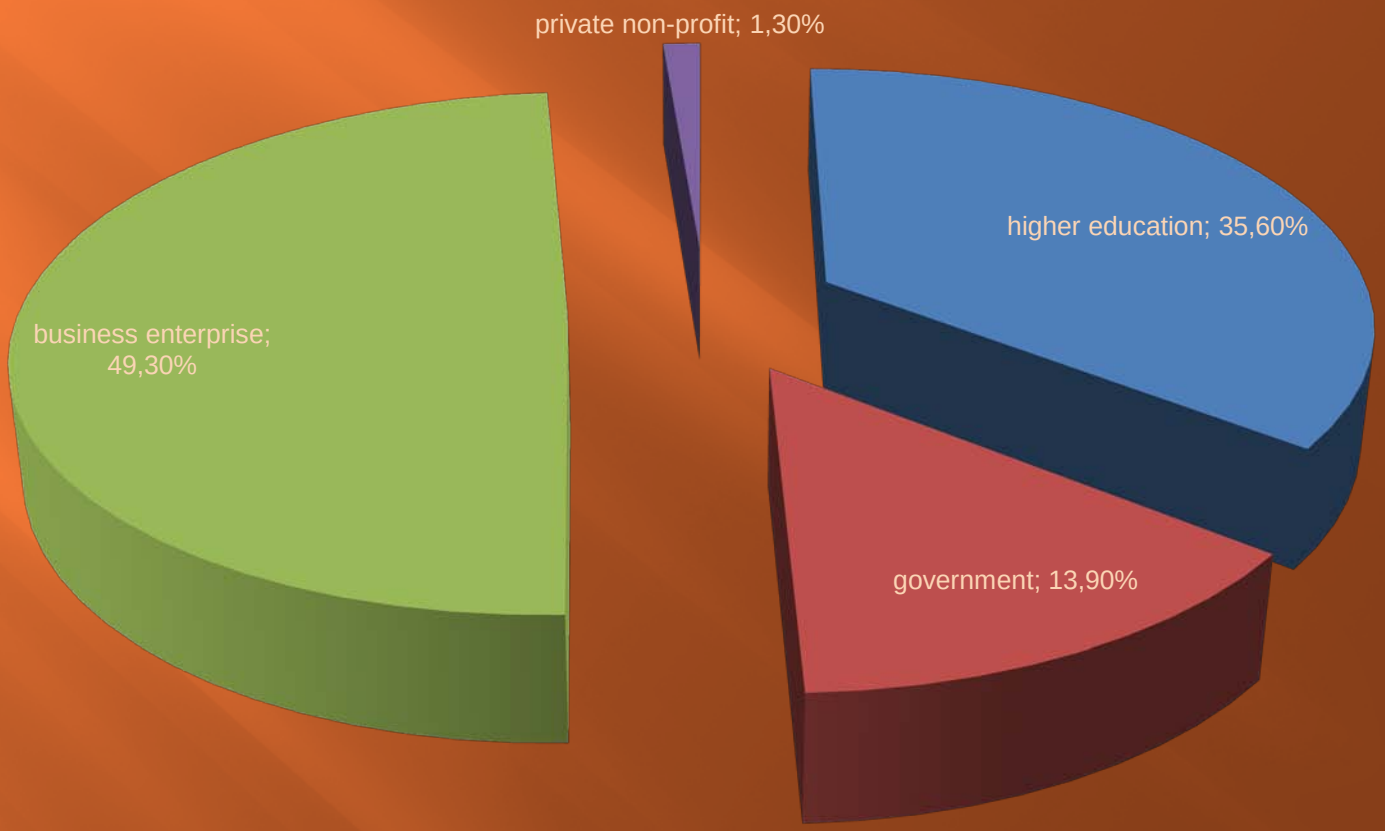


EUROSTAT YEARBOOK 2009

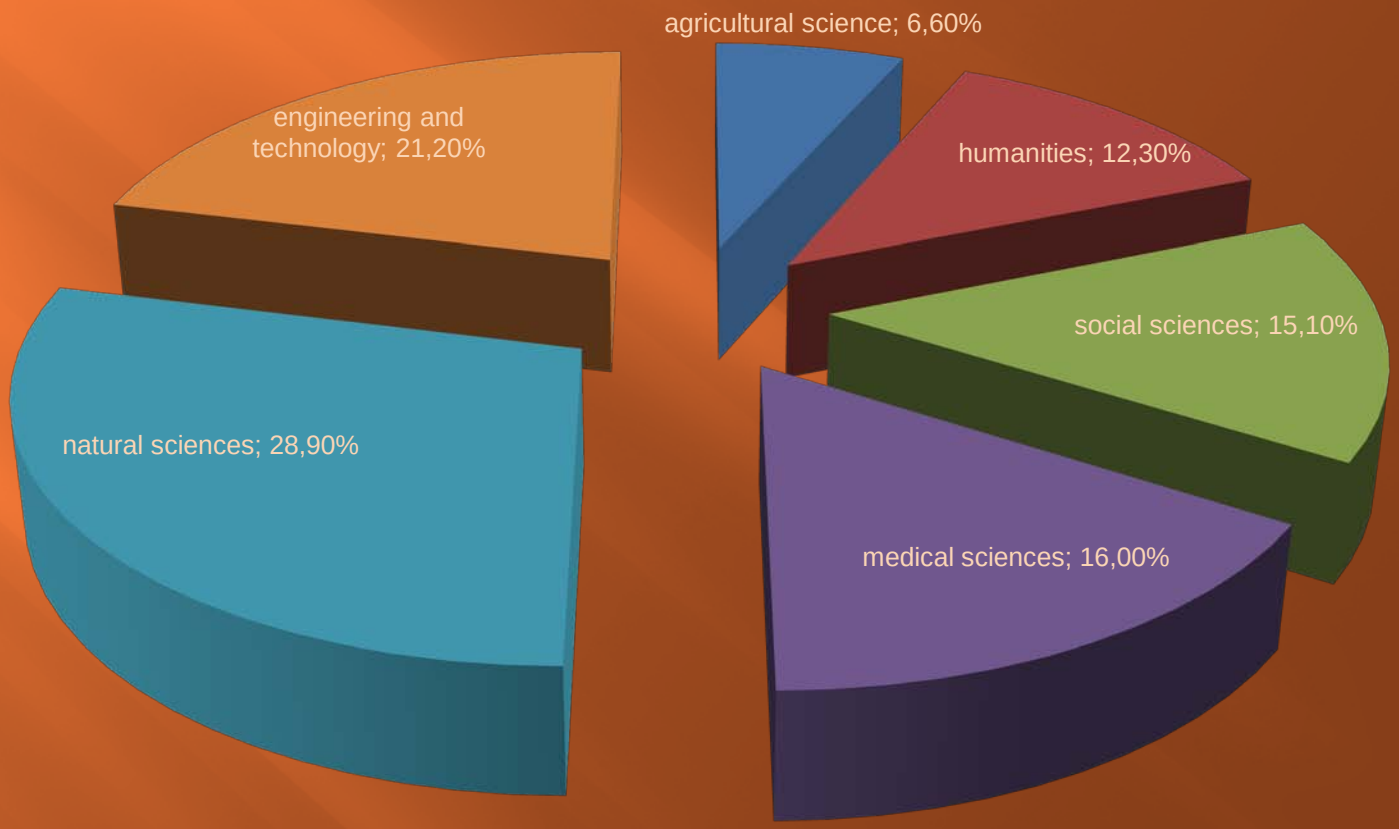
- Science and technology personnel
- The European Commission has placed renewed emphasis on the conversion of Europe's scientific expertise into marketable products and services, while also focusing on improving the mobility of

  European researchers, encouraging networks between researchers from different Member States.
- Science and technology personnel(EU-27:3.112.600)
- Researchers (EU-27: 1.891.100)(2006)

Researchers, EU-27, 2006 (% breakdown by sector of performance, based on full-time equivalents)



Government and higher education researchers, EU, 2006 (% breakdown by field of science, based on full-time equivalents)

