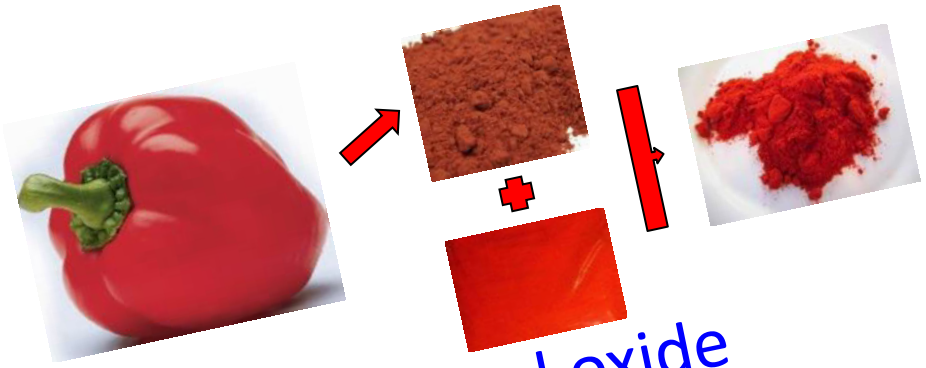
# The Global Harmonization Initiative (GHI) Food safety regulations based on science

*Kirsten Brandt & Huub Lelieveld*

# Safe and authentic food

- Food must correspond to ‘what it says on the tin’ and not contain banned substances
- Otherwise it is adulterated or contaminated
- Such food is considered fraudulent or unsafe or both
- When discovered, the food containing the illegal constituents is usually confiscated and destroyed

# Intentional illegal additives



Lead oxide
Hungary 1994

Melamine
China 2008


French fries
Belgium 1999

Diethylene Glycol
Austria 1985

# Unintentional illegal constituents

Arsenic in beer
Manchester 1900-1

Acrylamide
Worldwide 2011


DDT in fish
Worldwide since 1965

GM pollen
USA 2003-

- In some cases it is evident that consumption of the food would entail a health risk for the consumer
- In other cases this is not the case, and destruction of the food is an unjustifiable waste of food and money
- Science should be used to define appropriate distinctions between safe and unsafe food
- National regulations should be harmonised to prevent unnecessary waste of safe food

Chemicals that are not allowed but nevertheless present in food ***are not necessarily additives***. **Most man-made chemicals occur in nature in concentrations that can be detected now, but not previously**. They are produced by

- animals
- microbes (bacteria, fungi, parasites)
- plants
- geochemical processes (e.g. volcanos)

This includes chlorinated organic compounds. **More than 5000 different natural organic halogens have been identified in nature**

*G.W. Gribble. Chemosphere **52** (2003), 289–297 and Heterocycles, 84 (1) (2011), 157-207.*

30-03-2012 USA:

# Carbendazim in orange juice

Carbendazim is approved as pesticide in many countries, but not the United States.

MRLs (maximum residual levels) for carbendazim

EU: 100 ppb - 700 ppb

Canada: 500 - 6000 ppb

USA: **10 ppb**

US Environmental Protection Agency:

"... consumption of orange juice with carbendazim at the low levels that have been reported does not raise public health concerns."

