

Understanding the lengthy process to replace the Draize test

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Background of PhD project

- **Aim:** Elucidating why only a few of the alternatives have replaced animal tests
 - *Provide points of departure to speed up the replacement of animal tests*
 - *Gain insight in dynamics of change of highly institutionalized practices*



Source: whyhomeschool.blogspot.nl

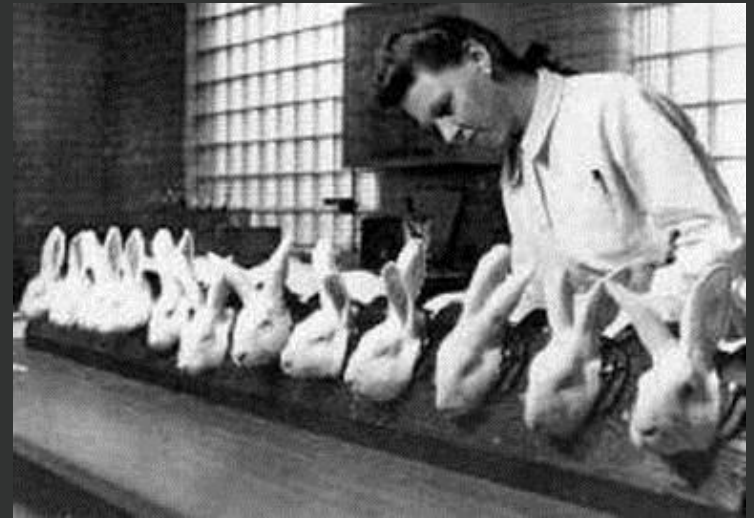


This project

- Draize eye irritation test in rabbits by innovative methods

Single exploratory case study

- Innovation literature



Source: occupyforanimals.org



Source: newbusinessintel.com



Innovation theory

- **INNOVATION** ≠ **GOOD IDEA**
- **INNOVATION** = good idea + developing + testing + experimenting + creating support etc.

Framework to analyze technological change:

- Technological Innovation System (**TIS**) **APPROACH** (Hekkert et al, 2007)

*Study of **7 key processes** over time:*

1. *Experimentation*
2. *Knowledge development*
3. *Knowledge diffusion*
4. *Guidance of the search*
5. *Market formation*
6. *Resource mobilization*
7. *Counteracting resistance to change*



"Your proposal is innovative. Unfortunately, we won't be able to use it because we've never tried something like that before."



Institutional theory

- TIS focuses on emergence of technologies
- **INSTITUTIONS** (*'the rules of the game'*) are also important

3 pillars of institutions (Scott, 2008)

- 1. Regulative rules (e.g. rules, laws, sanctions)*
- 2. Normative rules (e.g. norms and values)*
- 3. Cognitive rules (e.g. shared conceptions of reality)*



Method

Qualitative event history analysis

EVENTS related to:

- *Key processes of the TIS*
- *Institutional pillars*

NARRATIVE

Data gathering

- *Desk research*
- *Triangulation in 11 semi-structured interviews*



NARRATIVE

*Institutionalization of
the Draize test*

- Draize test adoption in **regulation** in 1960s

Testing in rabbits

***Subjective** scoring*

***Variable** results*

Only available method

*Turned out to be **successful***



NARRATIVE

The rise of the TIS

- Anti-Draize campaign in 1980

Created momentum

*Change in **normative** rule: Conducting the Draize test was not longer taken for granted*

*Increased activity in **all** key processes*

*Development of alternatives became **large-scale operation***

*Several **alternatives** were developed*



NARRATIVE

Momentum vanished

- 1985 -1993: Momentum faded

*Use of alternatives as **pre-screen** and **occupational hazard purposes***

*Development of alternatives took **long***

Normative rule** that it was too **challenging** to replace the successful Draize test gradually **prevailed over public concerns

*Activity in all key processes **declined***



NARRATIVE

Institutional pressure

- 1993 -1998: Increased **institutional pressure**

*Regulative rule concerning a **ban** on animal testing for cosmetics adopted by EU*

Increased activity** in many key processes including 6 multi-laboratory **validation studies

***None** of the alternatives (30) were approved
Deadline of the ban was **missed***



NARRATIVE

*Continuing Institutional
pressure*

- 1998 -2003: Continuing
institutional pressure

*Deadline ban was missed and **postponed 3 times**
Regulative rules concerning approval of alternatives
too challenging?*

*Draize test was **reference***

*Alternatives should predict eye irritation at least as
good as the Draize test*

***Zero tolerance** with regard to false-negatives*



NARRATIVE

Tiered testing

- 2003-2009: Implementation of **two alternatives**

*New regulative rule: a ban that **phased out** essential safety tests **before** alternatives are **formally validated***

