ZEBET as a National Body for Alternative Methods

The German Chemical Industry Perspective

Dr. Walter Aulmann

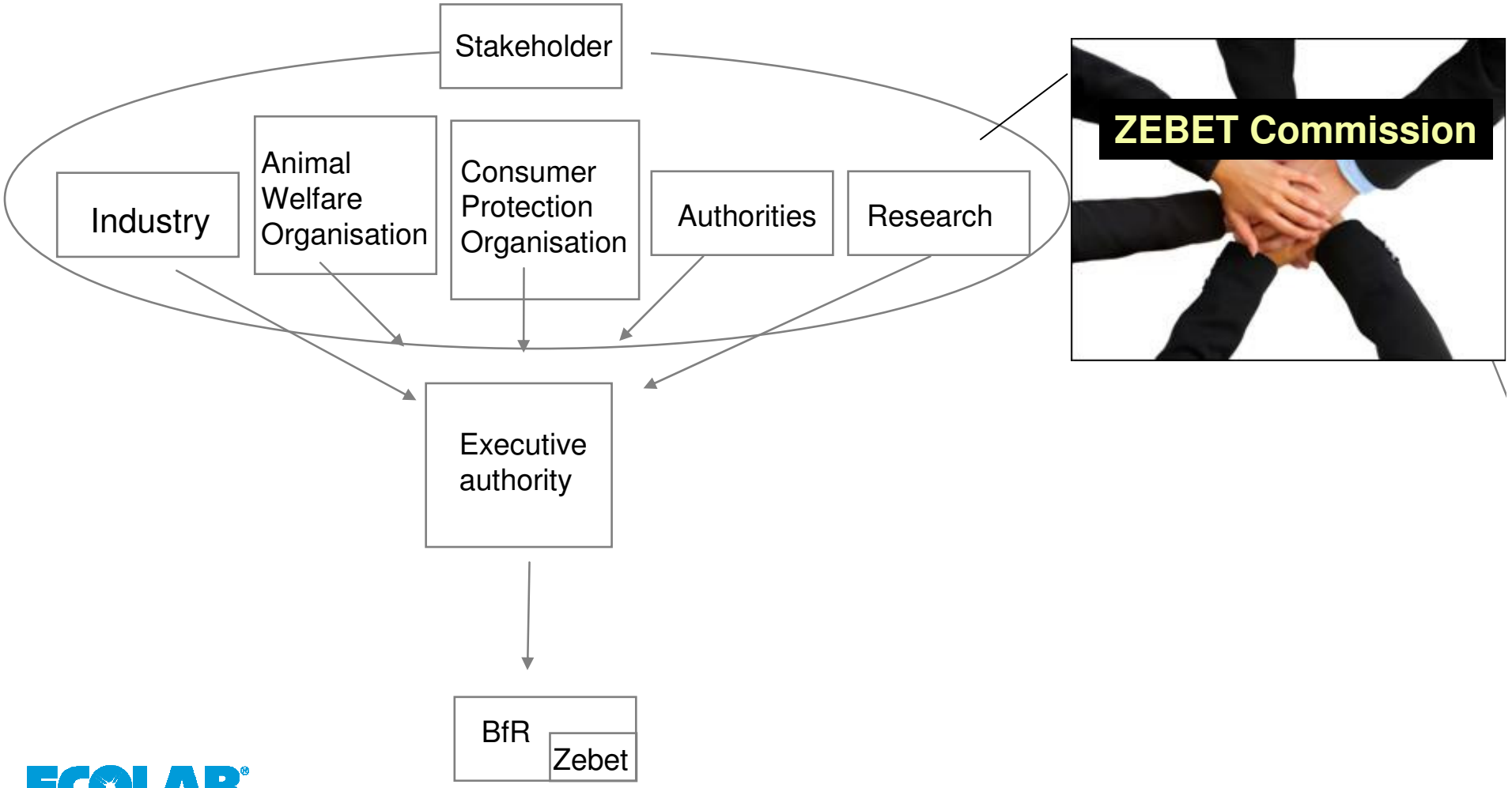
On occasion of the 20th anniversary of ZEBET at the BfR