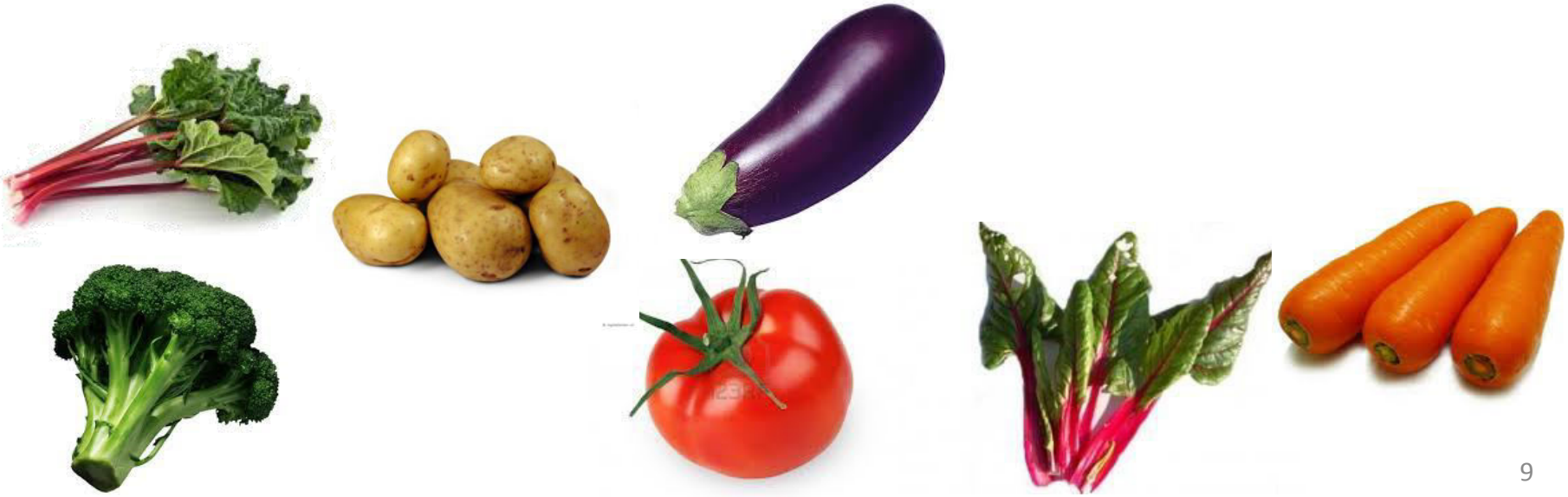


**Organic food contain more natural pesticides than conventional food**

**Most pesticides are organic**

# Natural, potentially toxic substances in food

- solanine **(potatoes, tomatoes, aubergines)**
- tomatine **(tomatoes)**
- oxalates **(rhubarb, chard)**
- polyacetylenes **(carrots)**
- glucosinolates such as progoitrin **(broccoli)**



Acetaldehyde
Benzaldehyde
Benzene
Benzofuran
Benzo(a)pyrene
Caffeic Acid
Caffeine
Catechol
Formaldehyde
Furan
Furfural
Hydroquinone
Isoprene
Limonene
Styrene
Toluene
Xylene

Etc.

# Differences in regulations

- result in needless destruction of healthy food in a world where a billion people have very little or no food
- hamper international trade and innovation

# The making of food safety regulations

The main problem is the lack of understanding of toxicity by

- politicians
- general public
- activists (antis)
- press

and the strong influence of professional lobbyists

# Alert on cancer chemical found in thousands of processed foods

By SOPHIE BORLAND
**UPDATED:** 01:19 GMT, 22 April 2011



A chemical which causes cancer has been found in a huge range of foods including bread, crisps and baby food.

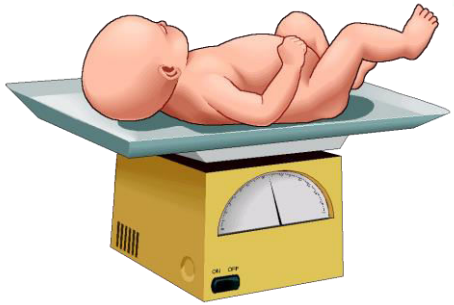
Scientists have identified high levels in thousands of cooked and processed products.

The substance, acrylamide, has been linked to several types of cancer including bowel, bladder and kidney, and is known to cause infertility and loss of muscle control.

# Absurd regulations

**ZERO-TOLERANCE** **= ABSENCE OF …**

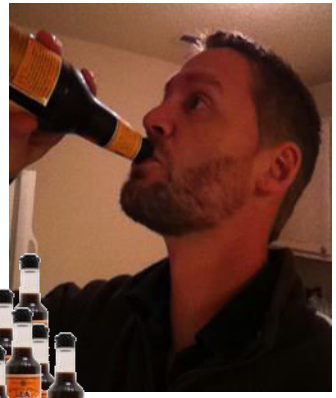
- **Antibiotics in food**



20.000 kg/day 800.000 kg/day

- **Sudan Red**

ppt* in products with ingredients from China



800 l per day life long

* About 1 grain of 2mm in an Olympic swimming pool)