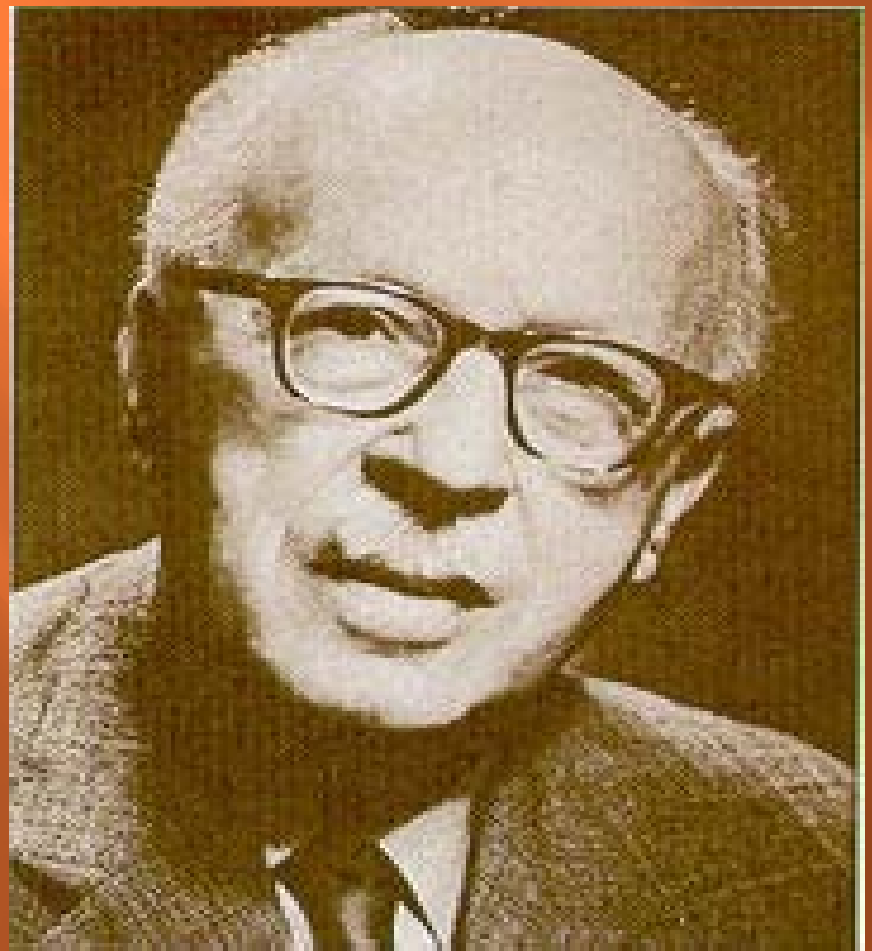


Science in Croatia

- Ancient history
  - application and only empirical knowledge
  - can not be considered as scientific work
- Middle ages
  - structured education in the monasteries
  - Croats, studying and working abroad
- Modern age
  - 16. c.
    - Nikola Nalješković, Nikola Gučetić, Nikola Sagroević, Andrija Dudić, Franjo Petrić-Patricius
  - 17. c.
    - Marin Getaldić, Marko Antun Dominis, Faust Vrančić, Santorio Santorio, Ivan Lučić, Stjepan Gradić
  - 18. c.
    - Ruđer Bošković, Ivana Luka Zuzorić, Benedikt Staya, Šimun Stratik, Ivan Paskvić, Josip i Ljudevit Mitterpacher, Josip Franjo Domin, Franjo Bruna, Mirko Danijel Bogdanić, Mihaela Lipšić, Ferdinand Konščak, Ignacije Szentmartony, Mijo Šiloboda Molšić, Mate Zoričić, Matija Katančić, Ivan Krstitelja Lalanguea, Matija Antun Relković
  - 19.c.
    - Ivan Paskvić, Šimun Stratik, Franjo Klohammer, Šimun Čučić, Robert Visiani, Grgur Bučić

Science in Croatia

LAVOSLAV RUŽIČKA
1887. – 1976.



VLADIMIR PRELOG
1906. – 1998.

