New perspectives on safety:

Insights from EPAA's Platform on Science

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EPAA - An innovative and dynamic approach

The European Partnership on Alternative Approaches to Animal Testing

A cooperation between industry and the European Commission, joining forces for the promotion of the 3Rs and alternatives in regulatory testing:

- Services of the European Commission
- European trade federations, covering 7 sectors
- Individual companies, currently 39 in number

Open for participation by industry sectors and companies committed to the 3Rs and willing to share expertise

EPAA Principles and Values

- Science based improvement in implementation of 3Rs

- Consensus based approach between industry and authorities

- Pragmatic mechanisms and a workable structure

- Dialogue and transparency towards stakeholders and interested parties

- Commitment of partners to act in a coherent and consistent way

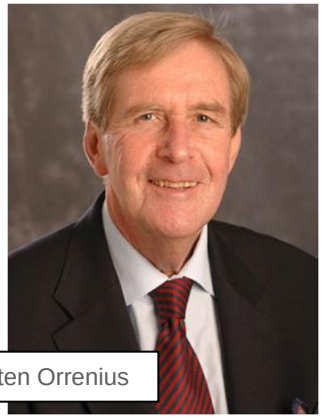
Main areas of EPAA activities

- How to get the best out of Research
- Streamlining Validation and Acceptance
- Improving Information and Dissemination

EPAA's Platform on Science: Bringing cutting edge science to:

- Follow up to New Perspectives on Safety workshop (2008)
- Involving scientists from groups previously unconnected with 'alternatives' and doing new way of science
- Development of integrated testing strategies to reduce animal numbers and ultimately replace animals in safety assessment
- Collaborative approach: academia (test developers), industry (test appliers), ECVAM (test validation) and regulators (users of test data)

New Perspectives on Safety
Brussels
April 2008

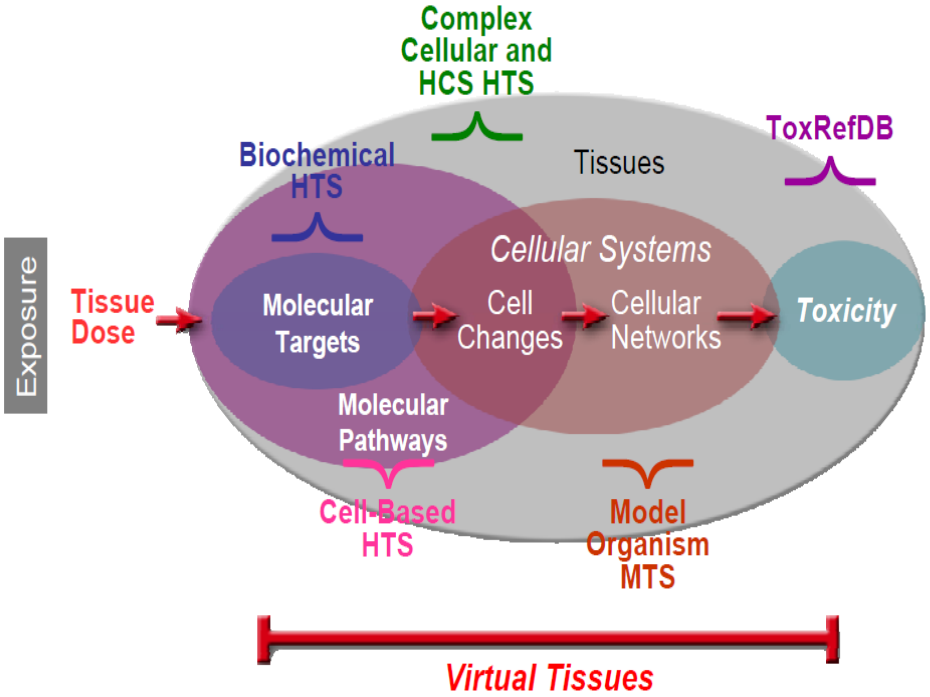


REMIT – The Exam Question

‘In a world without animals, how would we assess the potential of chemicals and drugs to cause adverse health effects in humans following repeated systemic exposure?’