# The Netherlands, June 2014
# Furazolidon from feed into meat

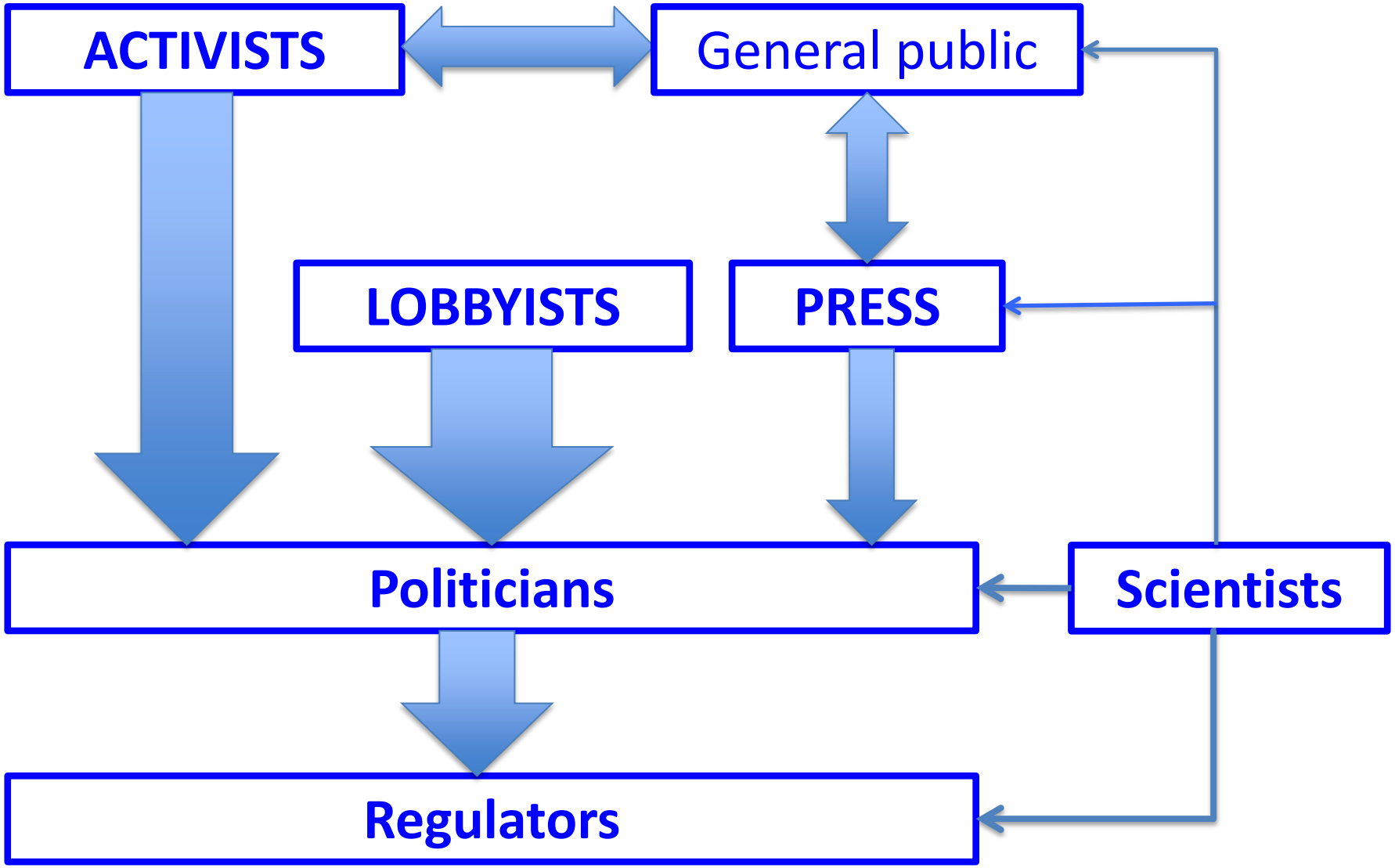
- Average exposure to humans eating meat 1.2 µg per meal (and **worst case 8 µg per meal**)
- Internationally recognised potential harm at 3 µg per day **during a life time** (i.e. 50 or 70 years)
- There are NO reports of harmful effects of therapeutic doses of **200 mg** per day during 21 days (WHO) **- this is 25,000 times more** than the worst case amount
- Conclusion: the meat is safe
- Destruction of 2474 calves and 100 companies closed

*Source: Netherlands Food and Consumer Product Safety Authority*

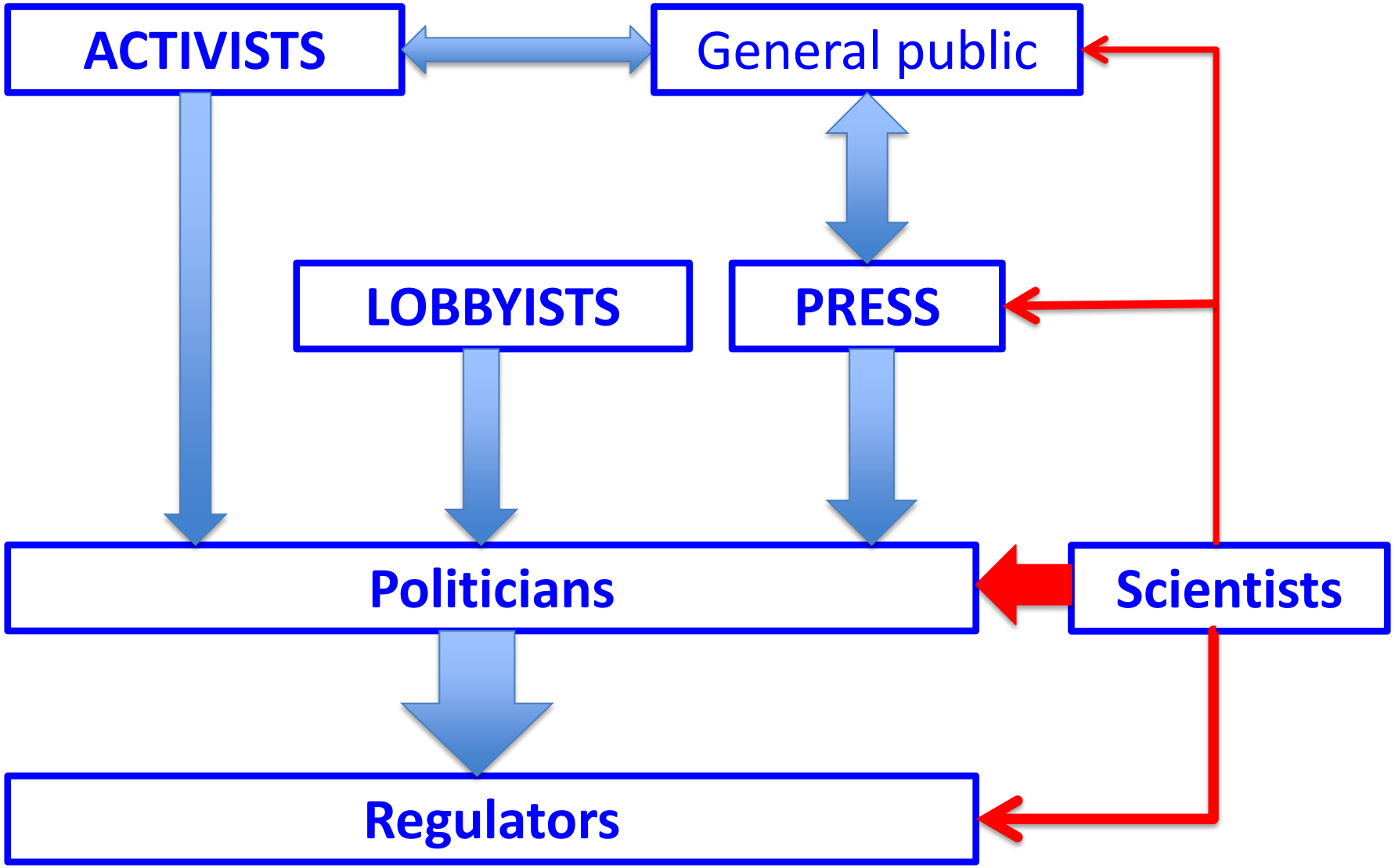
## If chemicals have been added illegally:

- those responsible should be prosecuted
- the product should be confiscated
- but **if safe**, the product should not be destroyed

# Now

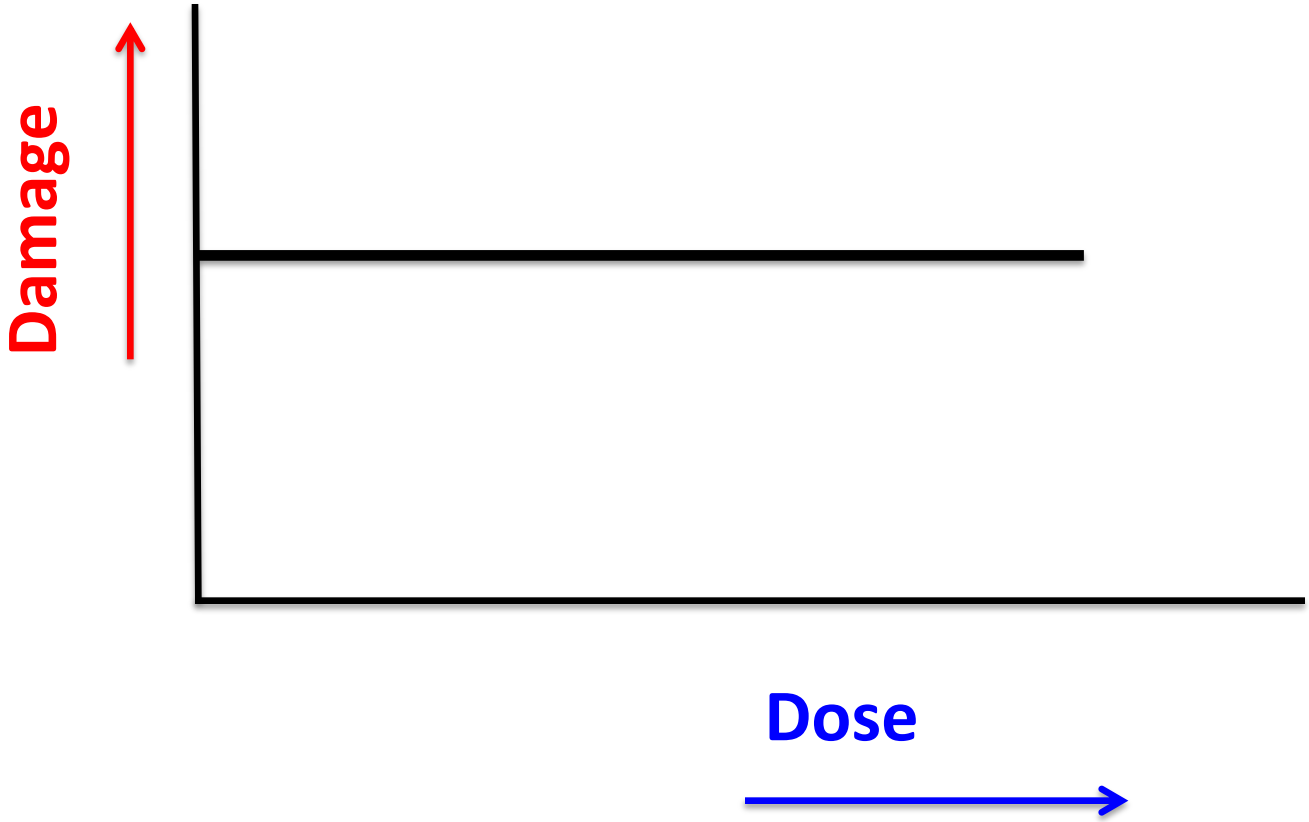

ACTIVISTS
General public
LOBBYISTS
PRESS
Politicians
Scientists
Regulators

# Future

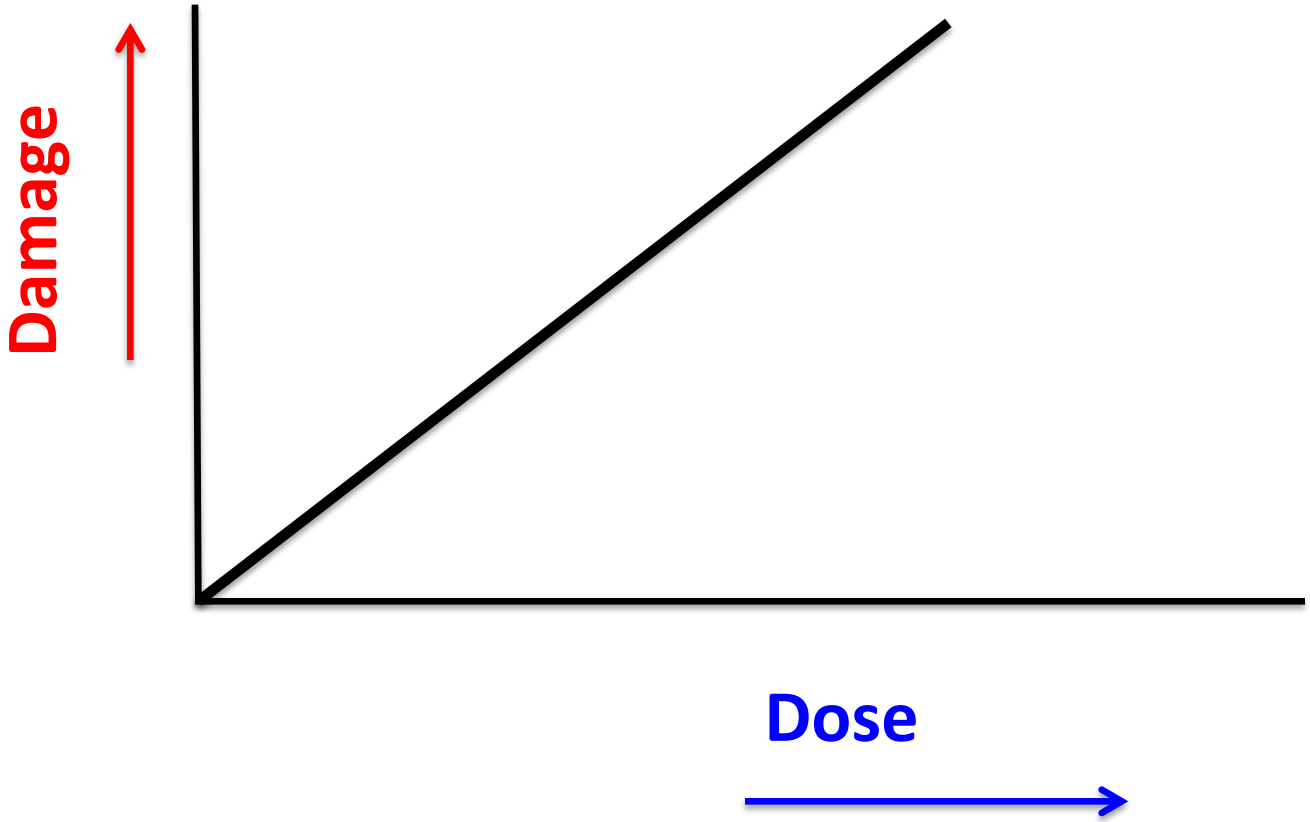

