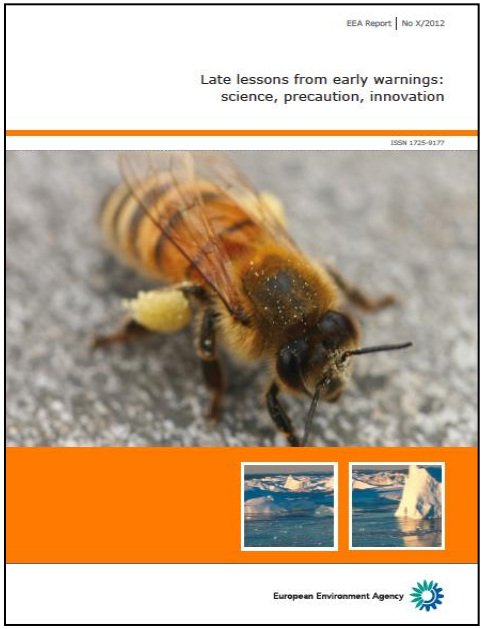
« Health Risks, Precaution and Innovation »
Sciences Po – ANSES symposium
June 24, 2015 (Paris)

Precaution and the Myth of Overregulation



Steffen Foss Hansen

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Late Lessons Vol. I

Late Lessons from Early Warnings

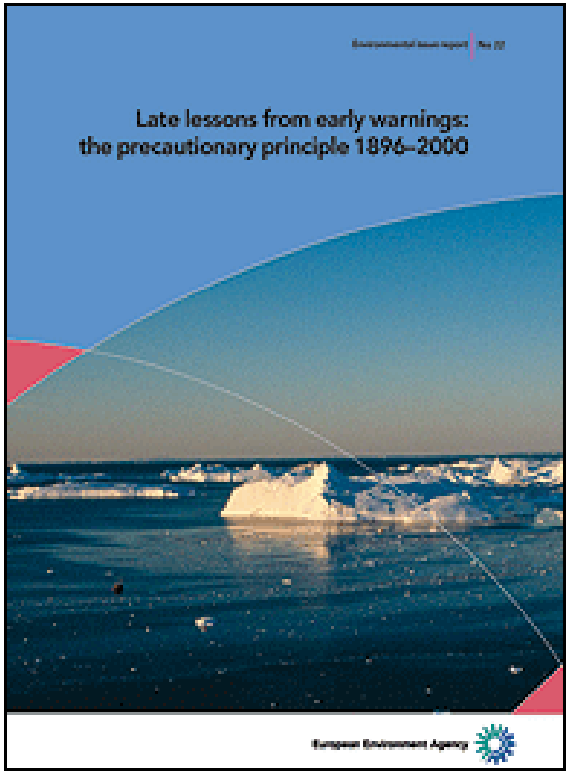
- European Environmental Agency

- 14 case studies where early warnings were ignored incl. asbestos, PCBs, Ozone depletion, Great Lakes

Conclusions

- Lack of action = Very costly + unpredicted consequences to health and environment

- Decision-makers ignored not only early warnings, but also ”severe and late warnings” e.g. asbestos

