

ASAT

Assuring Safety without Animal testing

What is it about?

ASAT is about

1. Science
2. Public health protection
 - Environmental protection
3. Animal testing
4. Risk replacing Hazard
5. Reversing toxicological paradigms

6. Solution to regulatory/political Catch 22 situation
7. Something we all want

1. Science

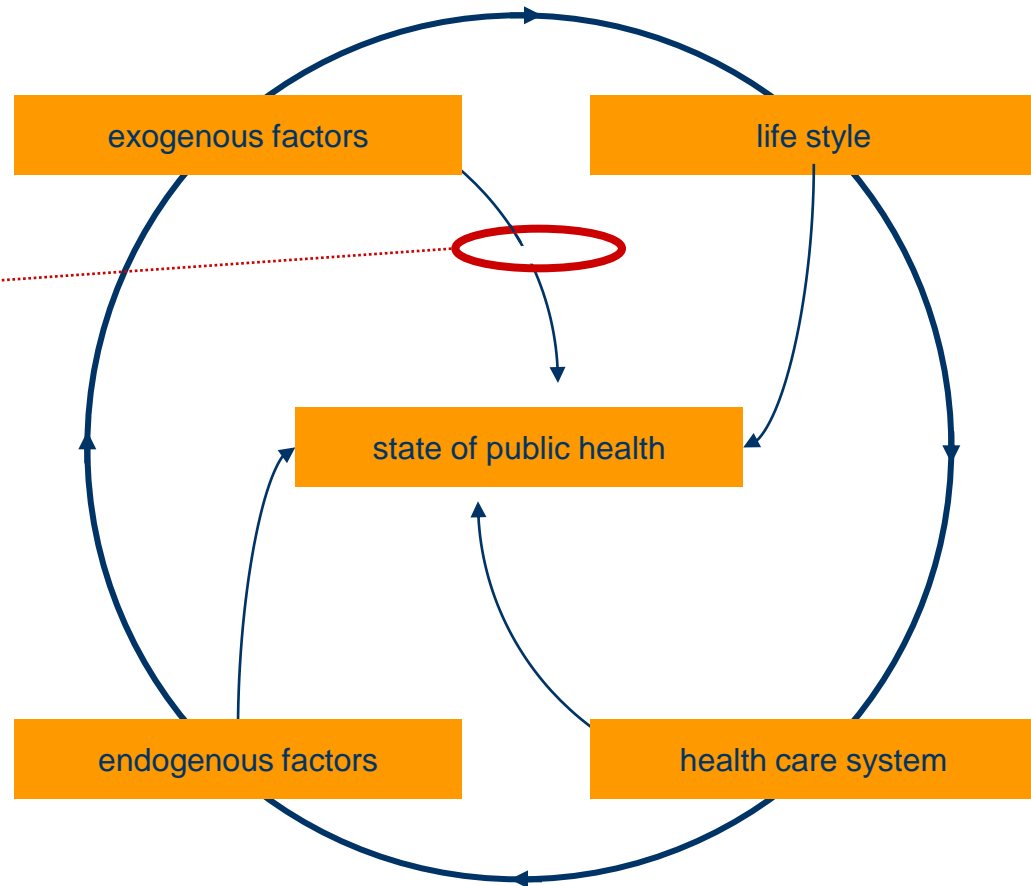
- New science and technology is arriving
- Gene based: Genomics, Proteomics, Metabolomics, etc
- Bioinformatics
- Systems Biology
- Computational science → mathematics, statistics
- This will allow
 - New insights in biological processes
 - Understanding of biological networks
 - Management and processing of complex data

2. Public Health Protection

- Delivering safety to people
- Preventing harm and disease
 - Due to chemicals
 - Biological agents
 - Physical factors
- By regulating exposure

REACH
EFSA
Scientific Committees:
• Consumer Products
• Health and Environmental Risks
EMEA

