



Ministerie van Volksgezondheid,
Welzijn en Sport

SenterNovem
Agentschap voor duurzaamheid en innovatie

ASAT Innovation Programme

ASAT

Science & Perspective

Bart Sangster

ASAT

Assuring Safety

without

Animal Testing

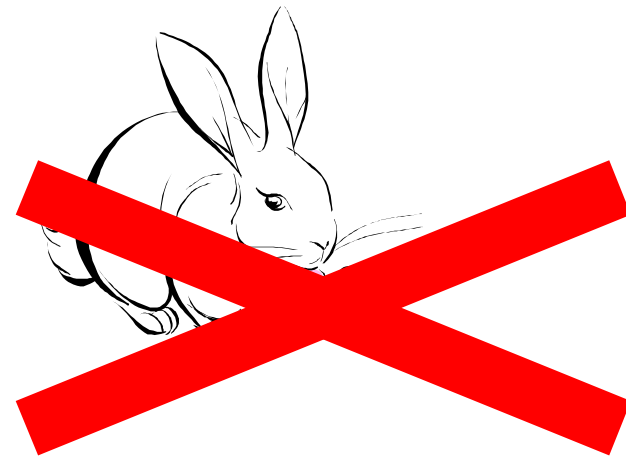


Is about

Public Health Protection

Preventing harm or disease in man

Protection of biotic Environment



Is about

Exposing animals to chemicals

Data on effects in animals

Current Approach to Safety

Assuring Safety

with

Animal Testing



Is about

Public Health Protection

Exposure of man below
1:100 or 1:1000 of level
that shows no difference in animals
Is very likely to be safe

Exposing animals to chemicals
Data on effects in animals

Highest dose with
'no adverse effect'



NOAEL

NOAEL : 100(0)

Safety Factor

Current Approach

Assuring Safety

with

Animal Testing



Is about

Public Health Protection

Preventing harm or disease in man

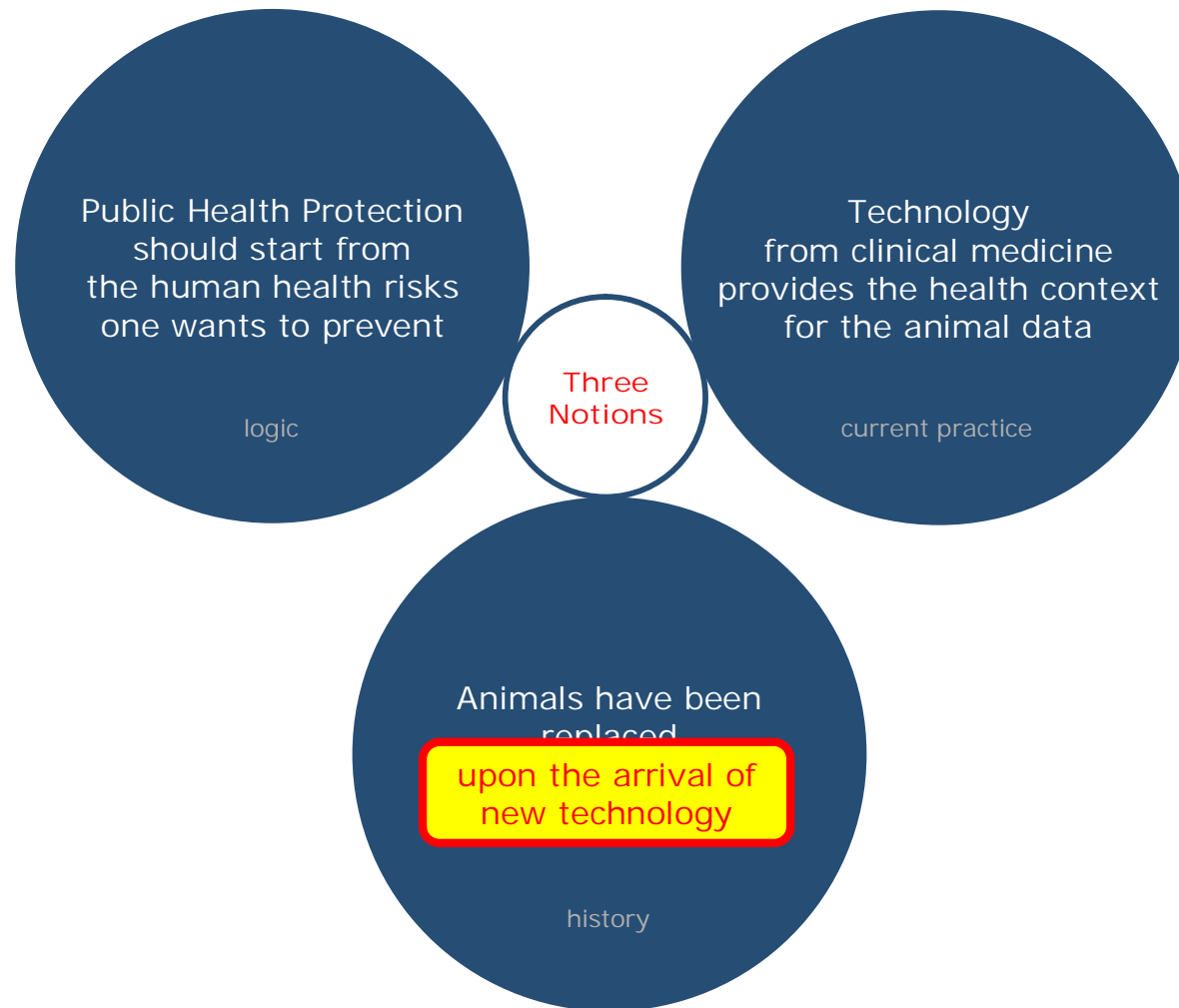
Has proven to be reasonably effective
in preventing
major public health problems