26 October 2009

ZEBET Commission Advisory Role

Consumer Protection

Animal Welfare



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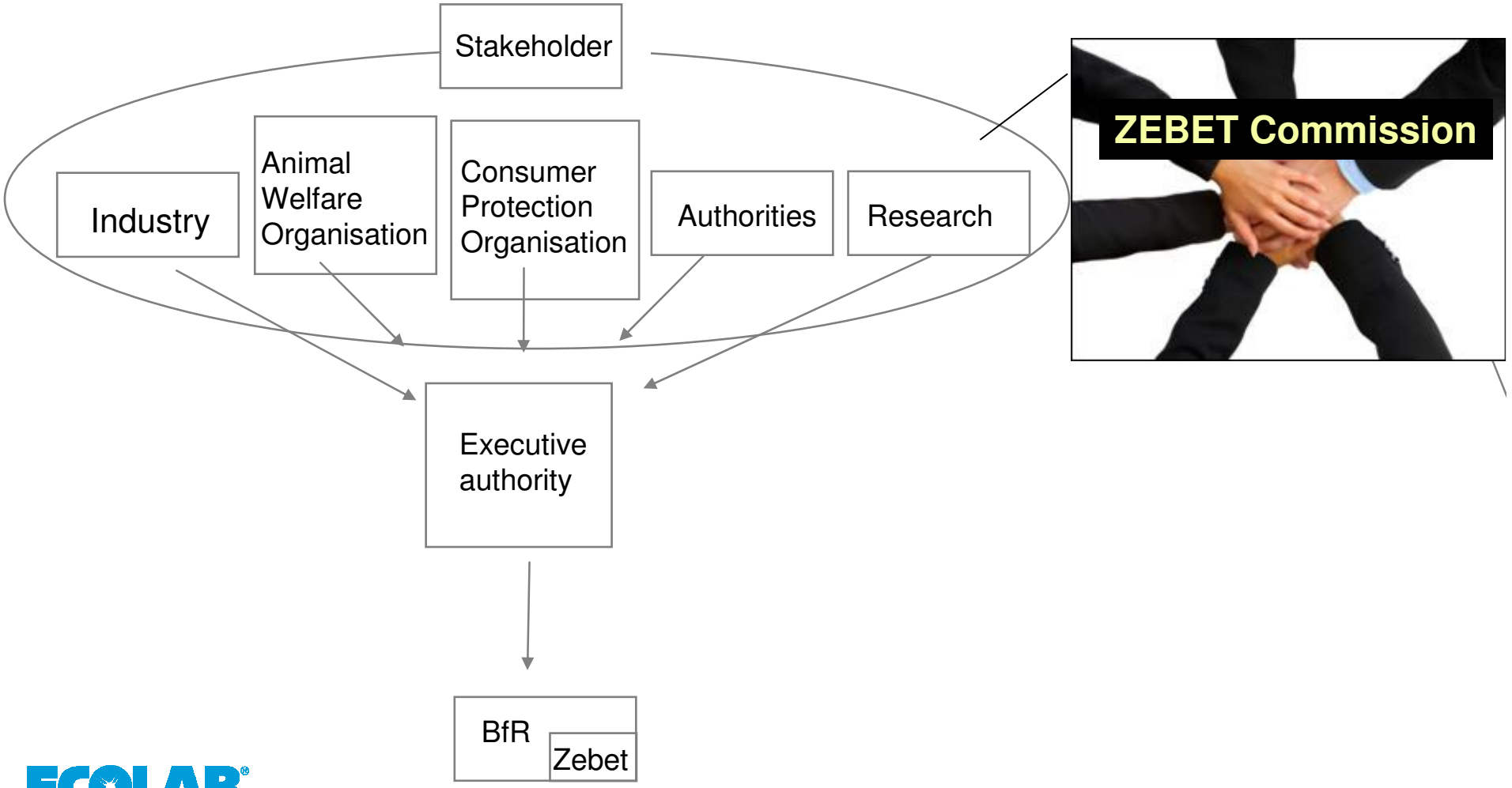

Drivers for the work of ZEBET

- Overall objective and mission
- Key deliverables
- Core Processes
- Enablers

Stakeholder / ZEBET Commission Input

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Industry Survey on ZEBET Deliverables

(as of March 2007)

Industry Sectors

- Cosmetics
- Detergents
- Pharmaceuticals
- Agro-chemicals
- Speciality Chemicals
- Commodity chemicals

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Strategy Map for ZEBET
The Chemical Industry Perspective

ZEBET Objective	**Sound scientific advice and support for executive authorities and stakeholders**			
ZEBET Deliverables	**3 R methods accepted for Hazard- und risk assessment**	**Risk assessment concepts**	**Consultancy, Knowledge Transfer**	**Knock-on Research Funding**
Core Processes	Method development/ Research	Validations	Evaluations on methodolgy	Risk assessment
Enabler for Core processes	Expertise natural scientific methodological legal	Allocation of Roles and Responsibilities	Ressources Staff reference lab IT …	Networks / relationships