ACTIVISTS
General public
LOBBYISTS
PRESS
Politicians
Scientists
Regulators

**The Global Harmonization Initiative wants to improve food regulations and remove absurd regulations by obtaining global scientific consensus**

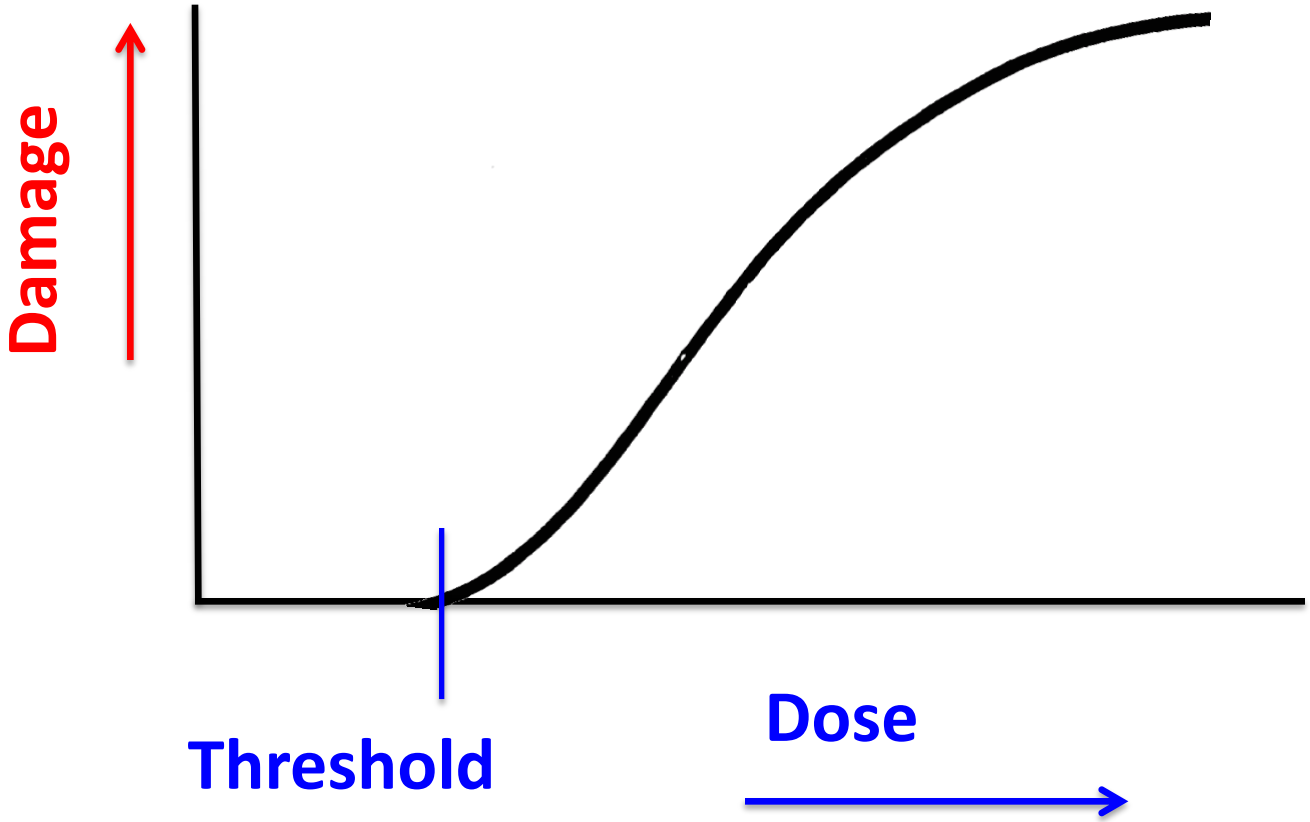
**and convincing those who need to know**