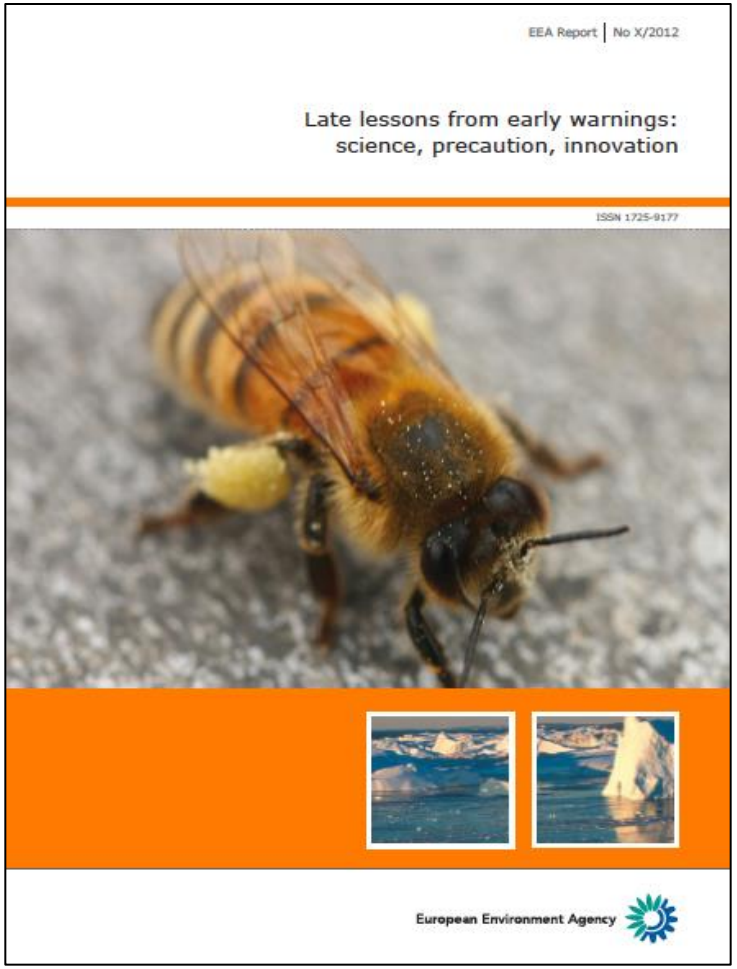


Critic of the Precautionary Principle

- Anti-science
- Anti-technology
- Anti-innovation
- …
- …
- Will lead to "un… …y regulatory …
  - Lo… …omic benefits
  - Los… …human and environmental health benefits

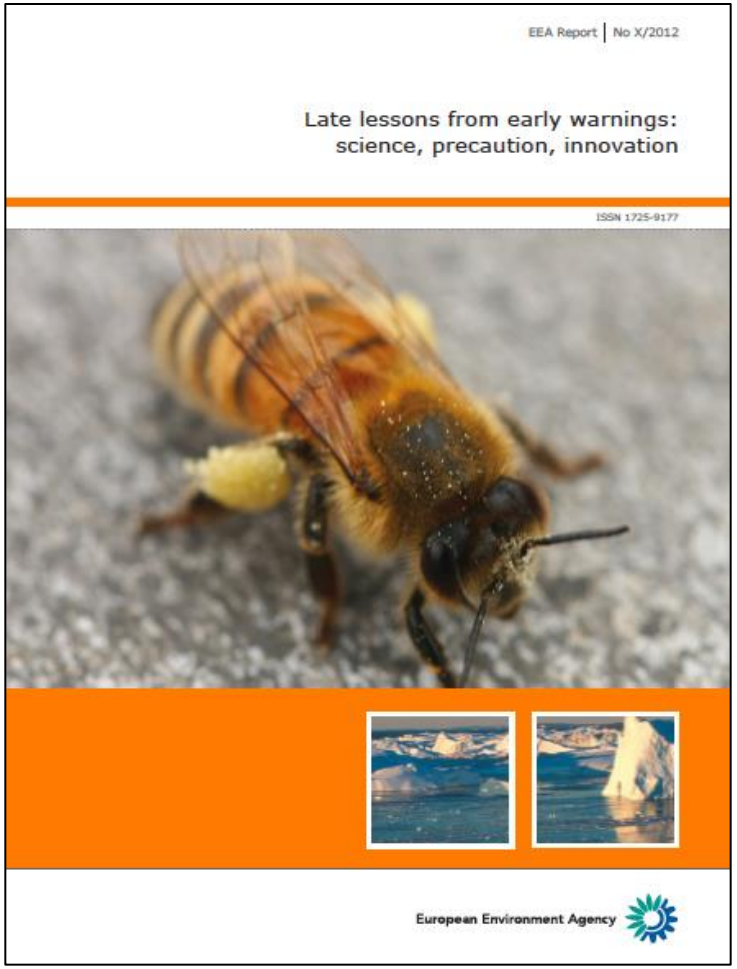
True or false?