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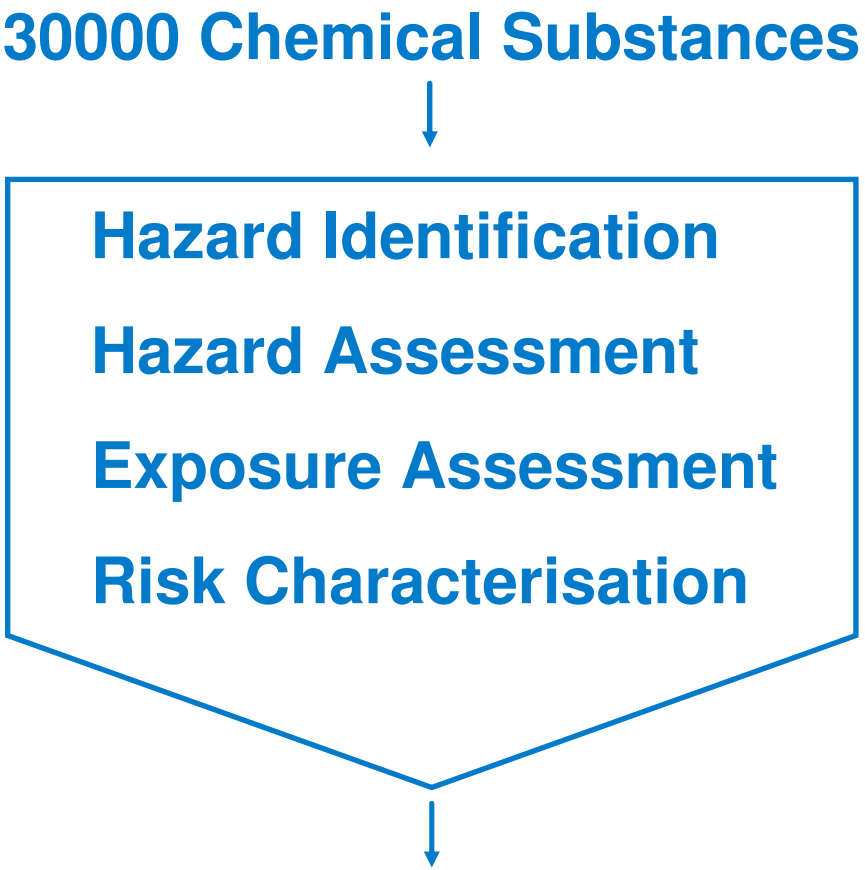
Risk Assessment for REACh



(EU Joint Research Center, 2006)

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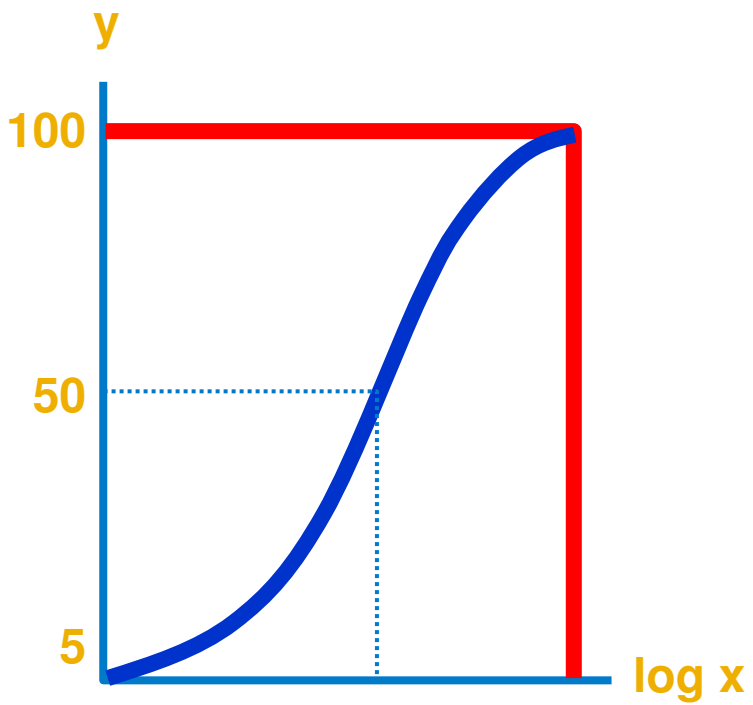
Threshold of Toxicological Concern

Statistical approach

For y % of all substances, pooled in a metaanalysis no-adverse-effects are below a dose x



Lit: ECETOC, 2003; Kroes et al, 2004;
Ford et al, 2000; Cheeseman et al, 1999

For exposures below the TTC no systemic toxicity data are required

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Endpoint specific reduction requirements for experimental animals

Acute toxicity	6
Skin irritation / corrosion	3
Eye irritation	3
Mutagenicity in vitro	0

Skin sensitization	16
Mutagenicity in vivo	40
Cumulative toxicity	80 (40)
Reproductive Toxicity	2600
Cancerogenicity	400

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Threshold of Toxicological Concern Saving Options