Does not clarify
what harm or disease has been prevented

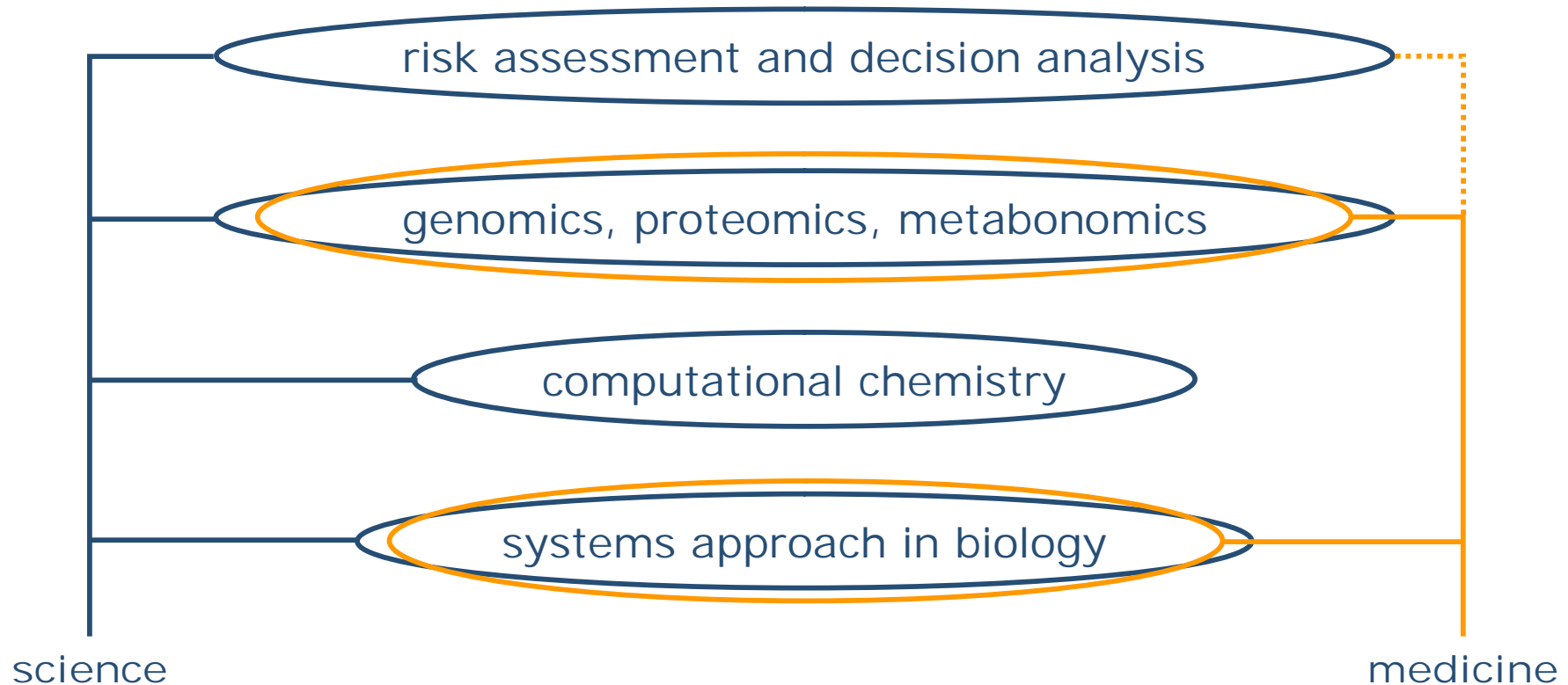
Its strength is the huge safety factor
the extensive screening in the animal

