



Sveriges lantbruksuniversitet
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Mistra Biotech



Chemicals and GMOs – a comparison

Sven Ove Hansson



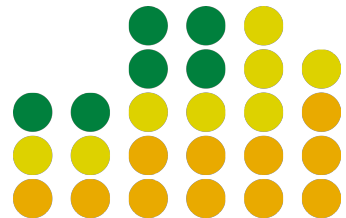
food crops

Chemicals and ~~GMOs~~
– a comparison

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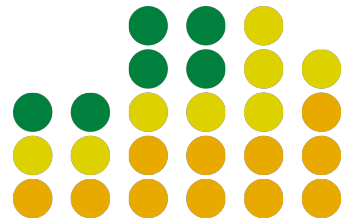
Part 1: A brief summary of chemicals regulation

Part 2: Comparison



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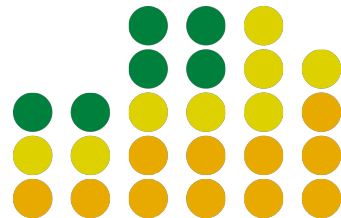
Generalities

○The international picture

- Similar legislations in different countries. (Other such “technical legislations” also tend to be similar).

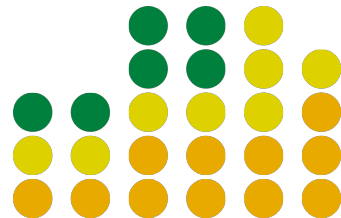
○The structure of legislations

- A basic part concerning what substances are allowed and about documentation requirements and products information.
- Many supplementary legislations on emissions, environmental protection, workplace safety, consumer safety etc.



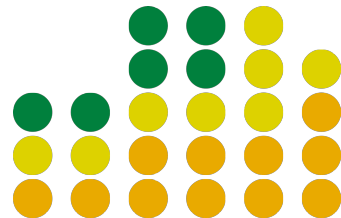
TSCA (toxic substances control act)

- USA 1976, relatively few changes since then.
- Covers industrial (general) chemicals and chemical products.
- Three big exceptions: drugs, food additives, and pesticides that have special legislations.
- “Chemicals in non-chemical products” are not systematically regulated.



TSCA (toxic substances control act), cont.

- The three big exceptions are regulated with a “prohibition default”.
- General chemicals have a “permission default” in TSCA.



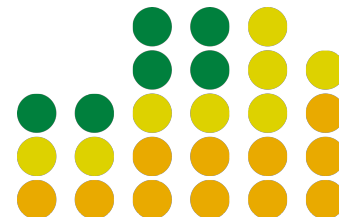
TSCA (toxic substances control act), cont.

- An inventory list from 1976 distinguishes between “existing” and “new” substances. (Inappropriate but established terminology.)
- Notification of new substances: Very little data is required. The authority (EPA) relies on structure-activity relationships (SAR).
- Inefficient attempts to catch up with existing chemicals.



The pre-REACH European system

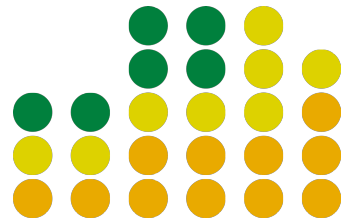
- Similar to TSCA.
- Same three big exceptions.
- Inventory from 1981.
- More data required for the notification of new substances.
- Equally inefficient attempts to catch up with existing chemicals.



REACH

(Registration, Evaluation, Authorisation and Restriction of Chemicals)

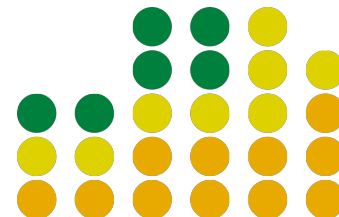
- In force since 2006, last registration deadline in 2018.
- Gives up the novelty requirement.
- Documentation requirements according to production volume.



REACH, cont.

(Registration, Evaluation, Authorisation and Restriction of Chemicals)

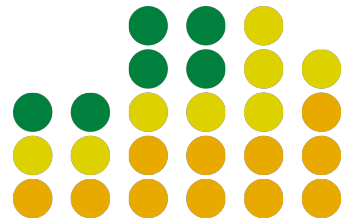
- Low volumes: In practice no meaningful toxicological or ecotoxicological information requirements.
- Medium volumes: Meaningful toxicological and ecotoxicological information but not sufficient to satisfy the labelling requirements.
- Highest production volumes: Toxicological and ecotoxicological information that is sufficient to satisfy the labelling requirements .