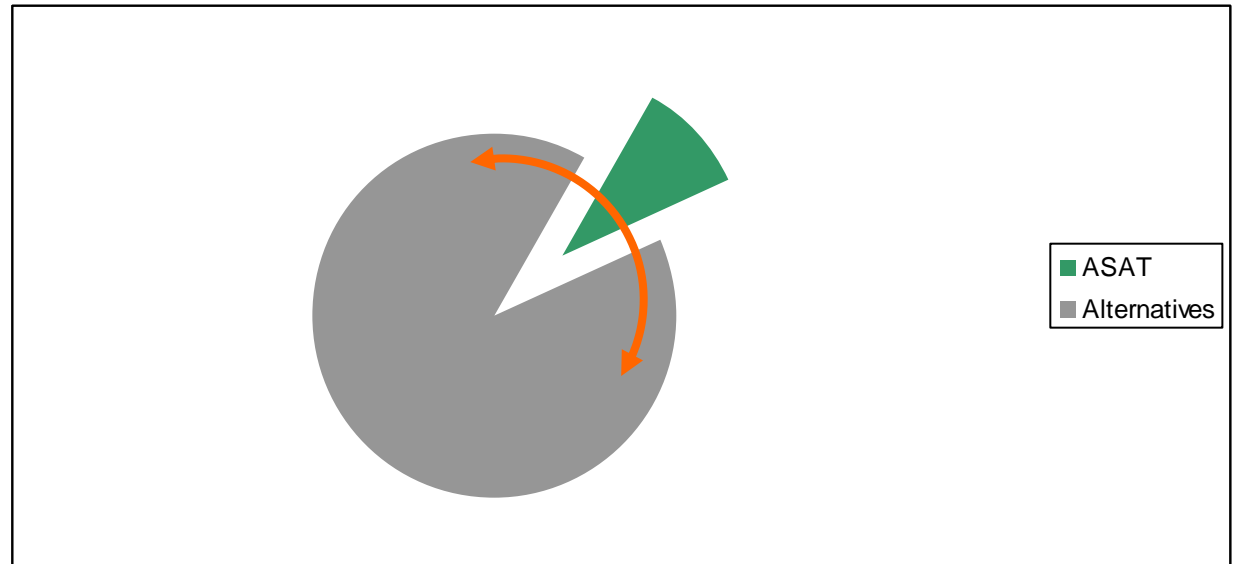
National Laws
Food
Medicines
Water
Air
Consumer goods etc