Its weakness is that it is hazard based
not 'everything' is being screened

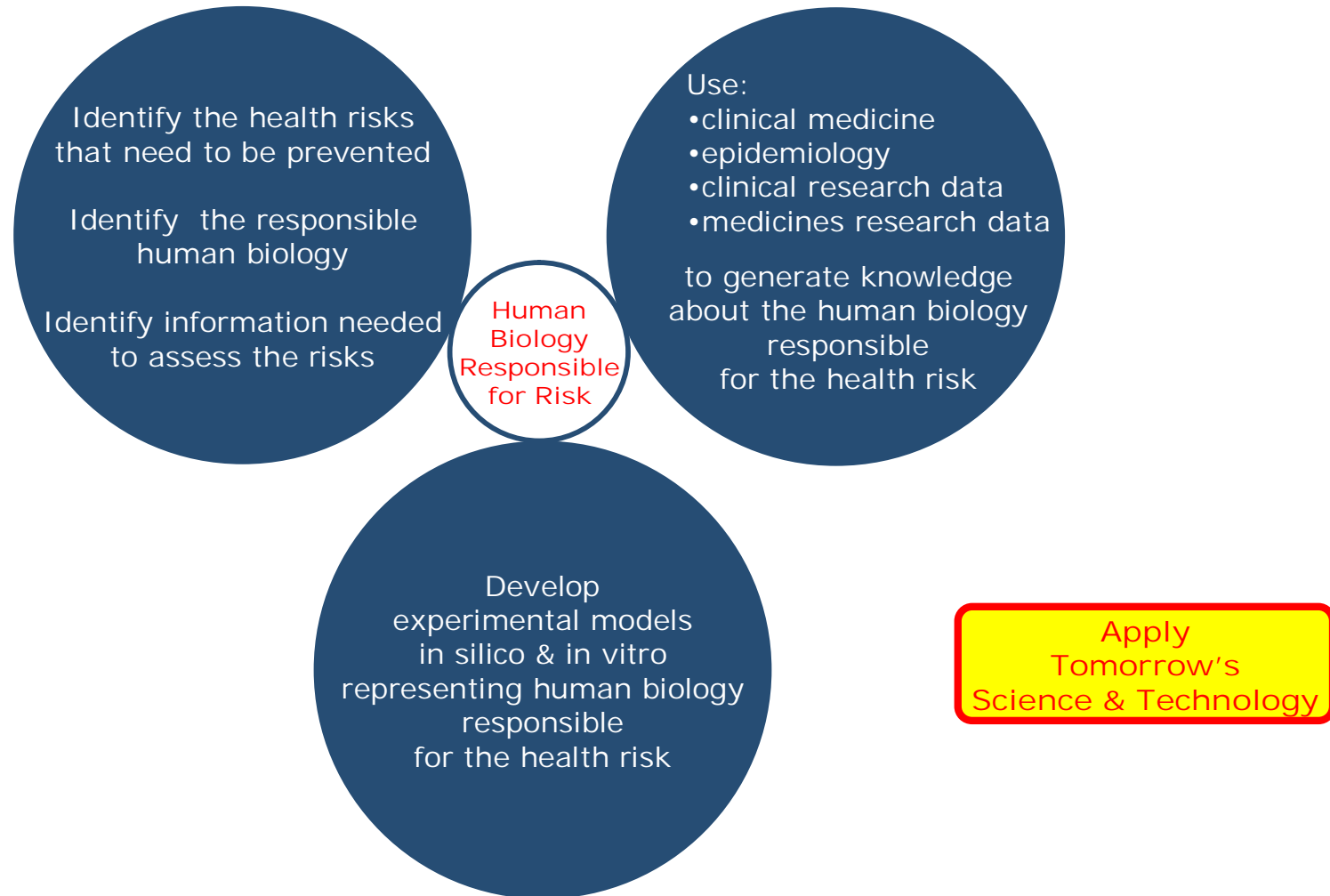
