ASAT
Assuring Safety without Animal Testing

Bart Sangster
Chair

ASAT-Foundation
This presentation

• Concept
• Development
• Application
• Perspective
Origin of ASAT-concept

Three Notions

1. Public Health Protection should start from the human health risks one wants to prevent

2. Technology from clinical medicine provides the health context for the animal data

3. Animals have been replaced upon the arrival of new technology

ASAT-Foundation
Arriving New Technology

Building the bridge

- risk assessment and decision analysis
- genomics, proteomics, metabonomics
- computational chemistry
- systems approach in biology

science  |  medicine
Building the bridge

TECHNOLOGY
EXPERIMENTAL MODELS

HEALTH RISK ASSESSMENT

SYSTEMS APPROACH

TECHNOLOGY
CLINICAL MEDICINE

ASAT-Foundation
ASAT-concept in a nutshell

**Identify the health risks that need to be prevented**

**Identify the responsible human biology**

**Identify information needed to assess the risks**

**Use:**
- clinical medicine
- epidemiology
- clinical research data
- medicines research data

To generate knowledge about the human biology responsible for the health risk

**Develop experimental models in silico & in vitro representing human biology responsible for the health risk**

**Human Biology Responsible for Risk**

ASAT-Foundation

**Building the bridge**
Building the bridge

**ASAT-concept in a nutshell**

- Identify the health risks that need to be prevented
- Identify the responsible human biology
- Identify information needed to assess the risks

**Use:**
- clinical medicine
- epidemiology
- clinical research data
- medicines research data

To generate new knowledge about the human biology responsible for the health risk

- Develop novel experimental models in silico & in vitro representing human biology responsible for the health risk
Building the bridge

**ASAT development**

- Chemical & application
- Human health risks
  - e.g. Inflammation, Allergy, Neoplasia, Degeneration, Functional change
- Risk assessments
- Information
  - Data
  - Experimental models
  - Technology

Decision:
- Safe
- Not-safe

Risks:
Using the bridge

Application in a nutshell

chemical & application

human health risks

risk assessments

information

data

experimental models

technology

chemical metabolites exposure

safe

decision

risks

not-safe
History

- 2003 concept developed
- 2004 concept published
- Unilever has invested €3 mio p.a. since
  - Supports EPAA
  - Supports Colipa/EU fund launched this summer
- ASAT-Initiative
  - Workshops 2008 and report
  - www.ASAT-Initiative.eu
- Netherlands Government
  - October 2008-2009 ASAT Innovation Programme
  - €1,2 mio one off
  - What next decision is pending
ASAT-Foundation

- Founded Oct 2008:
  - Independent, neutral and science based
  - Charity not for profit
- Funding
  - Donations, gifts
  - Subsidies
- Objectives:
  - Supporting ASAT research activities
  - Making the ASAT approach known
  - Advancing ASAT communication
  - Developing ASAT community
- Does not fund research activities
Back up
Risks – Chemical - Application

Safety = No Harm and Disease
Safe = Risk we are prepared to accept

What are the risks we want to assess in order to be satisfied that their use is safe?

human health risks

risk assessments

e.g.
Inflammation
Allergy
Neoplasia
Degeneration
Functional change

ASAT-Foundation
## Matrix

<table>
<thead>
<tr>
<th>Chemical Application</th>
<th>Primary contact</th>
<th>Systemic: Liver, Kidney, Bladder, Lung, Heart, Pancreas, etc</th>
<th>Systemic: Thyroid, Parathyroid, Adrenals, etc</th>
<th>Systemic: Bone, muscle, connective tissue, etc</th>
<th>Systemic: CNS, Ear, Eye, etc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allergy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neoplasia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degeneration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional change</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>......</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Warp & Woof

<table>
<thead>
<tr>
<th></th>
<th>medicines</th>
<th>rodenticides</th>
<th>insecticides</th>
<th>herbicides</th>
<th>fungicides</th>
<th>disinfectants</th>
<th>other</th>
<th>chemical by intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>reduce &amp; refine</td>
<td>reduce &amp; refine</td>
<td>reduce &amp; refine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>safety general</td>
<td>safety relating to mechanism of action</td>
<td>efficacy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**ASAT-Foundation**

**Benefit**

**Look**

**ASAT**
This paper was produced for a meeting organized by Health & Consumers DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission’s or Health & Consumers DG’s views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.