New “Late Lessons”



- Lead in petrol;
- Mercury pollution of Minamata Bay and beyond;
- DBCP pesticide and male infertility;
- The pill and feminised fish;
- Bisphenol A and harm to children;
- DDT;
- Booster biocides: an alternative to TBT;
- Climate change;
- Floods;
- Ecosystems and resilience;
- Perchlorethylene and drinking water;
- Beryllium exposure in the nuclear industry;
- Environmental tobacco smoke;
- Nicotinoid pesticides and the French bee decline;
- Nanotechnology;
- Genetically modified organisms;
- Mobile phones-head cancer link
- Nuclear power;
- Invasive alien species;
- Economic costs of inaction;
- False positives;
- Governance of innovation and risks;
- The role of progressive business;
- Towards better victim compensation and protection of early warning scientists.

New “Late Lessons”



2 The precautionary principle and false alarms — lessons learned

Steffen Foss Hansen and Joel A. Tickner

Most of the cases examined in the *Late lessons from early warnings* reports are 'false negatives' — instances where early warnings existed but no preventive actions were taken. In debates surrounding the precautionary principle it is often claimed that widespread application of the principle will lead to a large number of regulatory false positives — over-regulation of minor risks and regulation of non-existent risks, often due to unwarranted public 'fears'. Understanding and learning from past false positives as well as false negatives is essential for improving decision-making about public health and the environment.

This chapter reviews incidents of 'false positives', where government regulation was undertaken based on precaution but later turned out to be unnecessary. In total 88 cases were identified to be alleged false positives, however, following a detailed analysis most of them turned out to be either real risks, or cases where 'the jury is still out', or unregulated alarms, or risk-risk trade-offs, rather than false positives.

The analysis revealed four regulatory false positives: US swine flu, saccharin, food irradiation, and Southern leaf corn blight. Numerous important lessons can be learned from each, although there are few parallels between them in terms of when and why each risk was falsely believed to be real. This is a lesson in itself: each risk is unique, as is the science and politics behind it and hence a flexible approach is therefore needed, adapted to the nature of the problem. The costs of the false positives identified were mainly economic, although the actions taken to address swine flu in 1976 did lead to some unintended deaths and human suffering, and diverted resources from other potentially serious health risks. Determining the net costs of mistaken regulatory action, however, requires a complete assessment of the impacts of the regulation, including the costs and benefits of using alternative technologies and approaches.

Overall, the analysis shows that fear of false positives is misplaced and should not be a rationale for avoiding precautionary actions where warranted. False positives are few and far between as compared to false negatives and carefully designed precautionary actions can stimulate innovation, even if the risk turns out not to be real or as serious as initially feared. There is a need for new approaches to characterising and preventing complex risks that move debate from the 'problem' sphere to the 'solutions' sphere. By learning from the lessons in this chapter, more effective preventive decisions can be made in the future.

The scarcity of genuine false positives compared to the large number of 'mistaken false positives' could partly be the result of a deliberate strategy in risk communication. Several references and leaked documents have shown that some regulated parties have consciously recruited reputable scientists, media experts and politicians to call on if their products are linked to a possible hazard. Manufacturing doubt, disregarding scientific evidence of risks and claiming over-regulation appear to be a deliberate strategy for some industry groups and think tanks to undermine precautionary decision-making.

Purpose

- *Should we as a society fear unnecessary precautionary action when applying the Precautionary Principle?*
  - *Are there many false positives occurring in the regulation of public health and the environment?*
  - *Are false positives always bad for society?*
- *What lessons can be learned from cases where unnecessary precautionary action was taken in the past?*