3. Animal Testing

today Total EU: 10.7 million animals

- 1- Clinical diagnostics 0 %
- 2- Health protection 10 %
- 3- Science 90 %

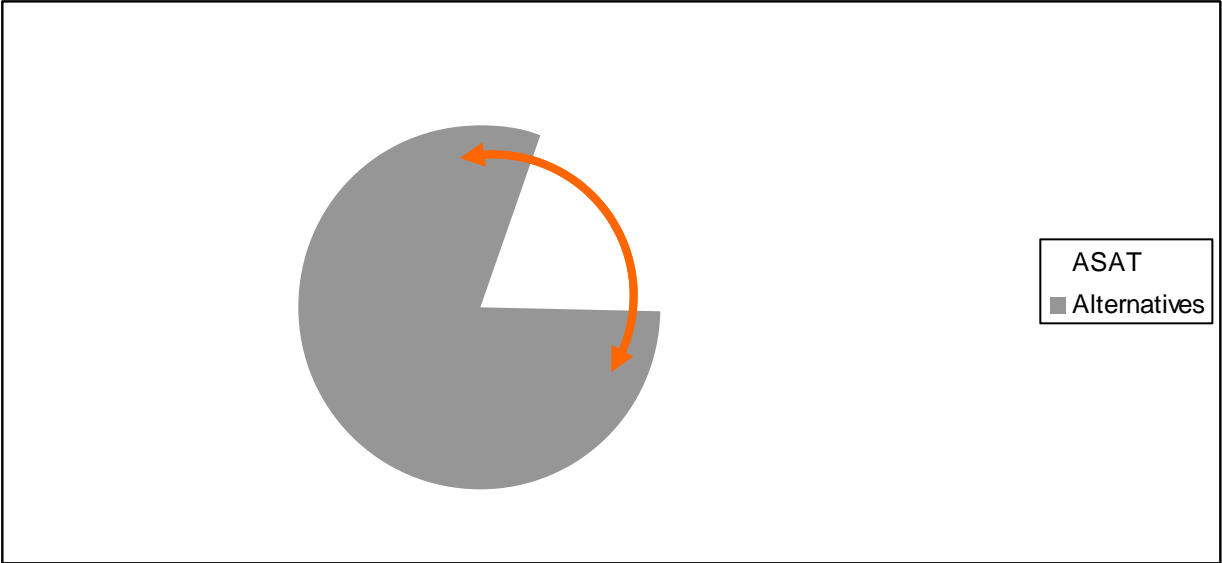


3. Animal Testing

'tomorrow' Total: [redacted] animals



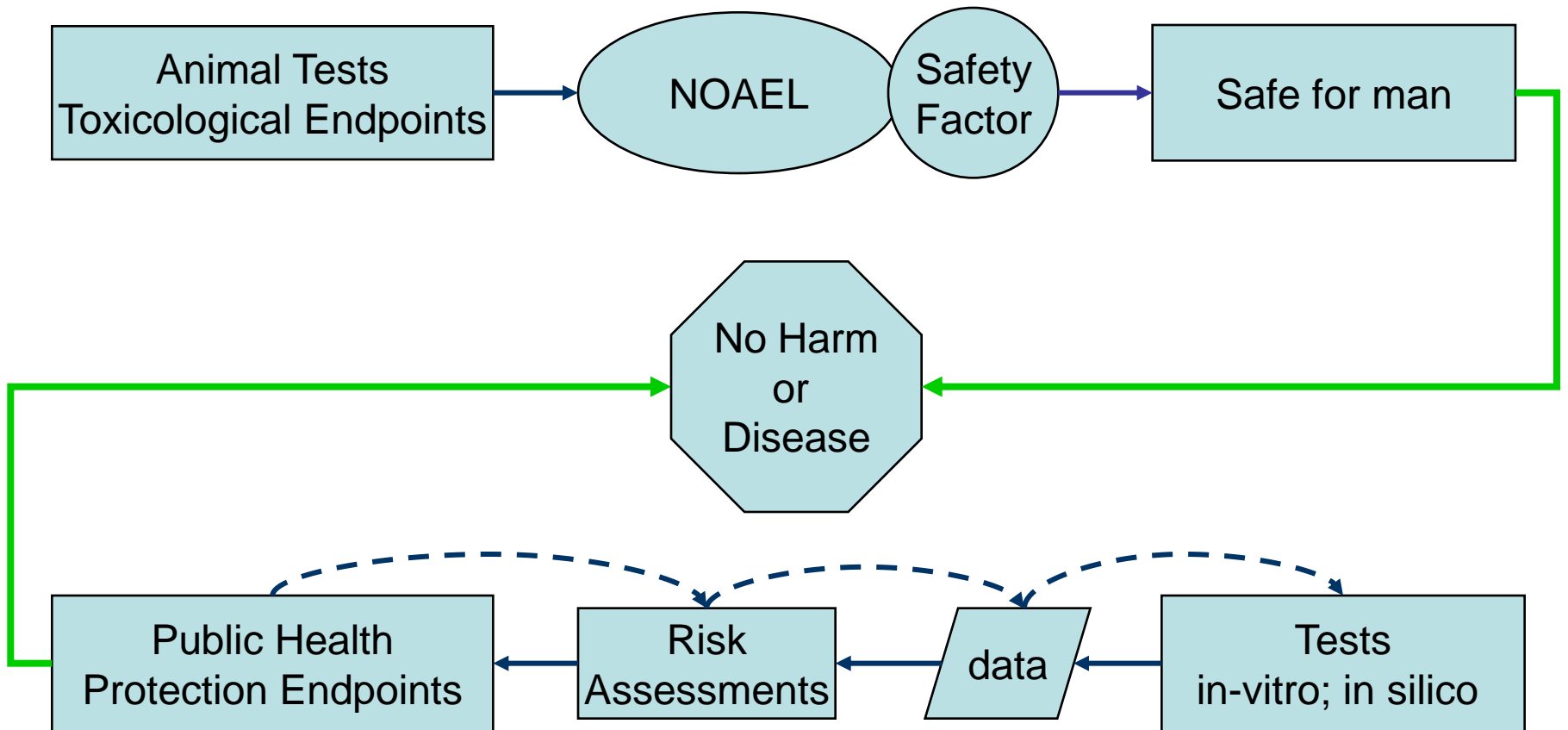
- 1- Clinical diagnostics 0 %
- 2- Health protection 0 %
- 3- Science 100 %



4. Risk replacing Hazard

- New technologies will decrease NOAELs
 - by orders of magnitude
- A Hazard can
 - either be accepted
 - or reject
- A Risk can be
 - accepted
 - rejected
 - reduced
- Safe:
 - = 'no' Harm or Disease
 - = the risks that have been accepted

5. Reversing Toxicological Paradigms



Context

Regulatory, Political, Societal

- High failure rate of new drug candidates
 - due to unmanageable toxicity,
 - accounting for approximately 30%
 - EU Chemical Regulation REACH
 - Registration, **E**valuation and **A**uthorization of **C**hemicals
 - existing and new substances to be subject to assessment in a single system
 - large numbers of additional tests required
 - 30,000 existing chemicals already placed on the market since before 1981 and sold at > 1 tonne per year
 - Future EU regulations on food ingredients
- Increasing demand for risk assessment of chemicals
- Increasing demand for (animal) testing - initially