Origin of ASAT-concept



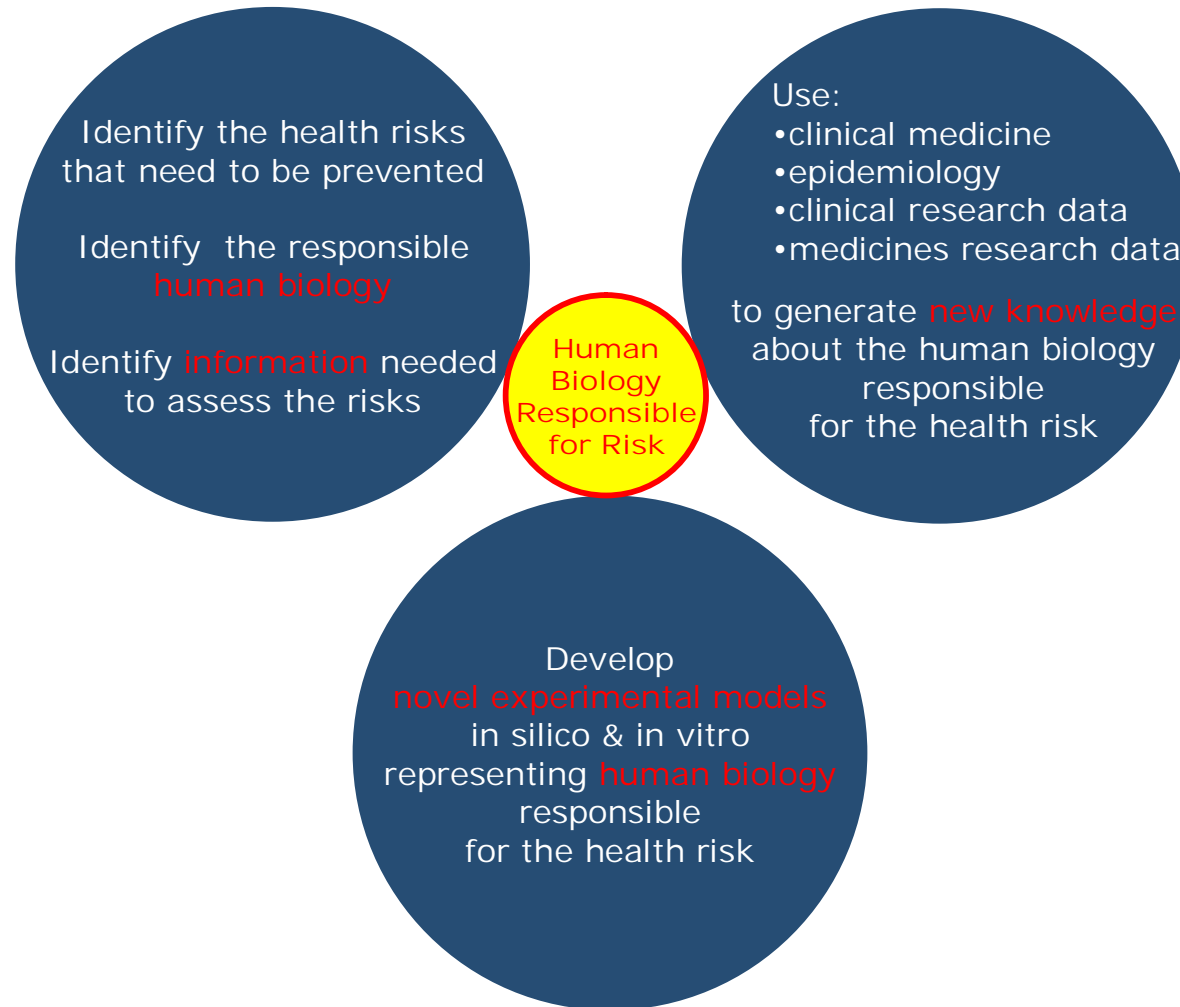
Arriving New Technology



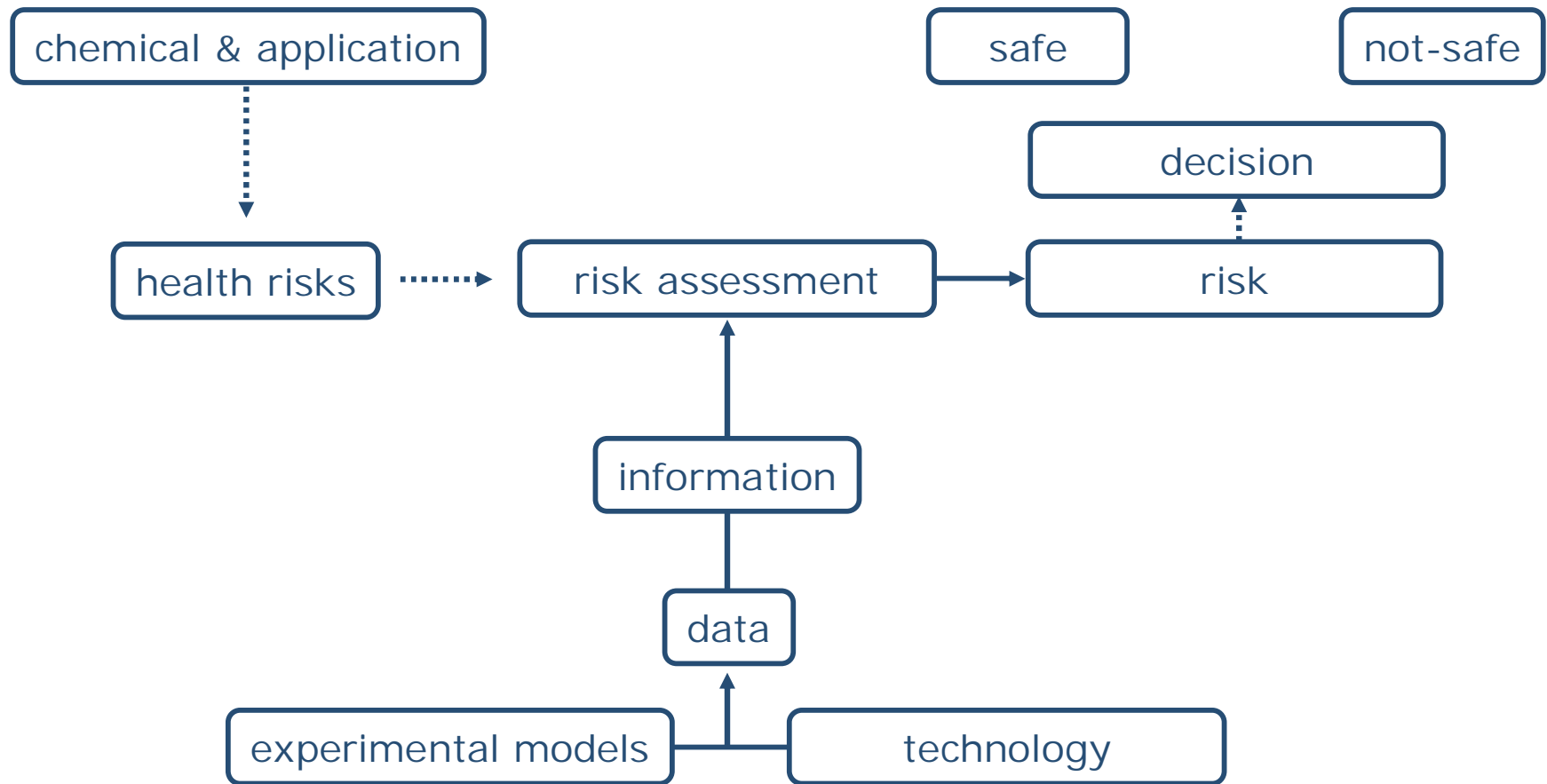