False Positives

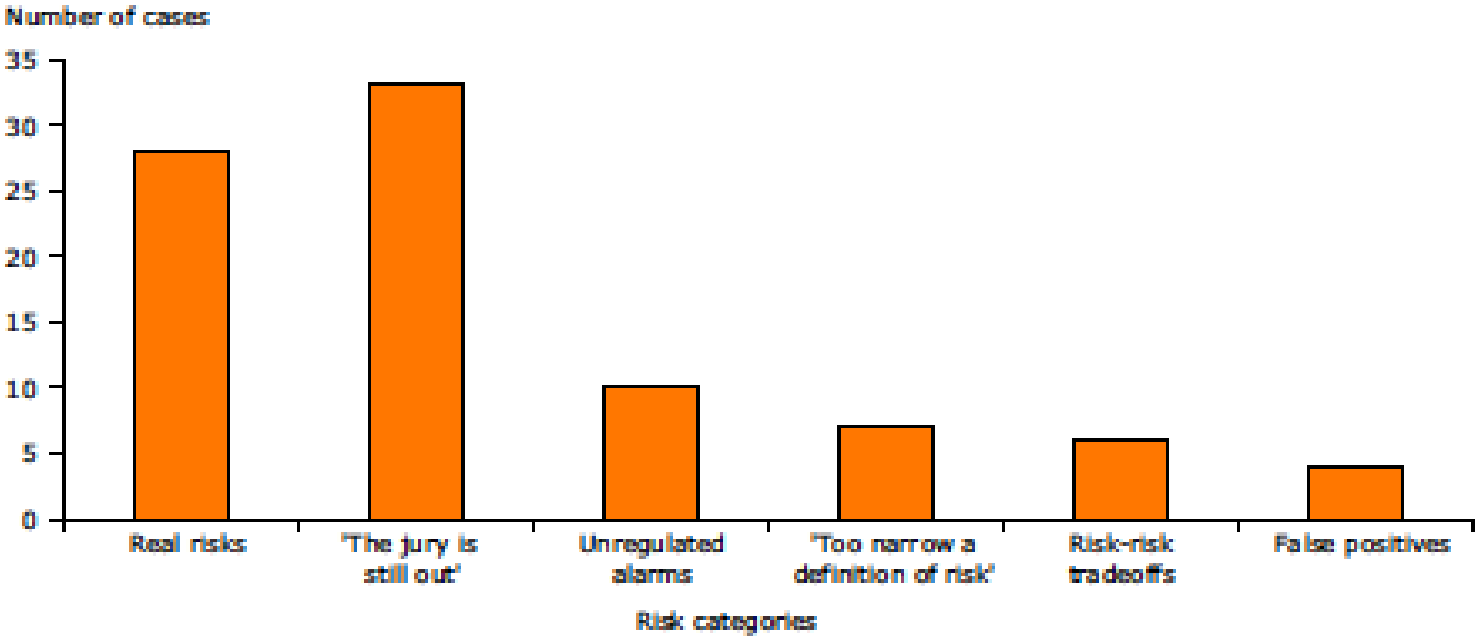
- *"…Where action was taken on the basis of a precautionary approach that turned out to be unnecessary…"* [EEA 2001:12]
- What should be defined as "action"
  - We defined it as "regulatory action", not public concern, not additional research
  - How to determine "unnecesary"?

Table II. Scale for Assessing State of Knowledge Used by IPCC (Moss & Schneider, 2000)

95–100% Very high confidence	
67–95% High confidence	← Level used in this study
33–67% Medium confidence	
5–33% Low confidence	
0–5% Very low confidence	

Proclaimed False Positives

Figure 2.1 Distribution of 88 proclaimed false positives



Hansen et al. 2007. Risk Analysis 27(1): 255-269
Hansen and Tickner 2013 LLII, Sci, Pol, Inn, EEA

Identified False Positives

- **The Southern Corn Leaf Blight** - the decision in the U.S. in 1971 to plant more corn in anticipation that the Southern Corn Leaf Blight would return and destroy a large part of the harvest;
- **The Swine Flu of 1976** - the decision in the U.S. in 1976 to mass immunize the entire American population in anticipation of a return of the Swine Flu, which never reappeared;
- **Saccharin** - the decision to require saccharin to be labelled in the U.S. in 1977 because of it was believed to be a human carcinogen;
- **Food irradiation in relation to consumer health** - the reluctance to allow a seemly safe and wholesome technology that could help reduce the large number for food pathogens and increase shelf life.