Science in Croatia – today (2008)

- Lisbon strategy
  - Policy of increasing investments into research and development
  - Increase of funds for research and development in individual member countries, as well as achieving the goal of 3% GDP allocation at EU level

Science in Croatia

- The R&D and higher education sector

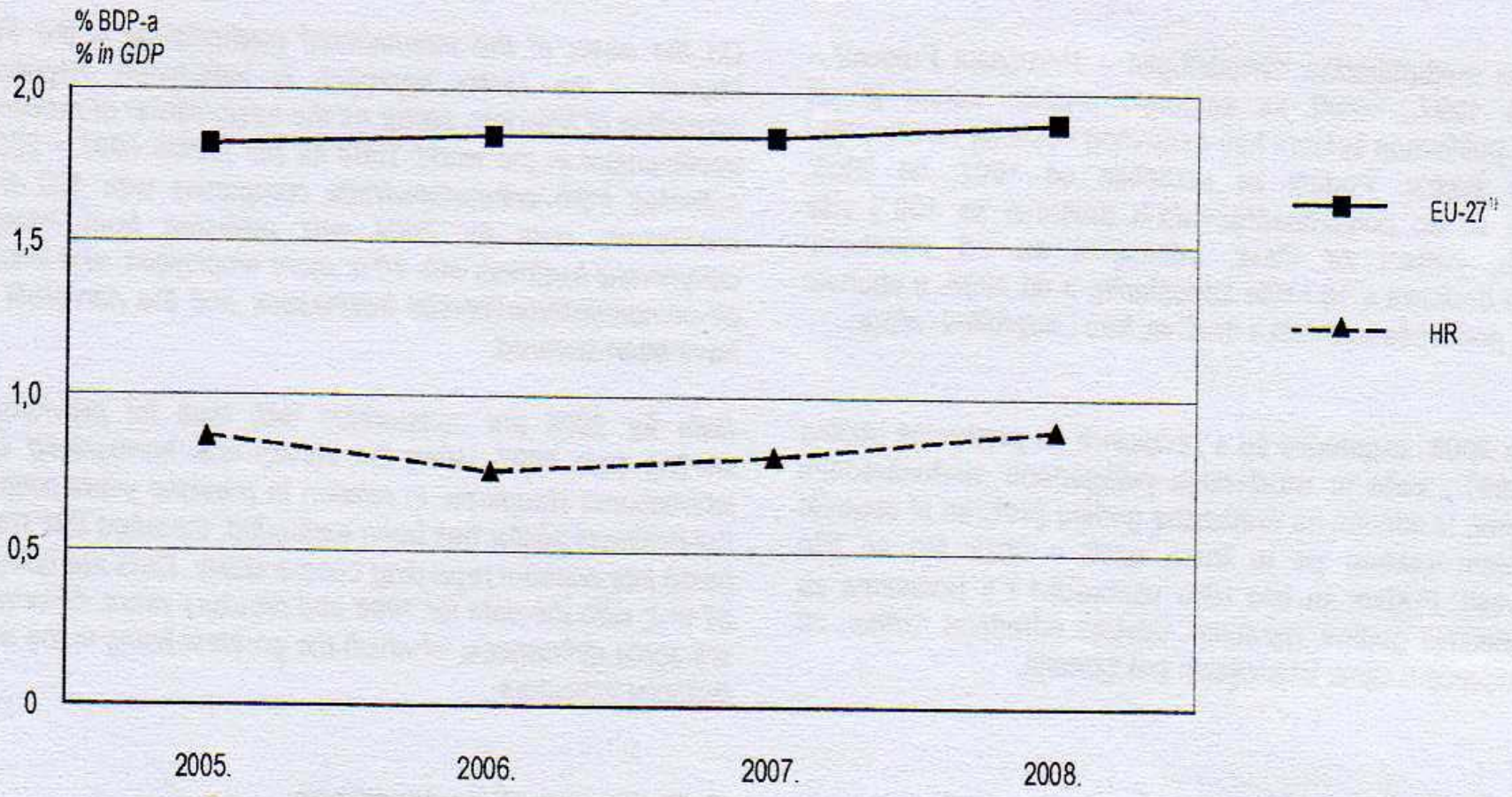
  - 26 public institutes
  - 13 private scientific institutions
  - 6 technology and research and development centers
  - 11 research centers in industry
  - 1 military research center

  - 7 universities
  - 16 public colleges ans polytechnics
  - 16 private colleges and polytechnics

Science in Croatia

- 15.755 persons in research and development (biotechnical science: 1.597)
- Researchers 10.767
  - (biotechnical science: 878)
- 10.567 published research works
  - (15,9% biotechnical science)
- Gross domestic expenditure (3.073.965.000 kuna)
  - (biotechnical science 295.305.000 kuna)
- Legal entities in R&D: 205
  - (biotechnical science: 28)

