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: newbusinessintel.com

Source: occupyforanimals.org
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
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
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
• 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
• 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
• 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
• 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

Draize test

ICE

No innovative method validated

BCOP

Severe Moderate Mild

Cosmetics

Personal care

Household

Industrial chemicals
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