Analysis

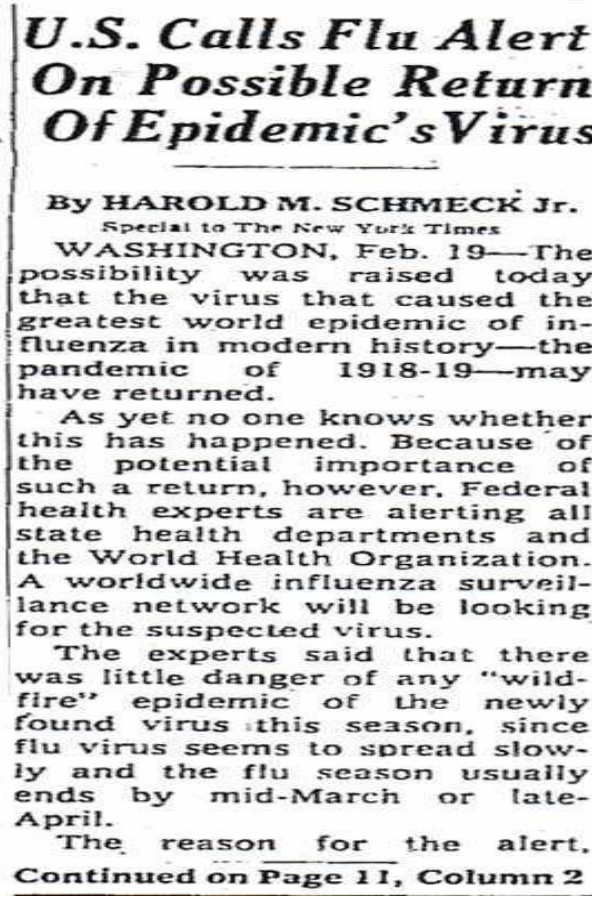
- When and why was it believed that the risk was real?
- When and what were the main actions taken?
- Were alternative courses of action considered?
- When and why was it realized that the risk was not real?
- What were the resulting monetary costs and benefits?
- Were there indirect benefits or negative unintended consequences from the false positives?

Swine flu of 1976 - the beginning of a false positive

- Jan 1976: Outbreak at Fort Dix NJ
- Cause: A new virus closely related to the Spanish flu virus
- Spanish flu = > 50 mill death worldwide in 1918-19

ACIP recommendation to mass immunize

- March 1977: 500 infected
- Impossible to project
  - probability and severity of having a pandemic
- 5 months till begin of next flu season
- Plan for vaccine administration should be developed
- Four courses of action were discussed



U.S. Calls Flu Alert On Possible Return Of Epidemic's Virus

By HAROLD M. SCHMECK Jr.
Special to The New York Times

WASHINGTON, Feb. 19—The possibility was raised today that the virus that caused the greatest world epidemic of influenza in modern history—the pandemic of 1918-19—may have returned.

As yet no one knows whether this has happened. Because of the potential importance of such a return, however, Federal health experts are alerting all state health departments and the World Health Organization. A worldwide influenza surveillance network will be looking for the suspected virus.

The experts said that there was little danger of any "wildfire" epidemic of the newly found virus this season, since flu virus seems to spread slowly and the flu season usually ends by mid-March or late-April.

The reason for the alert,

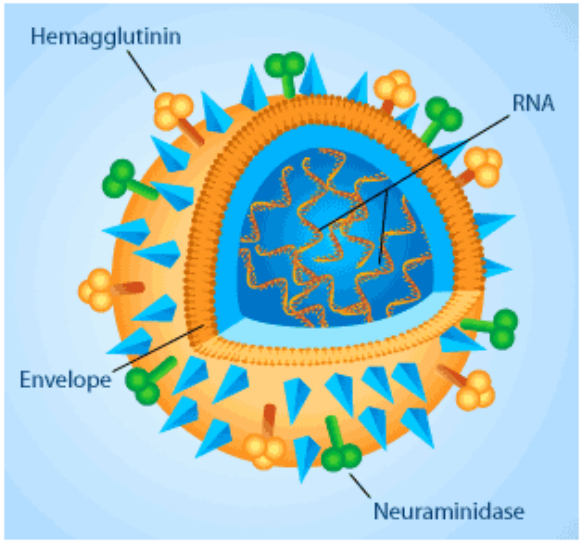
Continued on Page 11, Column 2

The *"Combined Approach"*

- Federal purchase of vaccine for 200 mill people
- Safety and efficacy testing by the Bureau of Biologics (BoB)
- Field trials by the National Institute of Allergy and Infectious Diseases
- Distribution and final immunization of the public by State, local, and private medical services