The perception of the general public




Understanding of most politicians and policy makers

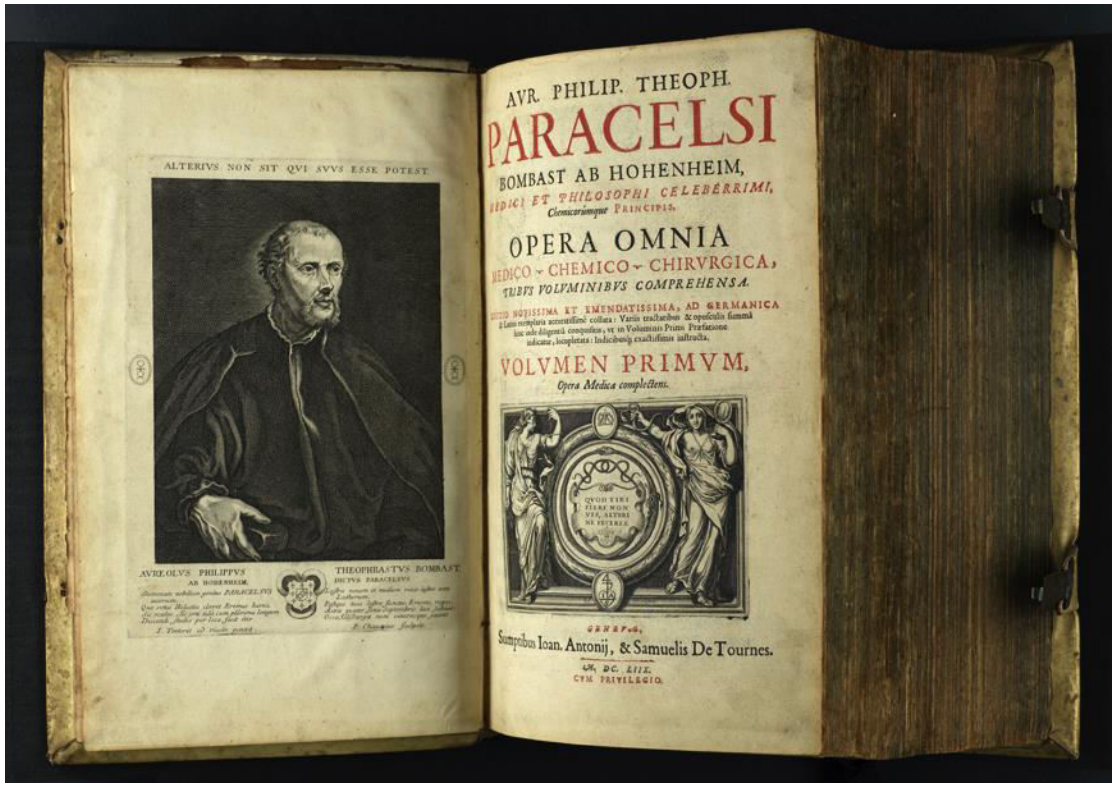


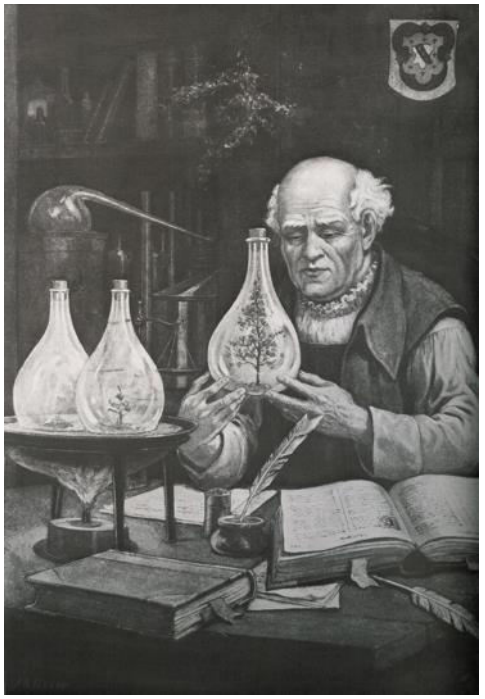

Toxicologists: agree there is a threshold of no concern (NOAEL: No Observed Adverse Effect Level). All food contains toxins.