Context

Regulatory, Political, Societal

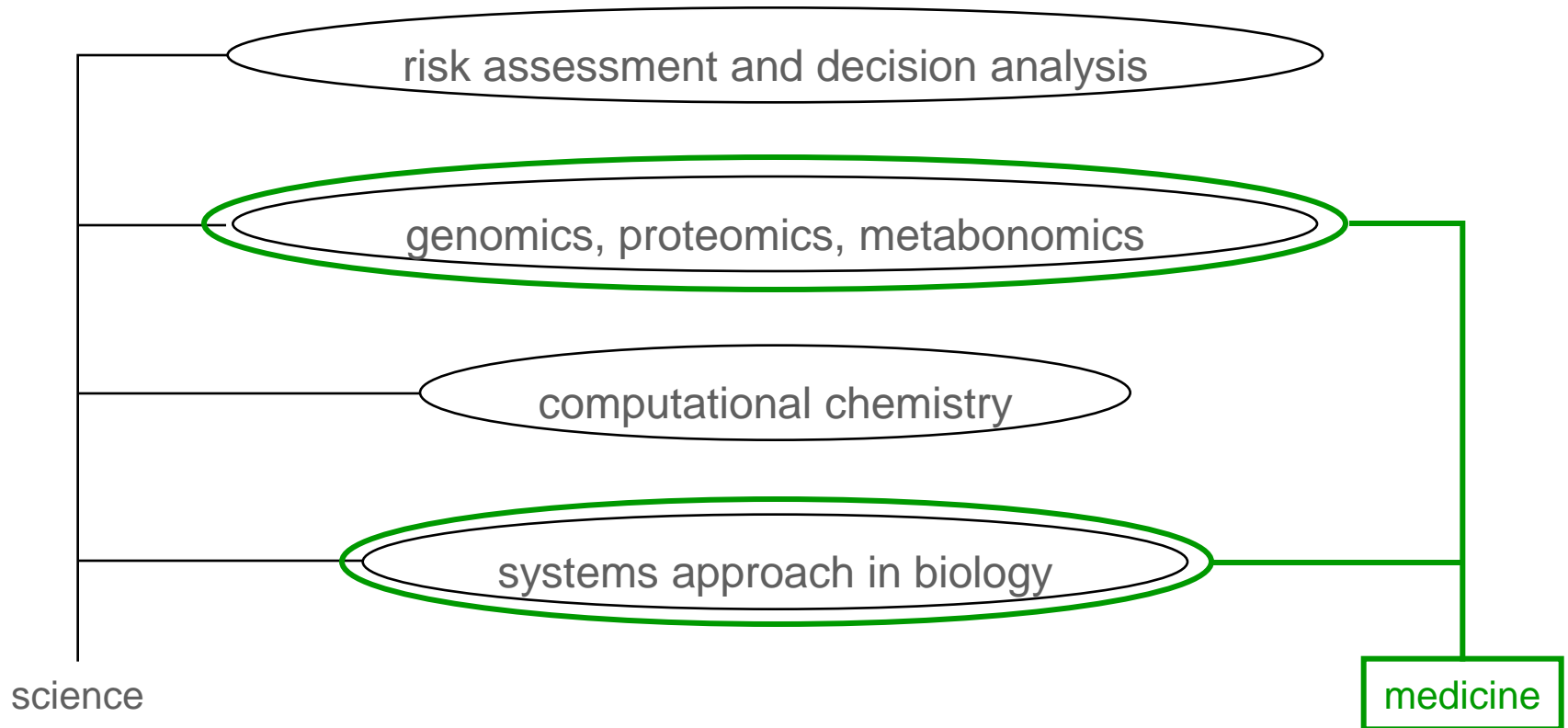
- Political: Directive 76/768/EEC
 - 7th Amendment to the Cosmetics Directive
 - If a cosmetic product is to be marketed in the EU
 - animal testing and marketing bans on finished products and prototypes - from SEPTEMBER 2004
 - animal testing and marketing bans on ingredients - from MARCH 2009
 - marketing ban on ingredients for three types of animal tests (repeated dose toxicity, reproductive toxicity and toxicokinetics) - from MARCH 2013 (possibility to extend)
- Societal: Increasing resistance to animal testing in general

→ Increasing demand for Safety without Animal Testing

Catch 22

6. Solution to Catch 22 situation

Learning from the future



7. Something we all want

- Let's take this direction
- Let's not speculate about the future
- It is plausible

- Join us:
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