



**THE EUROPEAN CONSENSUS
PLATFORM ON 3R-ALTERNATIVES**

VERA ROGIERS

Dept. of Toxicology
Vrije Universiteit Brussel
Belgium



WHAT ?



European Consensus Platform on 3R-Alternatives

- **International Not-For-Profit Organisation according to Belgian law (Statutes Moniteur Belge- 21/4/2004, n°04061510)**
- **Non Governmental Organisation (NGO)**
- **Umbrella Organisation at the EU level of National Consensus Platforms**

NCPs



WHAT ?

NC

National Consensus Platform

- National Organisation: Not-For-Profit Organisation, Governmental Organisation, Scientific Association, → Legal Entity
- Quadripartite Organisation at the national level with 4 stakeholders

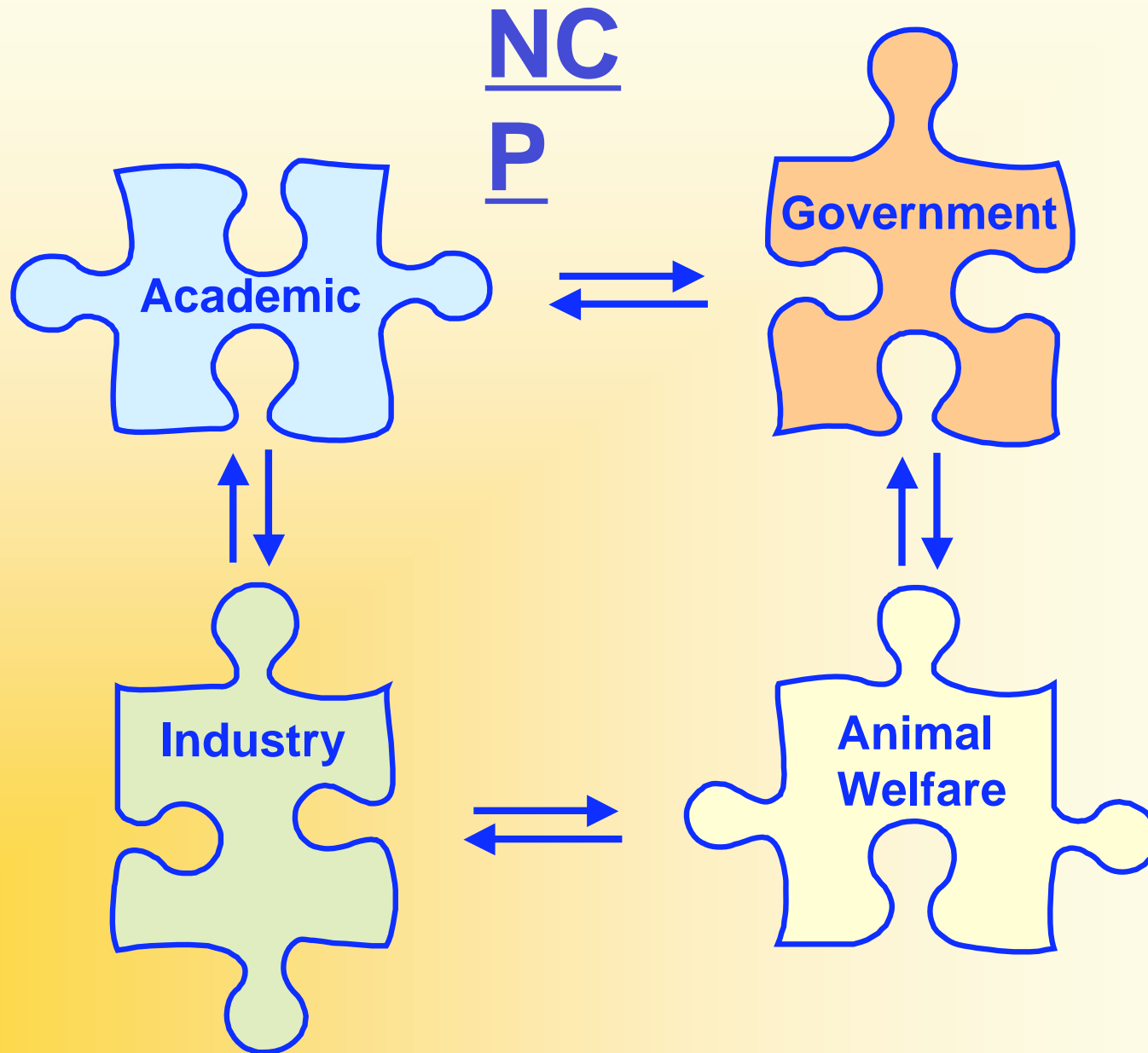
Academia

Government

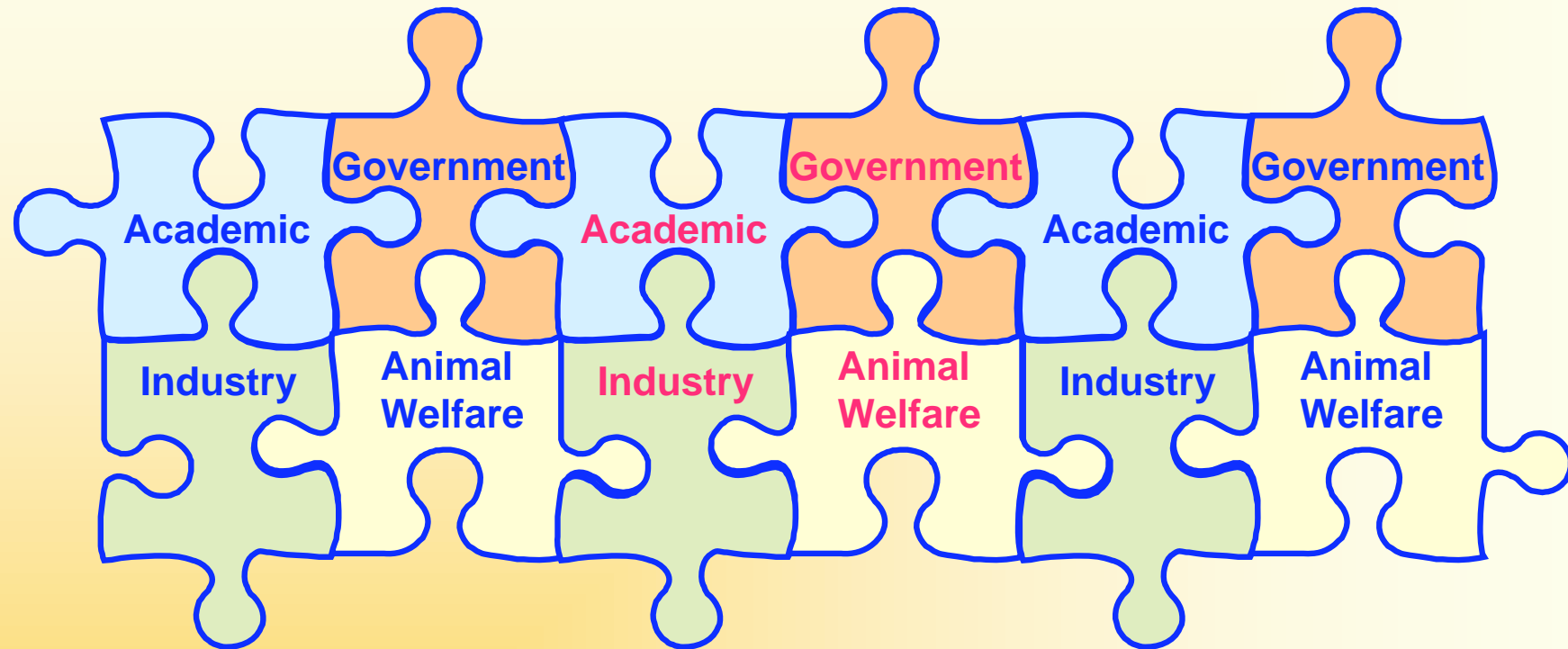
Industry

Animal Welfare

QUADRIPARTITE ORGANISATION AT NATIONAL LEVEL : *ecopa*



QUADRIPARTITE ORGANISATION AT EU LEVEL : *ecopa*



**NATIONAL
CONSENSUS
PLATFORM 1**

**NATIONAL
CONSENSUS
PLATFORM 2**

**NATIONAL
CONSENSUS
PLATFORM 3**



BACKGROUND



- ★ **IDEA TO BUILD AN EU ORGANISATION OF NATIONAL PLATFORMS : ECVAM**
- ★ **HETEROGENICITY OF EXISTING PLATFORMS WAS AN ACUTE PROBLEM !**

e.g. Germany: SET → no Ac representative
Belgium: several AW groups → no Ac, G, I representatives
Switzerland: 3R-Foundation
The Netherlands: ZON } all stakeholders present
Spain ? Italy ? Sweden ? France ? Denmark ?



BACKGROUND



- ★ **3RD WORLD CONGRESS
ON ALTERNATIVES AND ANIMAL USE
IN THE LIFE SCIENCES, BOLOGNA (1999) :**

**PROPOSAL FOR CREATION OF NATIONAL
CONSENSUS PLATFORMS AND
ecopa AS UMBRELLA AT EU LEVEL**



AIMS ?