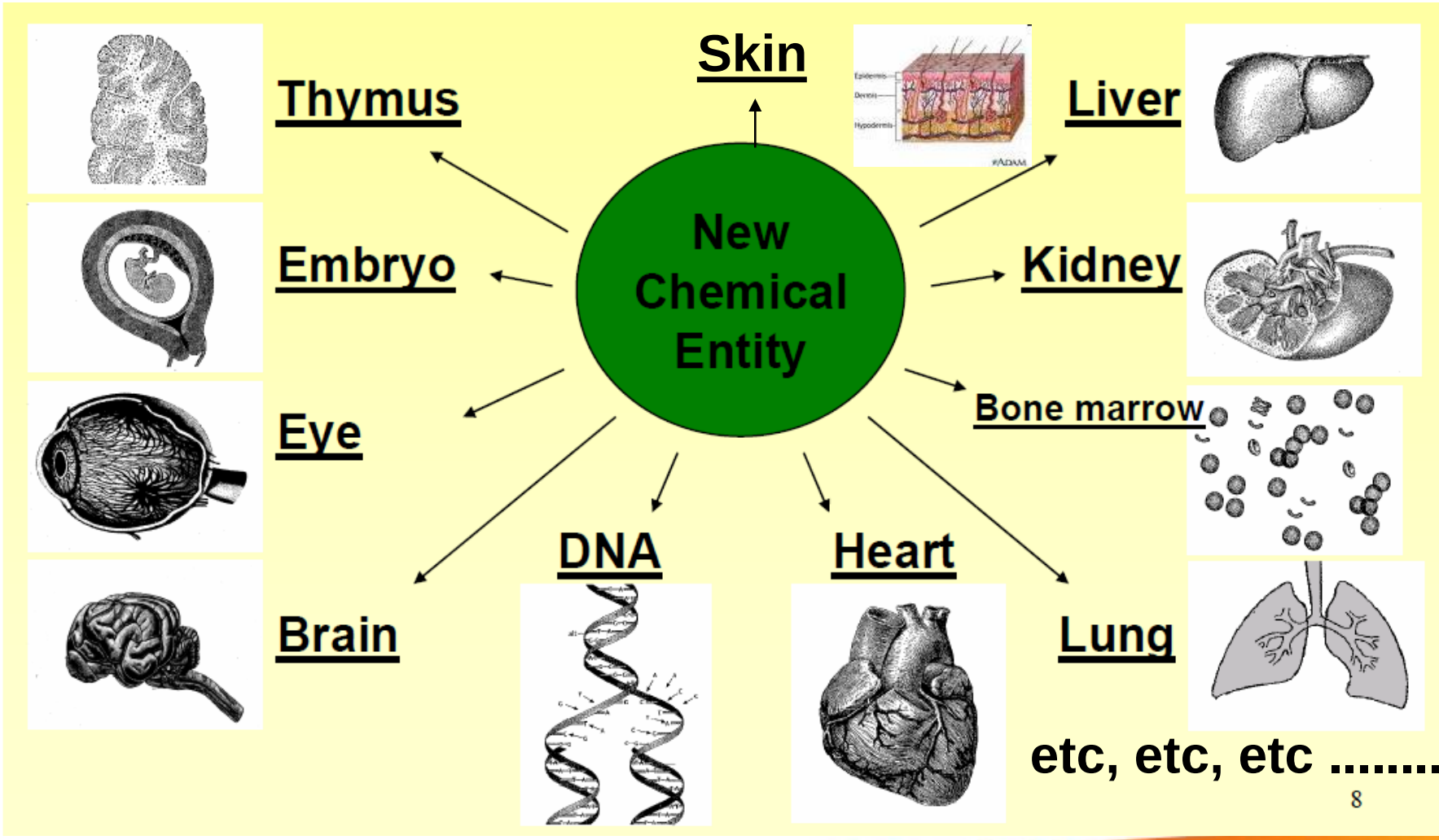
We must align the best that modern science and technology have to offer with the needs of toxicology and safety assessment

A grand challenge: Assuring safety in humans without toxicology studies in animals?