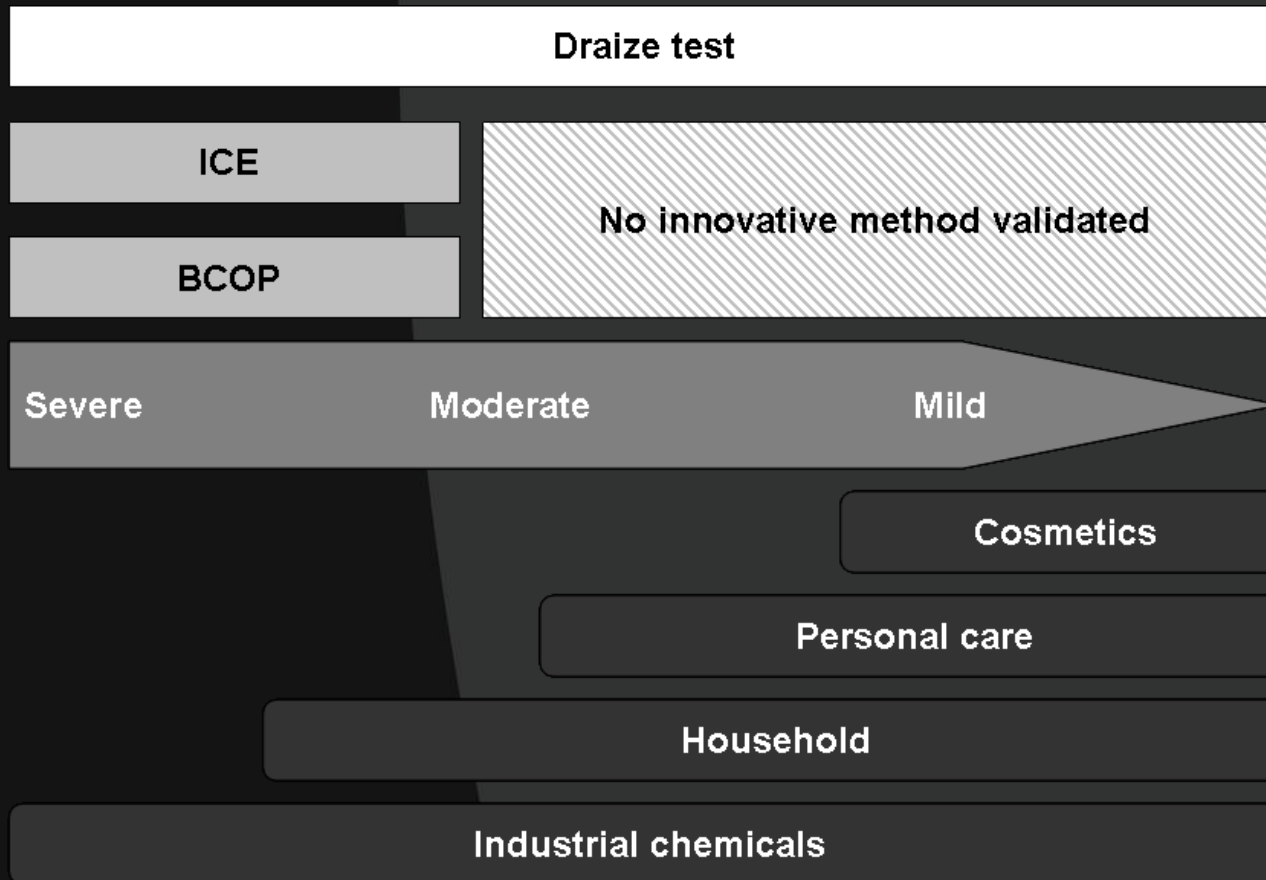
*Revision of cognitive rule: **tiered testing***

Retrospective analysis results validation studies 2 tests validated for moderate to severe eye irritation

*Implementation in **OECD guidelines***



Current situation



Conclusions

Innovation = **DIFFICULT**

Technology development is important

Main barriers **originate in the rules**

- *Regulative embedding of the Draize test*
- *Normative: the believe in the Draize test*
- *Cognitive rule to aim for a single test to replace the Draize test*

Institutionalization create **high barriers to change**

Political and public pressure are key for replacing animal tests



“The difficulty lies, not in the new ideas, but in escaping from the old ones, which ramify, for those brought up as most of us have been, into every corner of our minds.”

John Maynard Keynes, 1935