- ★ **FACILITATE THE EXCHANGE OF SCIENTIFIC INFORMATION, EXPERTISE AND EXPERIENCE BETWEEN NATIONAL PLATFORMS, ACADEMIA, ANIMAL WELFARE, INDUSTRY & GOVERNMENT AND EU**
- ★ **ENHANCE FURTHER DEVELOPMENT AND IMPLEMENTATION OF 3R-METHODS IN EU AND WORLDWIDE**
- ★ **RAISE PUBLIC, GOVERNMENTAL AND SCIENTIFIC AWARENESS FOR A BETTER ACCEPTANCE OF ALTERNATIVE METHODS**



TOOLS ?



- ★ **CONFERENCES, SEMINARS, PUBLICATIONS, COLLECTION & CIRCULATION OF INFORMATION, SCIENTIFIC & EDUCATIONAL INITIATIVES, CO-OPERATIVE ACTION**
- ★ **MEMBERSHIP OF RELEVANT BODIES**
- ★ **CRITICAL & SCIENTIFIC POLITICAL STATEMENTS !**



ACTUAL STATUS ?



★ **11 FULL MEMBERS** : EXISTING CONSENSUS PLATFORMS

Austria, Belgium, Czech Republic, Finland, Germany, Italy, The Netherlands, Spain, Sweden, Switzerland and United Kingdom

★ **3 ASSOCIATE MEMBERS** : CONSENSUS PLATFORMS
UNDER FORMATION

Denmark, Norway and Poland



ACTUAL
STATUS ?



- ★ <http://www.ecopa.tsx.org/>
- ★ **CRITERIA TO FORM NCPs**
STATUTES OF *ecopa*
(discussion point)



ACTUAL STATUS ?



EXCECUTIVE BOARD: DAILY WORK

☞ V. Rogiers (B, Ac); J. Castell (E, Ac); B. Garthoff (D, I)

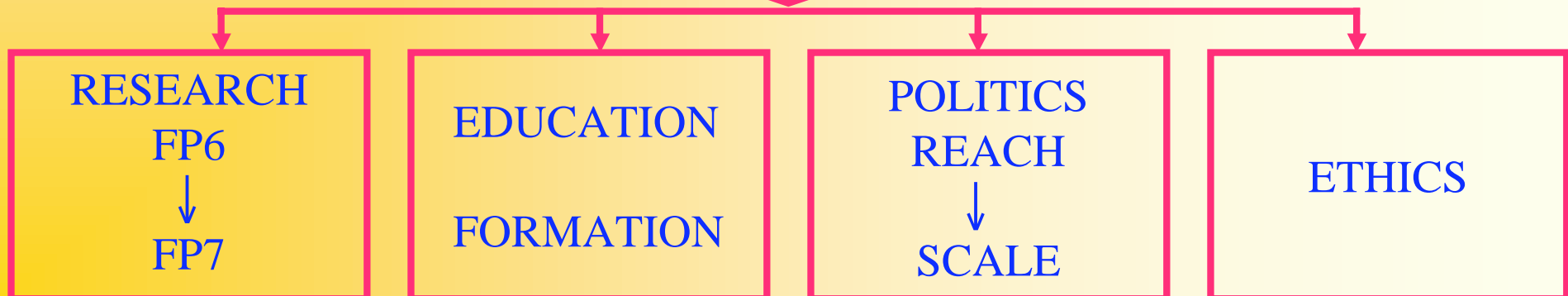
BOARD:

☞ 10 ELECTED NCP REPRESENTATIVES

☞ 3 ELECTED 3R-EXPERTS:

F. Zucco (I, Aw); W. Pfaller (A, Ac); H. Spielmann (D, G)

4 WORKING GROUPS





WHY WAS AND IS
ecopa NECESSARY ?



WHY WAS AND IS
ecopa NECESSARY ?

NECESSARY BECAUSE OF

- ‡ EU POLICY ON CHEMICALS
- ‡ EU POLICY ON COSMETICS
- ‡ ECVAMS POLICY ON ALTERNATIVES
- ‡ EU RESEARCH POLICY

**EU WHITE PAPER STRATEGY
FOR A FUTURE CHEMICALS POLICY**

EINECS

100.000 “old” substances

ELINCS

3000 NEW substances

> 95% ???

REACH

Registration, Evaluation, Autorisation, with **PRIORITIES**
30.000 chemicals

9.6 – 12.8 million animals

**EU WHITE PAPER STRATEGY
FOR A FUTURE CHEMICALS POLICY**

HIGH NEED FOR 3R-ALTERNATIVES



9.6 – 12.8 million animals

**7th AMENDMENT OF
EU COSMETICS LEGISLATION**



**ANIMAL TESTING BAN
AND
MARKETING BAN OF COSMETIC INGREDIENTS
& FINAL PRODUCTS TESTED ON ANIMALS**



HIGH NEED FOR 3R-ALTERNATIVES

ECVAM

**STRATEGIC PLAN FOR FUTURE DEVELOPMENT
AND VALIDATION OF ALTERNATIVE METHODS**

**WITHIN NEXT 5 YRS ALTERNATIVES
FOR MOST ENDPOINTS**

HIGH NEED FOR 3R-ALTERNATIVES

**6th FRAMEWORK PROGRAMME OF THE EC
FOR RESEARCH, TECHNOLOGICAL DEVELOPMENT
AND DEMONSTRATION ACTIVITIES
(2002-2006)**



**NO SPECIFIC KEY ACTION, NO SPECIFIC BUDGET
FOR RESEARCH ON ALTERNATIVE METHODS !**



CREDIBILITY ???