ASAT-concept in a nutshell



ASAT-concept in a nutshell



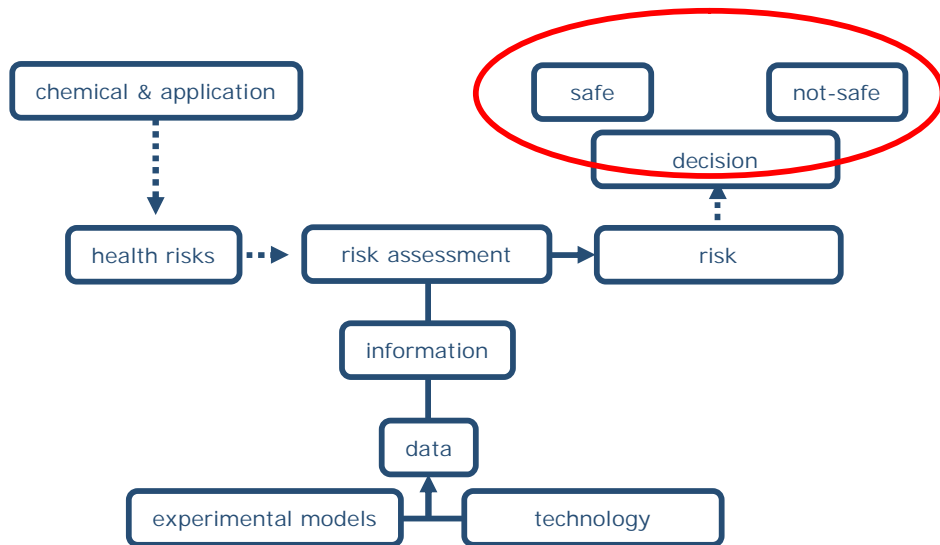
Application in a nutshell



ASAT ?