REACH, cont.

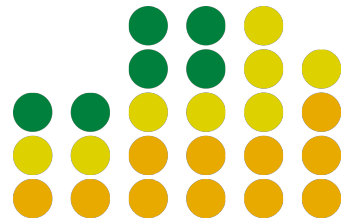
(Registration, Evaluation, Authorisation and Restriction of Chemicals)

- Other countries may be going in the direction of REACH, but probably not the US in the near future.



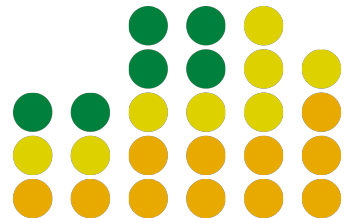
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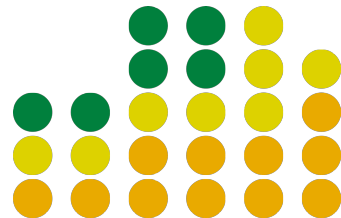
Generalities

- Complex policy/science issues.
- Both toxicology and ecotoxicology. For foodstuff also other ecological issues. For chemicals also other safety issues.
- The number of chemicals in use is in the order of magnitude 10^5 .
The number of crops is much smaller, but the number of crop varieties in use may be comparable to the number of chemicals.



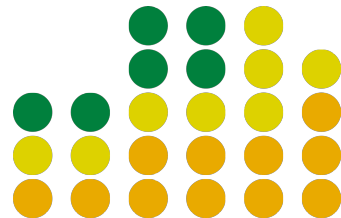
The science

- Both chemicals and food are related to major public health issues but in complex and not fully known ways.
- In both cases acute health effects are often easy to ascertain.
- In both cases extensive studies are needed to determine chronic health effects. Such effects may be unknown for long in spite of widespread use.
- In both cases, there is a common tendency to overestimate the safety obtainable by long experience of use.
- In both cases, there is a tendency to regard “natural” products as safer than products perceived as unnatural. In neither case is this supported by science.



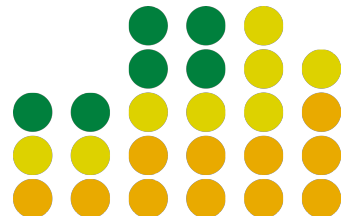
Conflicts and complications

- In both cases regulation, and in particular documentation requirements, run into conflict with industry interests.
- In both cases, regulation can lead to trade barriers.
- In both cases, public opinion and NGOs put pressure on decision-makers.



Criteria for documentation requirements

- In both cases some products have been selected for much higher documentation requirements than others. In both cases the selection criteria are highly questionable.

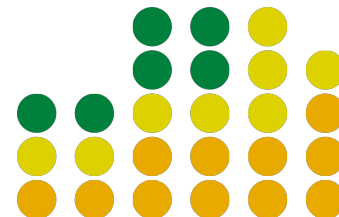


Criteria for documentation requirements, cont.

For **chemicals**, production volume is a problematic criterion for several reasons:

- Production volume is probably a bad predictor of human and environmental exposure.
- Differences in toxicity/ecotoxicity are at least as large as differences in production volume.
- There may be high individual/local exposures for instance in the production of low-volume chemicals.

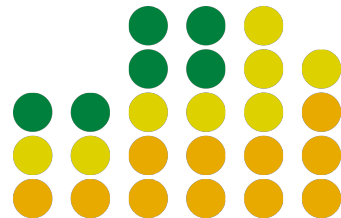
(Novelty would probably be an even worse selection criterion.)



Criteria for documentation requirements, cont.

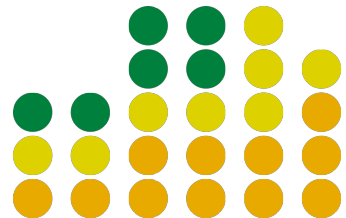
For **food crops**, genetic modification is a problematic criterion for one very basic reason:

- Genetic modification *per se* is not a useful predictor for human toxicity or ecological damage. Some genetic modifications are toxicologically and/or ecologically problematic and in need of special regulative attention. But so are some non-GM breeding outcomes.



In summary

These are two regulations that both make insufficient use of the available science. With better use of science, priority-setting for documentation criteria could be significantly improved.



Thanks for your attention!