Gross domestic expenditure for R&D (as share in GDP)

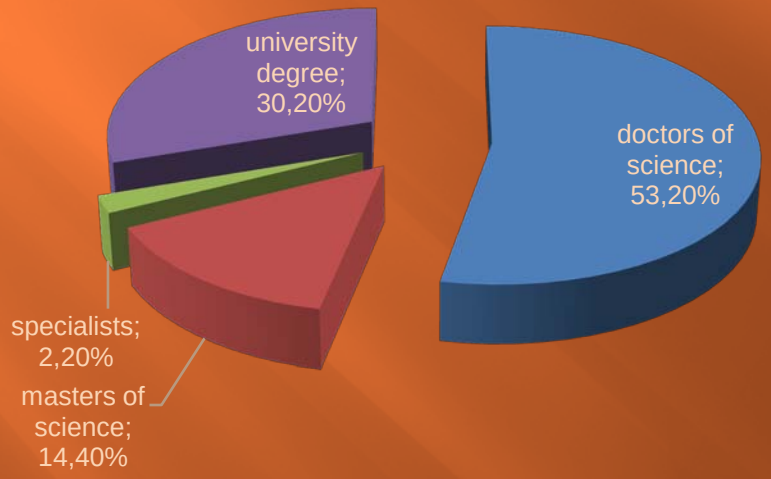


Science in Croatia

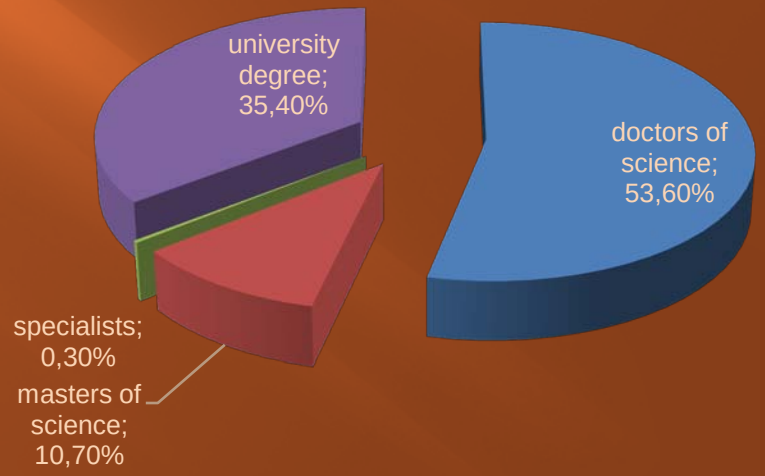
- Science and higher education
- Main goals:
  - Increasing investments into research and development, and their efficiency
  - Restructuring Croatia's science system
  - Strengthening cooperation between science, government and industry in the creation of new knowledge and goods
  - Increasing participation of Croatian scientists and other bodies in EU Framework Programmes

Researchers in full-time and part-time employment by academic degree

TOTAL



BIOTECHNICAL SCIENCES



Projects supported by MSES

- Sources of fundus for R&D
  - (own resources, government, private and public enterprises, non-profit institutions, foreign investors)

PERIOD	Biotechnical sciences (No. of projects)
1990-1995	127
1996-2002	131
2002-2005	no data
2007-	57 projects, 39 programmes

efsa
European Food Safety Authority

Risk assessment

World Health Organization

Food and Agriculture Organization of the United Nations

U.S. Department of Health and Human Services
Food and Drug Administration

Risk assessment FAO/WHO

- Microbiological risks publications: 34
- Chemical risks publications: 20
- Biotechnology (GM foods) publications: 21
  - risk assessments, characterisations, exposure assessment, hazards, guidelines, meeting reports, workshops, discussion papers, sessions, strategies