Acute toxicity	6
Skin irritation / corrosion	3
Eye irritation	3
Mutagenicity in vitro	0

Skin sensitisation	16
Mutagenicity in vivo	40
Cumulative toxicity	80
Reproductive Toxicity	2600
Carcinogenicity	400

Total saving option per substance (number of animals)	12	3080

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Expert judgement / Weight-of-Evidence-Approach - Impact

Experience from the US-HPV programme

Hazard assessments based on	Human Health	Environmental Effects
Studies	56 %	65 %
Expert Judgements	44 %	35 %

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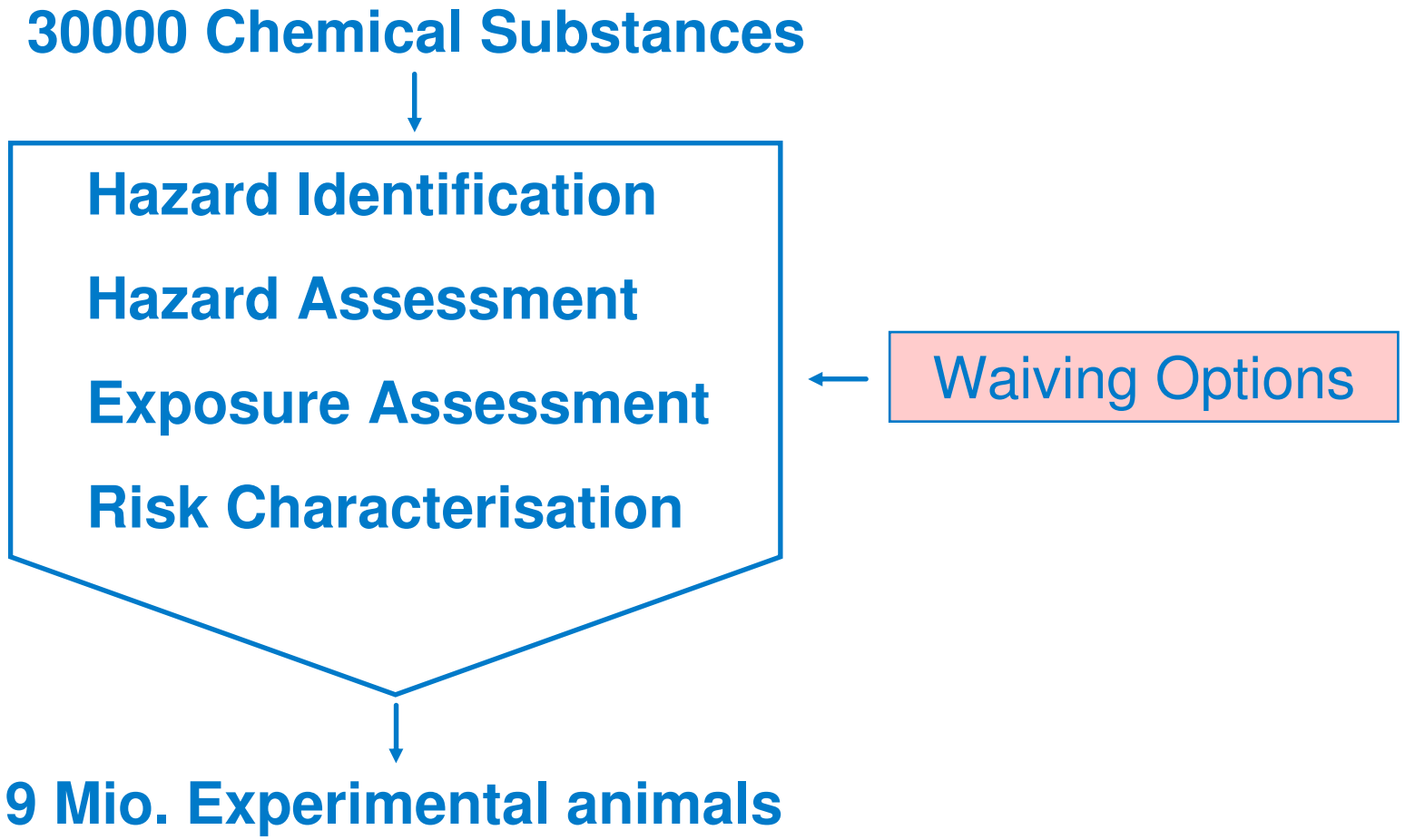
Risk Assessment for REACh integrating TTC / WoE



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On behalf of the German Chemical Industry

Happy

Birthday !

…to ZEBET

… for a 20-year-long successful engagement in the development of 3R approaches

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Keep in mind:

Only with integration of risk assessment strategies we can make a substantial break-through for the 3R concept

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Thank you for your attention!