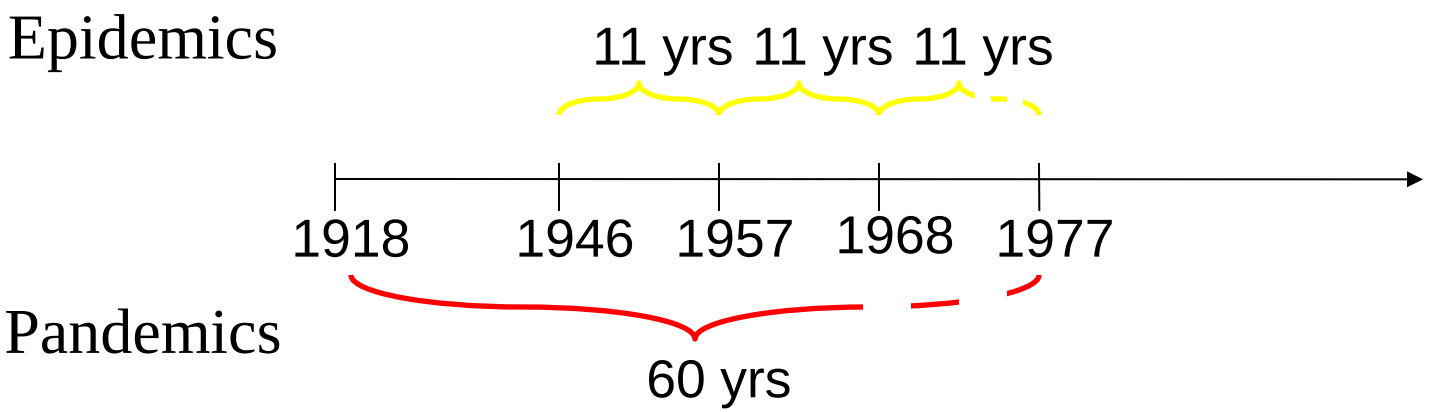
Background of Flu anno 1976

- Emergence of new flu strain
  - typically low levels @ end of one flu season
  - return in epidemic proportions the following flu season
  - new strain of flu = major epidemic



www.abc.net.au

Recycling flu epi-/pandemics



“You should recognize that science can only take you so far. It’s a social and political decision”

- Meyers, Director of Bureau of Biologics
  [cited in Bernstein 1985:243]

"As soon as I heard of swine flu and its implication for a pandemic, I realized that the political system would have to respond. There was no way out, as long as all of the scientists supported it. We had to assume a probability greater than zero, and that's all that we needed to know. You can't face the electorate later, if the pandemic arrives, and say that the probability was so low that the costs outweighed the benefits. The people would never forgive us"

- Mathews, Secretary of U.S. Health, Education and Welfare [cited in Neustadt and Fineberg 1978].

President Ford decides to act

- Mass Immunization Prgram
  - $ 135 mill. from Congress
  - Cover vaccinate 200 mill people
  - 4-5 months to complete before next flu season

"I think you ought to gamble on the side of caution. I would rather be ahead of the curve than behind it"

- President Ford

[cited in Neustadt and Fineberg 1978:25]

Information avail. to President Ford

- *ACIP recommendations*
- OMB document *"Uncertainties Surrounding a Federal Mass Immunization Program"* raising ?' s
  - the real probability of a pandemic occurring
  - the seriousness of the epidemic, should it come,
  - creation of precedents for similar future programs
  - whether the scientific community fully agreed

Mass Immunization Program

- One setback after the other e.g.
  - Tests trials: two-doses needed for children = 2 months delay
  - Reluctant insurance industry
    - Never before had such a program been mounted in such a short time
    - the risk was incalculable
    - costs of liability were enormous and uncertain
- Outbreak of Guiallain-Barre Syndrome
  - Mid-dec 1977: 107 cases (incl. six deaths)
  - one in a 100,000 to 200,000 vs. one in > a mill.