Risk assessment in EU - EFSA

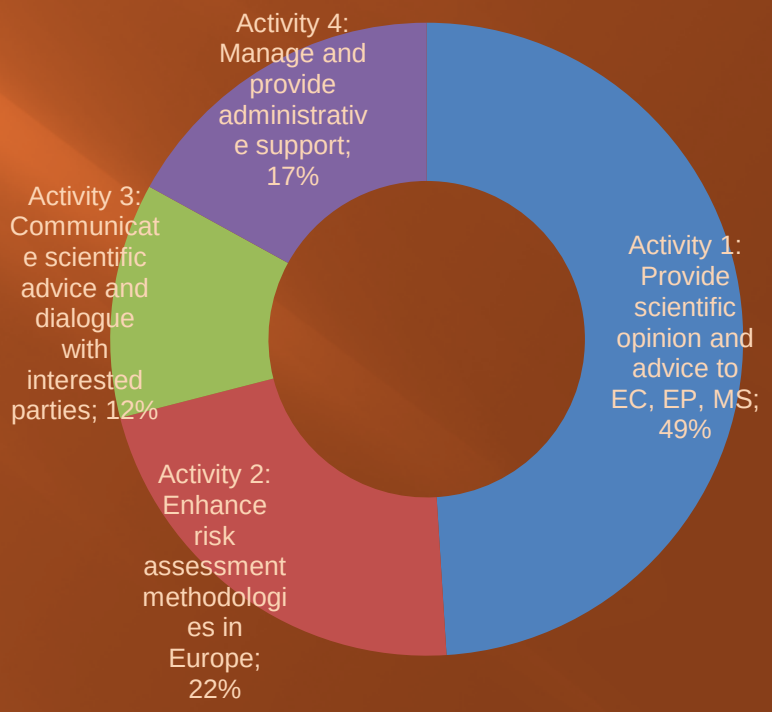
- Mission
  - provide the best scientific advice to ensure the safety of Europe’s food and feed chain
- December 2008, EFSA`s Strategic Plan 2009-2013
  - ensuring that public health is fully protected and consumers can trust Europe’s food safety system
  - Six objectives
    - Positioning EFSA at the forefront of risk assessment methodologies and practices in Europe and internationally.

from EFSA annual report 2008

FACTS

- 395 staff with 63% engaged in scientific activities
- Budget 66,4 mil. € (47% represent personnel expenses)
- over 1,200 external experts,
- 30 national food safety agencies
- nearly 400 national scientific organisations
- establishment of **Focal Points** in all 27 Member States
- Total scientific outputs:489
- Public consultations:38

BUDGET BY ACTIVITY



Risk assessment in Craotia - CFA

Risk assessment in Craotia - CFA

- Scientific opinions and recomendations done on request of MAFRD (9) ili MHSW (4)
- Scientific opinions and recomendations done on own iniciative (20)

CFA - tommorow

- Znanstvena studija o analizi i procjeni rizika od prehrambenih aditiva na hrvatskom tržištu
- Znanstvena studija vezana za procjenu rizika od mikotoksina u hrani za životinje – raspisan natječaj
- Znanstvena studija o procjeni rizika od teških metala u mesu divljači na zdravlje potrošača
- Znanstveni projekti:
  - Toksični i esencijalni teški metali u zrnu pšenice na kiselim i karbonatnim tlima RH
  - Mikotoksini u pšenici uskladištenoj u Slavoniji i Baranji
  - Mikotoksini u tipovima kukuruza namijenjenim ljudskoj prehrani

FOOD ADDITIVES SAFETY ANALYSE AND ASSESSMENT

- Country: CROATIA
-
- *Project Name*: Croatia Agricultural Acquis Cohesion Project (CAACP)
-
- *Loan No.: 7360 HR*
-
- *Source of financing*: Loan funds (International Bank for Reconstruction and Development (IBRD))

FOOD ADDITIVES SAFETY ANALYSE AND ASSESSMENT

- Objective

  The objective of this survey is to improve the safety of food in Croatia regarding food additive consumption through balance sheet data collection and estimation based on production and foreign trade, consumption habits and chemical analysis.

- Aim

  The aim of this survey is to identify the most frequently used food additives in various types of food in order to assess their amounts, which combined daily do not exceed acceptable daily intakes. The food additive safety assessment procedures definitely do not assess the risks of an additive. Instead, they identify a level considered safe for the population. In a sense, then, risks are managed rather than explicitly assessed with this technique. This does not make food additive safety assessment a lesser kind of assessment. The survey will design needs for database which will receive and provide structured reporting formats for further assessment.