Assuring Safety

Animal Testing



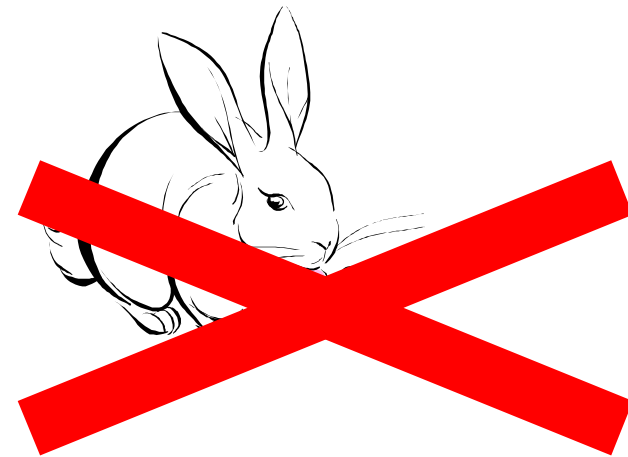
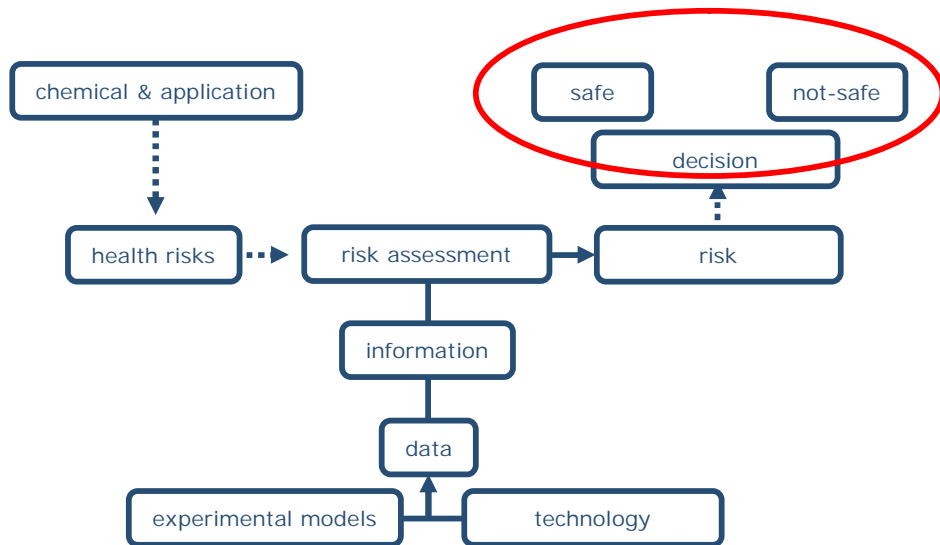
The need
for generating data in
experimental animals
will disappear