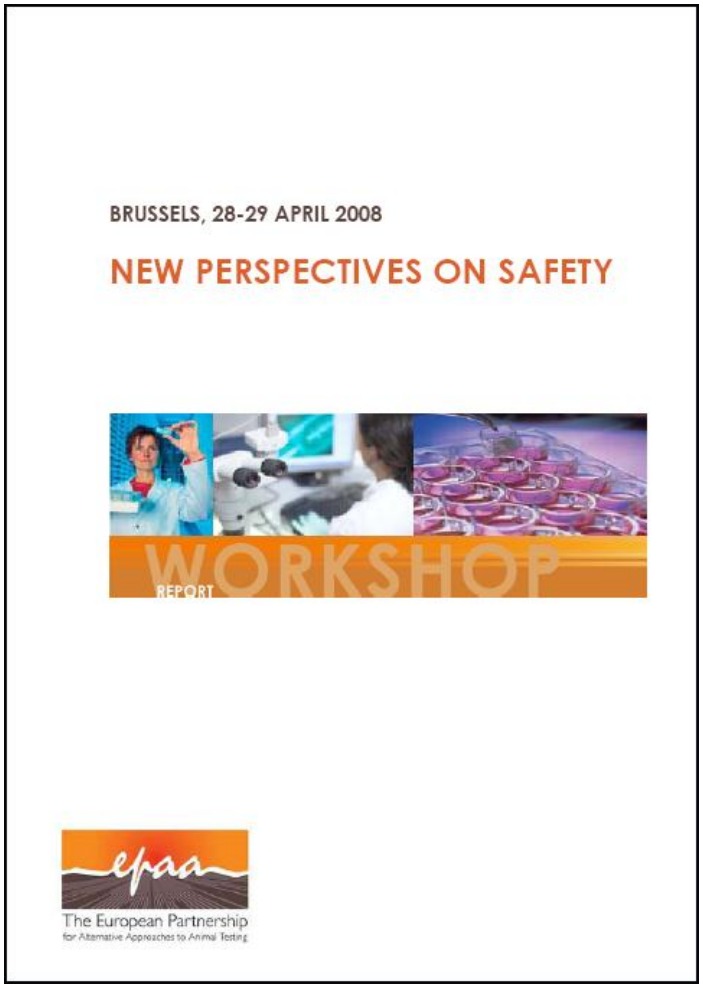


- It is not about “alternatives“ but alternative ways of doing safety assessment
- We are not looking for an 1:1 replacement of the current animal methods but for new ways of doing science

Target systems in safety testing



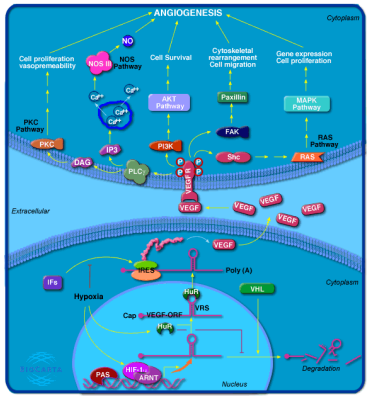
Workshop Report



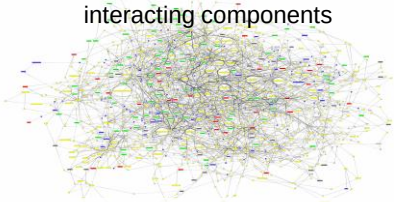
- 'The time is right to harness more effectively the very substantial achievements that have been witnessed in biology and chemistry during the last 10 years ……'
  - Toxicogenomics
  - Stem Cells
  - Chemistry and chem-informatics
  - Bioengineering
  - Genome, Modelling and Systems Biology
  - ……

http://ec.europa.eu/enterprise/epaa/3_activities/3_3_research/new_perspectives.pdf

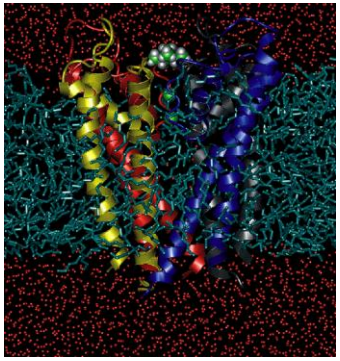
Computational chemistry and systems biology
part of the answer to the challenge?



Scientists are effective in reasoning about moderate numbers of interacting components



But in an experiment where tens of thousands of measurements result in hundreds or thousands of observed changes, the relevant networks are impossibly complex



- Design of completely novel compounds to target molecules (enzymes, receptor) is still a major challenge and works only sometimes.
- Modelling the interaction between a small molecule and a known protein works very well on average.
- Billions of compounds have to be analysed on several hundred thousands of proteins.
- Analysis is very complex since the proteins are interconnected in thousands of networks which differ in various organs.
- We believe that there is grand potential in these new technologies to reduce and replace animal studies.
- Therefore, EPAA has started initiatives bringing together basic scientists from computational chemistry, systems biology and toxicology. Workshop planned for July 2010

Some of the challenges

- The types of data from novel chemistry approaches will be very different from the animal-derived data currently used in safety assessment
- We are not looking for these new tools to provide 1:1 replacement of the current animal tests, but to produce information that will be used in a different way in our safety asssessments

Summary

- Continuous investment into science and technology contributes to a continuous replacement, reduction and refinement.
- Encourage the best minds to engage with the unique challenges that advancing the 3Rs brings to biology and chemistry
- Two additional challenges:
  - Regulatory acceptance of new technologies
  - International harmonisation of accepted methods is necessary to improve animal welfare on a world-wide basis
- Wide recognition among the international scientific community of the value and scientific challenges of research aligned with delivering animal welfare benefits