FOOD ADDITIVES SAFETY ANALYSE AND ASSESSMENT

- Beneficiaries
  - Croatian Food Agency
  - Institute of public health
  - Croatian central bureau of statistics
  - Croatian chamber of economy
  - Ministry of health and social welfare
  - Ministry of Agriculture, Fisheries and Rural Development
- Tasks
  - Hazard identification
  - Hazard characterization (Dose-response assessment)
  - Exposure assessment
  - Risk characterization

FOOD ADDITIVES SAFETY ANALYSE AND ASSESSMENT

- Phase 1:
  - In order to determine if food additive can become a health hazard to the typical consumption or exposure of consumers, must be estimated its presence through hazard identification. It will be obtained by collecting data.
- Phase 2:
  - It will be possible to estimate the most frequent foods or food groups which contain previously ranged food additives. In order to determine food additive quantity, in these steps will be maintained laboratory testing using specific analytical methods.
- Phase 3:
  - By summarizing data on data consumption and results of analytical testing it will be possible to calculate estimated daily intake (EDI). Based on ADI/EDI quotient, will be possible to make ranking of food additives.

Croatian scientific bibliography risk analysis

Author's books (25)
Editor's books (8)
Book chapters (12)
Textbooks and scripts (7)

Journal articles and review articles in CC journals (5)
Scientific papers in other journals (88)
Non-scientific papers in other journals (60)
Conference reports (abstracts) in other journals (15)
Papers in the publishing process (13)

Plenary/Keynote talks (5)
Published invited lectures (12)
Scientific conference papers with international peer-review (8)
Other refereed conference papers with peer-review (44)
Conference papers withouth peer-review (8)
Abstracts in Book of abstracts (133)

Unpublished papers (9)
Dissertations (111)
Master thesis (72)
Graduation thesis (47)

Other papers (42)

Croatian scientific bibliography risk assessment

Author's books (16)
Editor's books (5)
Book chapters (21)
Textbooks and scripts (5)

Journal articles and review articles in CC journals (2)
Scientific papers in other journals (58)
Nonscientific papers in other journals (62)
Conference reports (abstracts) in other journals (13)
Papers in the publishing process (10)

Plenary/Keynote talks (7)
Published invited lectures (10)
Scientific conference papers with international peer-review (11)
Other refereed conference papers with peer-review (32)
Conference papers withouth peer-review (9)
Abstracts in Book of abstracts (104)

Unpublished papers (8)
Dissertations (56)
Master thesis (41)
Graduation thesis (45)

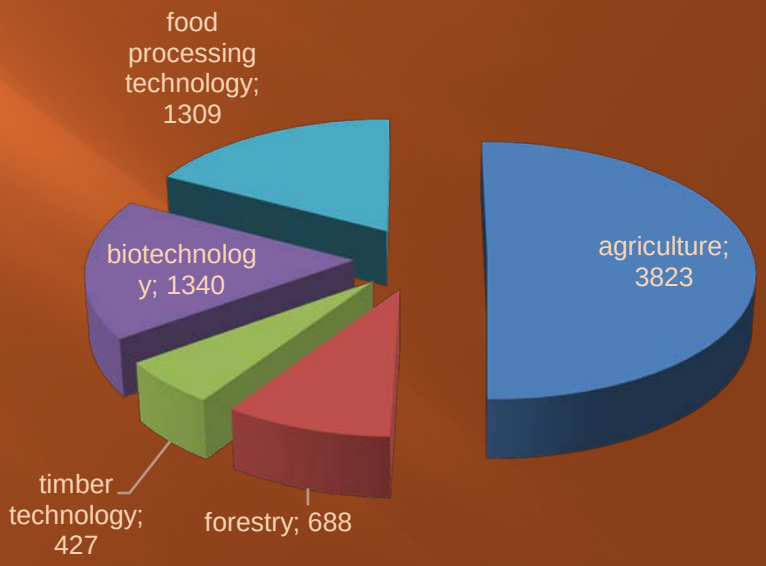
Other papers **(28)**

Sectors/Scientific fields

272.970 PAPERS

- Life science
- Engineering
- Biomedicine and health
- Biotechnical sciences
- Social scienzes
- Humanities
- Artistic field
- Interdisciplinary field of science

BIOTECHNICAL SCIENCES (7.587 PAPERS)