# Evolution

Humans and their predecessors have been exposed to all those most scary chemicals for millions of years and developed a **biological system** (with liver, kidneys, etc.) to cope with them or even use them beneficially.

**The system, however, can be overloaded and then the chemical becomes toxic.**



‘Poison is in everything, and no thing is without poison. The dosage makes it either a poison or a remedy.’

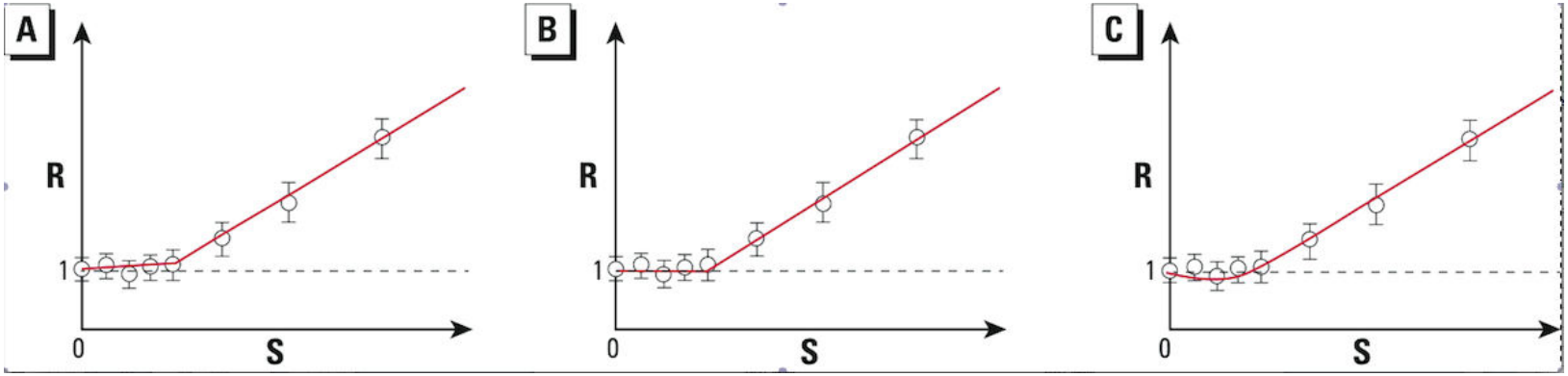
Or as we would say it today:

**There are no toxic substances, only toxic doses**

Two-stage-linear

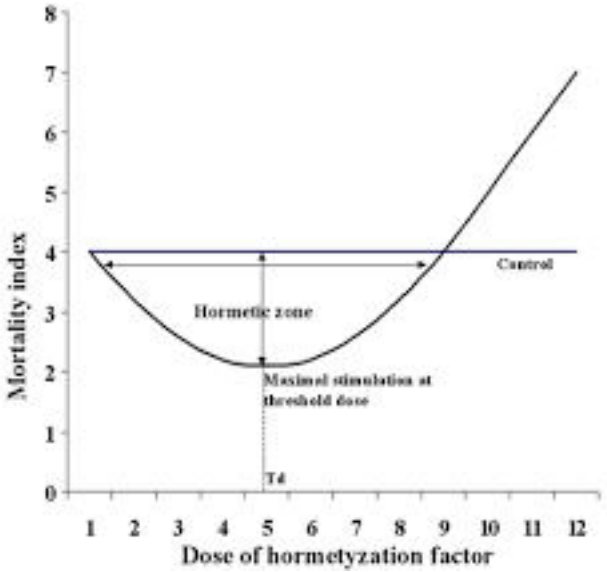
Threshold (hockey-stick shape)

Hormesis (J-shaped)