ASAT

Assuring Safety

without

Animal Testing



Was about

Exposing animals to chemicals

Data on effects in animals

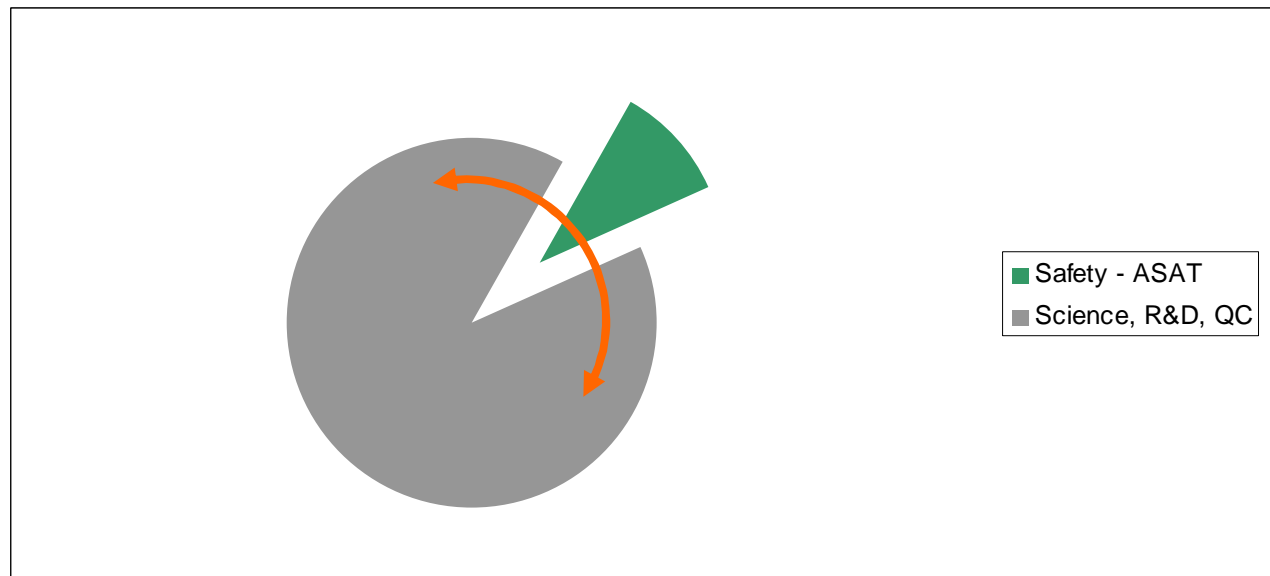
Animal Testing; numbers

today

Total EU: 10.7 million animals

- 1- Clinical diagnostics 0 %
- 2- Health protection 10 %
- 3- Science, R&D, QC 90 %

Switzerland
India
China
USA
Japan
.....



ASAT Innovation Programme

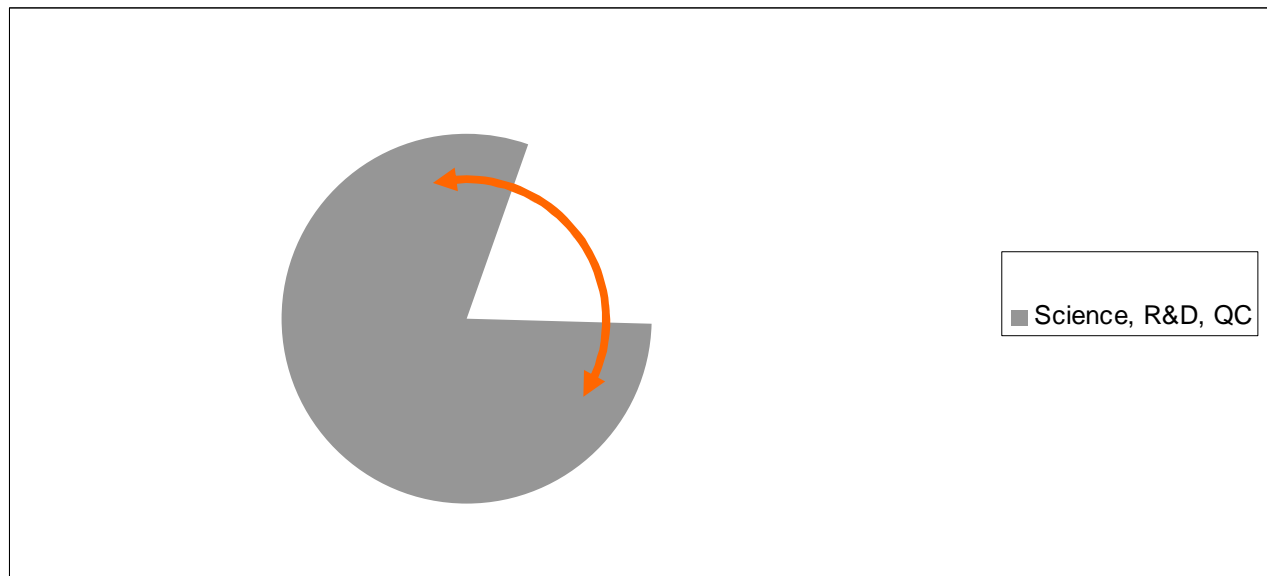
Animal Testing; future

'tomorrow'

Total EU: million animals



1- Clinical diagnostics	0 %
2- Health protection	0 %
3- Science, R&D, QC	100 %



ASAT and 'Alternatives'

- Working on 3Rs will be as important as it is today
 - refining, reducing and replacing
 - 90% of current use of experimental animals
- ASAT adds
 - public health dimension
 - health risk management perspective
 - human biology centre stage
- ASAT builds on many efforts that are going on
 - translational Toxicology
 - regulatory Toxicology
 - extrapolation and interpretation of data