Decision to halt the program

- 40 million received the vaccine
- *"…in the interest of safety of the public, in the interest of credibility, and in the interest of the practice of good medicine"*

  - Assistant secretary, US HEW Cooper

  [cited in Silverstein 1981:119]
- Media verdict: "fiasco"

Identified False Positives

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Why was the False Positive believed to be real?

- Few parallels can be drawn between the four cases
  - Swine flu: "Early warning" of an outbreak fit perfectly into the three generally believed scientific theories of the returning cycles of flu.
  - Saccharin: Concern was triggered by new scientific knowledge
  - Food irradiation: recognition that the existing scientific knowledge about safety had been flawed
- Why was precautionary action taken in these cases and not in other past cases?

Why was it realized that it was not?

- Food irradiation stands out - consensus about safety since 1981
- It would have been virtually impossible to foresee that the false positive was not real
  - Swine Flu: Impossible to put a specific number on the probability of whether or not the flu would return;
  - Saccharin: The mechanisms by which saccharin causes cancer in rats are specific to rats
  - SCLB: the blight did return - not as devastating impact

Cost & benefits of false positives

- Costs of unnecessary action:
  - Mainly economic,
  - Swine Flu did have more serious health effects and a wasted of resources due to bad planning

- Benefits of unnecessary
  - Sparked innovation within industry, government and scientific research
  - Swine flu lead to a nation-wide disease surveialnce program and a lot was learned about whole and split vaccines
  - Labelling of scaharin lead to the development of several new artificial non/caloric sweeteners

Lessons learned

- Lesson 1: More scientific research and scientific certainty **could not have** prevented the false positives from happening
- Lesson 2: **Transparency is key** about what is known and about uncertainties and make sure that these are made clear in the communication between the scientists, the regulating authorities, the politicians and the public
- Lesson 3: **The availability of alternatives** seems to minimize the total impact of the false positives, but a proper impact assessment is important to avoid Risk-risk tradeoffs

Lessons learned

- Lesson 4: Be extra careful when **implementing a new substance**, technology, etc. in a **large scale** because of the risk of unknown-unknowns
- Lesson 5: The decision-making process **should be flexible** so that decisions can be altered in the **light of new knowledge**
- Lesson 6: Unnecessary precautionary action can **lead to innovation** and policies should **be designed so that they do**

Lessons learned

- Lessons learned underlines:
  - the importance of being open, honest and transparent about what is (not) known and uncertainties and disagreement about policy alternatives.

- Precautionary approach + Impact- and alternatives assessment + flexible management