Biotechnical science risk analysis/risk assessment

- Interactions between dietary habits and complex phenotipic traits of inhabitants of the island of Vis (book)
- Overview of the official control results of feed for the purpose of risk identification (professional paper)
- Risk analysis and investment in horticulture (summary, book of abstracts)
- Arsenic occurrence in eastern Croatia drinking water (summary)
- Distribution of PCB congeners in human milk (book of abstracts)
- Interaction between dietary habits and complex phenotipic traits of inhabitants of the island of Vis (dissertation)
- Aspartame safety assessment in relation with acceptable daily intake (master thesis)
- The daily dietary intake of dietary fibre and iron as determined using the recall method (graduation thesis)

Biotechnical science risk analysis/risk assessment

- More does not mean better. An approach to the toxicological risk assessment of heavy metals lead and cadmium and herbicides linuron, fluazifop-p-butyl, and cycloxydim in dry true chamomile (*Chamomilla recutita* L. Rauschert) (scientific paper)
- Utjecaj prehrane ribom na opterećenje živom i procjena rizika u žena generativne dobi (book of abstracts)
- Nutrition and hidden salt content in school children meals-cardiovascular diseases risk factors (book of abstracts)
- Evaluation of daily calcium intake with validated q-ffq in women (book of abstracts)
- Radon in bottled waters produced in Croatia (graduation thesis)
- Radon in water sampled at water pipes and springs in Požega-Slavonia County (graduation thesis)
- 1.5. Level and impact of contamination in the urban "hot spot" areas Biomarkers of pollution 1.5.1. Systematic determination of metallothioneins in the digestive gland of Mytilus galloprovincialis (annual project report)

Croatian scientific bibliography risk analysis – biotechnical sciences

Author's books (1)

Nonscientific papers in other journals (1)

Other refereed conference papers with peer-review (2)

Abstracts in Book of abstracts (1)

Unpublished papers (1)

Graduation thesis (2)

Other papers (1)

Croatian scientific bibliography risk analysis – biotechnical sciences

- Risk Analysis in Veterinary Economics (book)
- Risk analysis in the production of freshwater fish (professional paper)
- Risk analysis of the introduction of Avian influenza virus to Croatia (proceedings)
- Ornithological knowledge for preliminary risk assessment of avian influenza (H5N1): the implementation of the European model in Croatia (scientific paper)

Croatian scientific bibliography
risk assessment – biotechnical sciences

- Scientific papers in other journals (2)
- Nonscientific papers in other journals (2)
- Conference reports (abstracts) in other journals (1)
- Papers in the publishing process (1)
- Other refereed conference papers with peer-review (1)
- Dissertations (1)
- Graduation thesis (3)
- Other papers (1)

Croatian scientific bibliography risk assessment – biotechnical sciences

- Puževi golaći u ratarskim kulturama-procjena rizika i mjere suzbijanja (scientific paper)
- Risk assessment of mosquito born deseases in relation to climate changes and introduction of exotic species (professional paper)
- Risk assessment against western corn rootworm *Diabrorica virgifera virgifera* LeConte in the Moslavina region (scientific paper)
- Risk assessment for biocidal products (proceedings)
- Risk assessment for Western Corn Rootworm in infested areas in 2004 (book of abstracts)
- Could hormesis be the main problem in ecological risk assessment of insecticides? (book of abstracts)
- Significance of variability of EROD induction in field experiments for risk assessment (book of abstracts)
- Risk assessment against western corn rootworm *Diabrorica virgifera virgifera* LeConte in the Moslavina region (graduation thesis)
- Risk assessment against western corn rootworm *Diabrorica virgifera virgifera* LeConte in the Bošnjak region (graduation thesis)

Instead of conclusions

In anticipation of:

- the beginning,
- realisation,
- the results

of first food additives risk assessment in Croatia

References

- http://www.who.int/foodsafety/publications/
- https://www.ippc.int/
- www.who.int/foodsafety/micro/riskanalysis/en/
- www.foodrisk.org/risk_analysis
- http://jifsan.umd.edu/
- www.fda.gov/Food/default.htm
- www.foodsafety.gov/index.html/
- www.nfs.gov/statistics/
- http://ec.europa.eu/
- http://cordis.europa.eu
- www.europa.eu.int
- www.efsa.europa.eu/
- www.dzs.hr
- www.mzos.hr/
- http://bib.irb.hr/

In the end ...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