WHY WAS AND IS
ecopa NECESSARY ?

NECESSARY TODAY BECAUSE OF

- ! EU POLICY ON CHEMICALS & ENVIRONMENT:
REACH & SCALE
- ! IMPLEMENTATION OF COSMETICS LEGISLATION
- ! DRYING UP OF SOURCES & RESOURCES
FOR ALTERNATIVES

REACH

- NO AGREEMENT YET !
- ALTERNATIVE METHODS NOT CONSIDERED APPROPRIATELY AND REALISTICALLY

SCALE

- NEAR FUTURE : FOCUS ON ENVIRONMENTAL SAFETY AND CHILDRENS HEALTH
 - ADDITIONAL ANIMAL TESTING IF NOT ENOUGH ALTERNATIVES AVAILABLE !

7TH AMENDMENT (2003/15/EC)

**- END OF ANIMAL USE FOR TESTING OF COSMETIC INGREDIENTS :
→ 11 March 2009**

- EXCEPTION:

- REPRODUCTIVE TOXICITY

- BIOKINETICS

- REPEATED-DOSE TOXICITY (CHRONIC/SUBCHRONIC TOXICITY)

→ 11 March 2013

NOT REALISTIC:

**PROCESS OF TEST DEVELOPMENT, VALIDATION
& IMPLEMENTATION
INTO LEGISLATION IS LONG: 6-8 yrs**

**WHAT 3R-ALTERNATIVES
DO WE ACTUALLY HAVE IN THE EU
FOR REGULATORY TESTING ?**

**4 VALIDATED
METHODS**



ANNEX V

Dangerous Substances Legislation

67/548/EEC

- **3 corrosivity tests**
TER, Epi Skin[®], Epiderm[®]
- **1 phototoxicity test**
3T3 NRU-PT

**WHAT 3R-ALTERNATIVES
DO WE ACTUALLY HAVE IN THE EU
FOR REGULATORY TESTING ?**

**4 VALIDATED
METHODS**

**7 METHODS
ACCEPTED BY ESAC**

NOT YET TAKEN UP IN EU LEGISLATION

- 1 skin sensitisation test: LLNA
- 1 *in vitro* percutaneous absorption test
- 1 additional corrosivity test: Corrositex[®]
- 3 embryotoxicity tests: WEC, MM, ECT
- 1 pyrogenicity test

**WHAT 3R-ALTERNATIVES
DO WE ACTUALLY HAVE IN THE EU
FOR REGULATORY TESTING ?**

**4 VALIDATED
METHODS**

**7 METHODS
ACCEPTED BY ESAC**

**TESTS UNDER
DEVELOPMENT & VALIDATION**

- skin irritation
- eye irritation
- acute (oral) toxicity
- skin corrosion (in silico)
- reproductive toxicity (just started)

**WHAT 3R-ALTERNATIVES
DO WE ACTUALLY HAVE IN THE EU
FOR REGULATORY TESTING ?**

**4 VALIDATED
METHODS**

***IN VITRO*
GENOTOXICITY TESTS**

**7 METHODS
ACCEPTED BY ESAC**

**TESTS UNDER
DEVELOPMENT & VALIDATION**

ALTERNATIVE TESTS NEEDED FOR :

- **PHOTO ALLERGY**
- **SUBACUTE TOXICITY**
- **CHRONIC TOXICITY**
- **TARGET ORGAN & SYSTEMIC TOXICITY**
- **BIOKINETICS**
- **NON-GENOTOXIC CARCINOGENICITY**

**COMPLETELY
LACKING TODAY**



**IRREALISTIC
TIME FRAME !**



**FUNDING OF RESEARCH PROJECTS ON
3R-ALTERNATIVES IN FP6**

\$ FIELD COVERED: NARROW

\$ PROJECTS PROPOSED: LIMITED NUMBER



CONSEQUENCES FOR FP7 ?



ACTION !



HOW TO TAKE ACTION ?

BY LEARNING OUT OF MISTAKES



- ACTION BY INDIVIDUAL PRESSURE GROUPS IS OK
- ACTION BY 4 STAKEHOLDERS TOGETHER IS MORE EFFECTIVE AND POWERFUL !



**BUILDING OF NCPs IN NEW EU COUNTRIES WITH
EXPERIENCE AND HELP OF *ecopa***