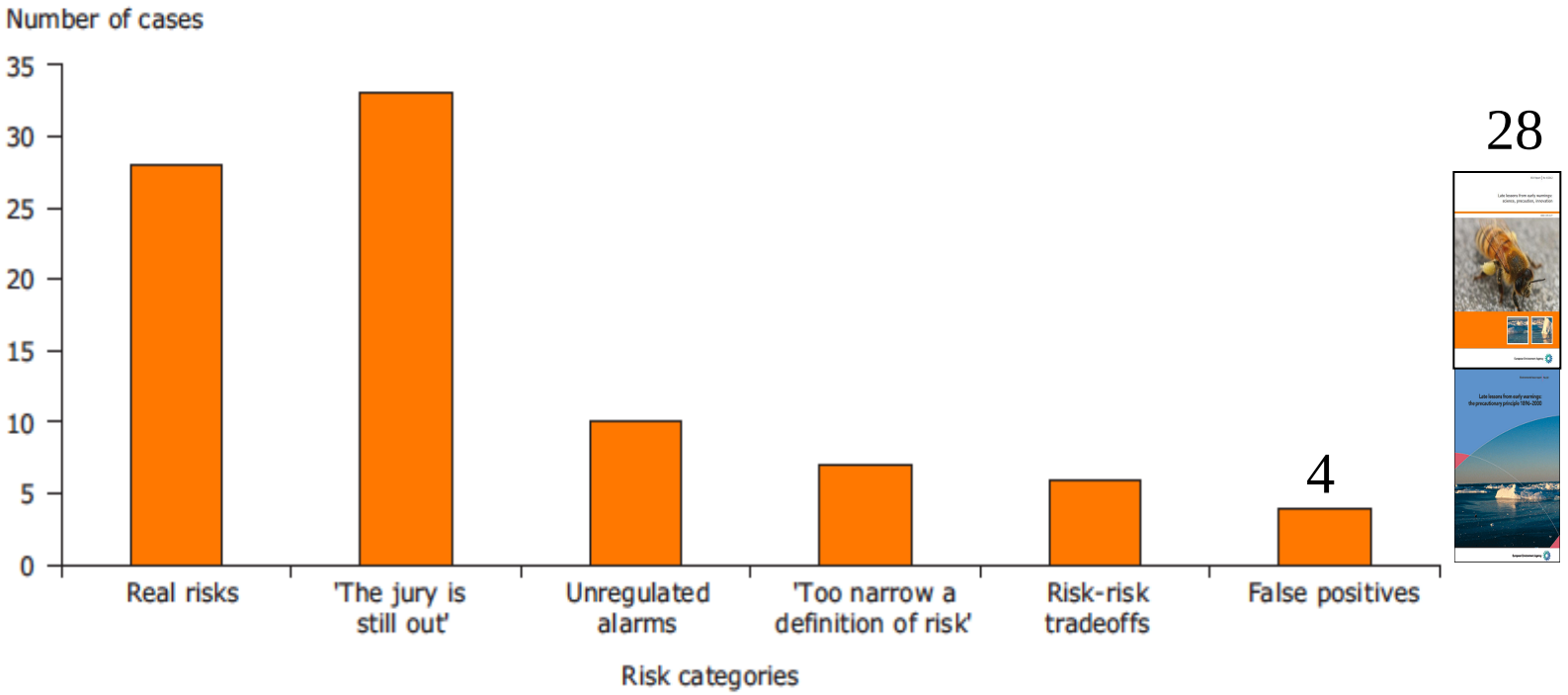
  =

  Min # of false positives and negatives and

  Max society's benefits from committing false positives

Overregulation vs. Underregulation

Figure 2.1 Distribution of 88 proclaimed false positives



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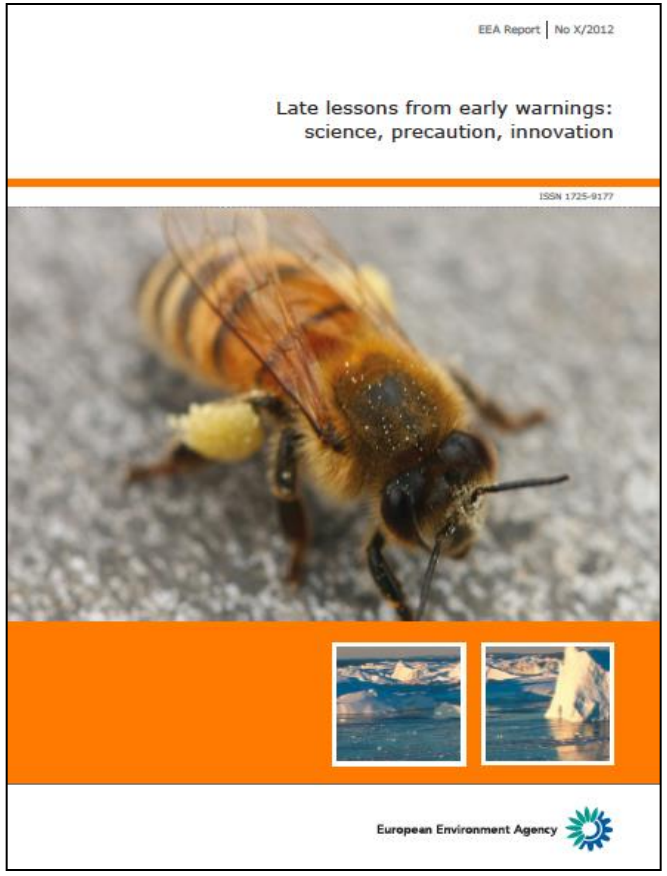

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