The way forward

- Understanding the science
- Convincing Politicians about need for providing public pull
 - will 'solve' REACH and innovation issue in cosmetics
 - will keep EU competitive
 - could be cheaper and providing better protection
 - is the right thing anyway
- Convincing Regulators about need for providing adequate push
- Convincing Industry it is better to
 - be innovative
 - win the 'replacement battle'

The way forward

- Convincing the Scientists that replacement =
 - big science
 - big funds
 - the future
- Developing an international network
 - scientists taking up responsibility for the execution of building blocks
 - interaction with stakeholders
 - regulators, policy makers
 - NGOs and media
 - funding organisations
 - general information

Precondition for

- acceptance and
- solving 'verification issue'

NL & ASAT

- ▶ Can take a lead position
- NL has a unique mix
 - toxicology strong
 - technology strong
 - infrastructure strong
 - e.g. NTC, TIP, institutes, universities
 - risk assessment strong
 - well-represented in international fora
- ▶ Benefit to
 - government
 - academia
 - economy
 - NL-based (international) companies

What happened before

- 2004
 - 28 July; Letter by ZonMw to Minister VWS; 'Notice on alternatives to animal testing';
- 2005
 - 3 October Invitational Conference hosted by ZonMw and KNAW on feasibility of ASAT at the request of Ministers VWS, OCW and LNV
 - 20 December; Letter from Minister VWS to Parliament
- 2006
 - 21 June, Vught; Toxicogenomics Workshop, organised by the Netherlands Genomics Initiative
 - 9 November: Genomics Momentum, organised by the Netherlands Genomics Initiative
- 2007
 - 4 January; ASAT; Naar een Duurzame Bescherming van Gezondheid en Milieu
 - April, Business Plan Netherlands Genomics Initiative 2008-2012
 - 12 June; Letter by Minister of OCW to Parliament
 - 22 augustus; "Start ASAT in Nederland". Rapportage van de kwartiermakers Quadrant
 - December 5-7 Lisbon: EuroBioForum
- 2008
 - Jan/Feb Four working conferences at the request of Ministry VWS
 - 54 scientists attending
 - From Food to Pharma
 - NL, EU, US
 - 1 March Report to Ministry

Recommendations Report

- Developing a road map for ASAT-Programme 2009-2014
- Preparing four case studies :
 - risk of affecting male fertility
 - risk of respiratory inflammation and sensitization
 - risk of liver damage due to inflammation and/or degeneration
 - risk of adenocarcinoma of the female breast
- Enlarging and expanding the existing network
- Employing the Network to
 - engage other (non-NL) research groups and authorities,
 - public and private funding organisations,
 - share responsibility for the ASAT-Programme.
- Developing a communication strategy
- Developing a supporting organisation and governance

What happened since

- June
 - Governments policy paper on Alternatives to Animal Testing
 - Kabinetsvisie 'Alternatieven voor Dierproeven'
- September
 - Ministry for Health, Welfare & Sports
 - took a decision on the ASAT-Initiative
 - initiating an 'ASAT Innovation Programme'
 - period 2008-09
 - SenterNovem responsible
 - Dr Conchita Callant-Cransveld

and since

- September - November
 - SenterNovem took decisions on:
 - selection of demonstration projects
 - selection of supportive activities
 - Scientific Advisory Board
 - Execution of Programme
 - reporting regularly to VWS
 - inter-Departmental Consultation Group

Today's Programme

- Introductions from different perspectives
- Demonstration Projects aiming at:
 - in silico prediction biotransformation and kinetics
 - accessing biology unique to man
 - exploiting clinical epidemiology with novel technology
 - potential of omics technologies for ASAT
- Scientific Advisory Board
 - Role and responsibilities

Next

In the pipeline:

- Workshops
- Improving the functionality of web site

Which leaves from the recommendations:

- The four case studies:
 - risk of affecting male fertility
 - risk of respiratory inflammation and sensitization
 - risk of liver damage due to inflammation and/or degeneration
 - risk of adenocarcinoma of the female breast
- Enlarging and expanding the existing network
- Employing the Network to
 - engage other (non-NL) research groups and authorities,
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- Developing a communication strategy
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Today

- Is the result of many years of
 - hard work by many friends and colleagues
- I am grateful for their efforts and their:
 - commitment to Animal Welfare
 - commitment to Public Health
 - commitment to Risk Assessment
 - commitment to Science
 - commitment to Technology
 - commitment to ASAT

The ASAT network will start from here

www.ASAT-Initiative.eu