From: http://ehp.niehs.nih.gov/1408244/

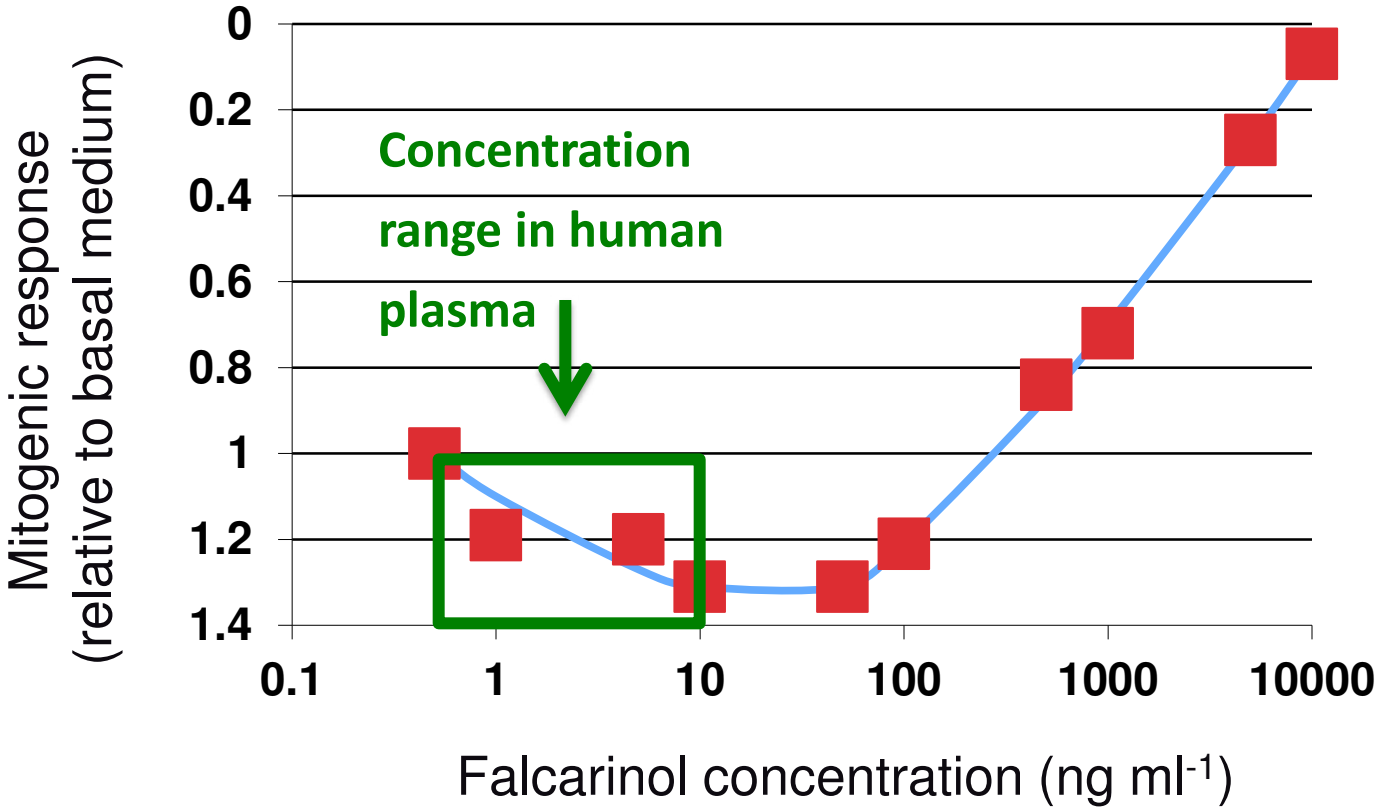
## Scientists: Still debating the detailed shape at low doses




A more detailed look at the hormetic response (note: **Not** consensus among GHI scientists!)

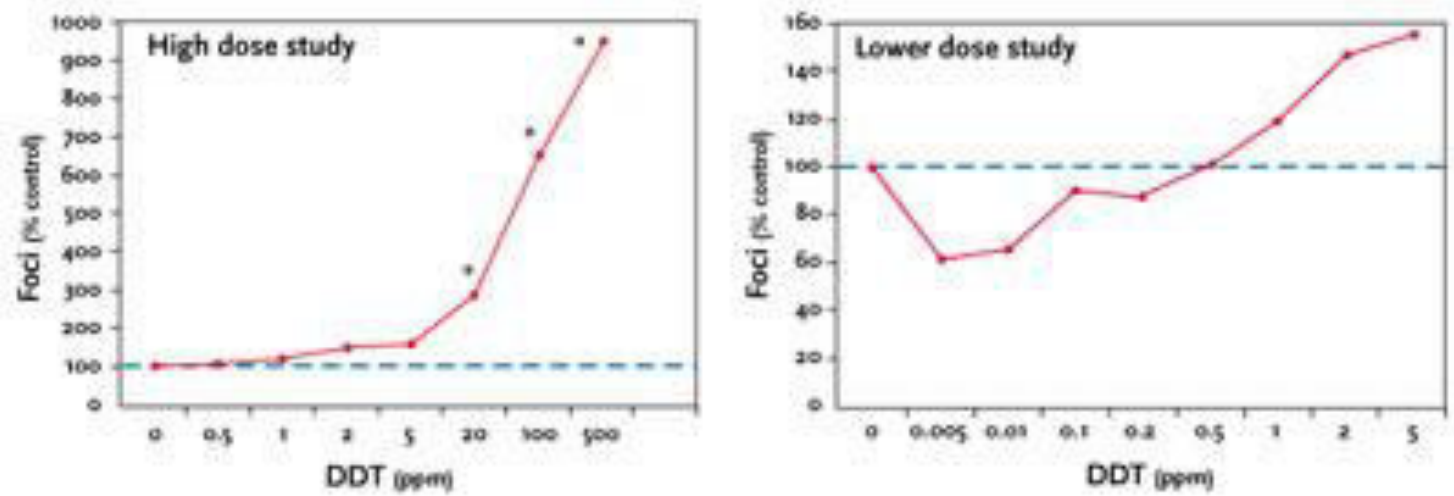
# Example with actual data- Natural pesticide

Effect of the polyacetylene falcarinol on viability of normal mammalian cells (Brandt et al. TIFS 2004)

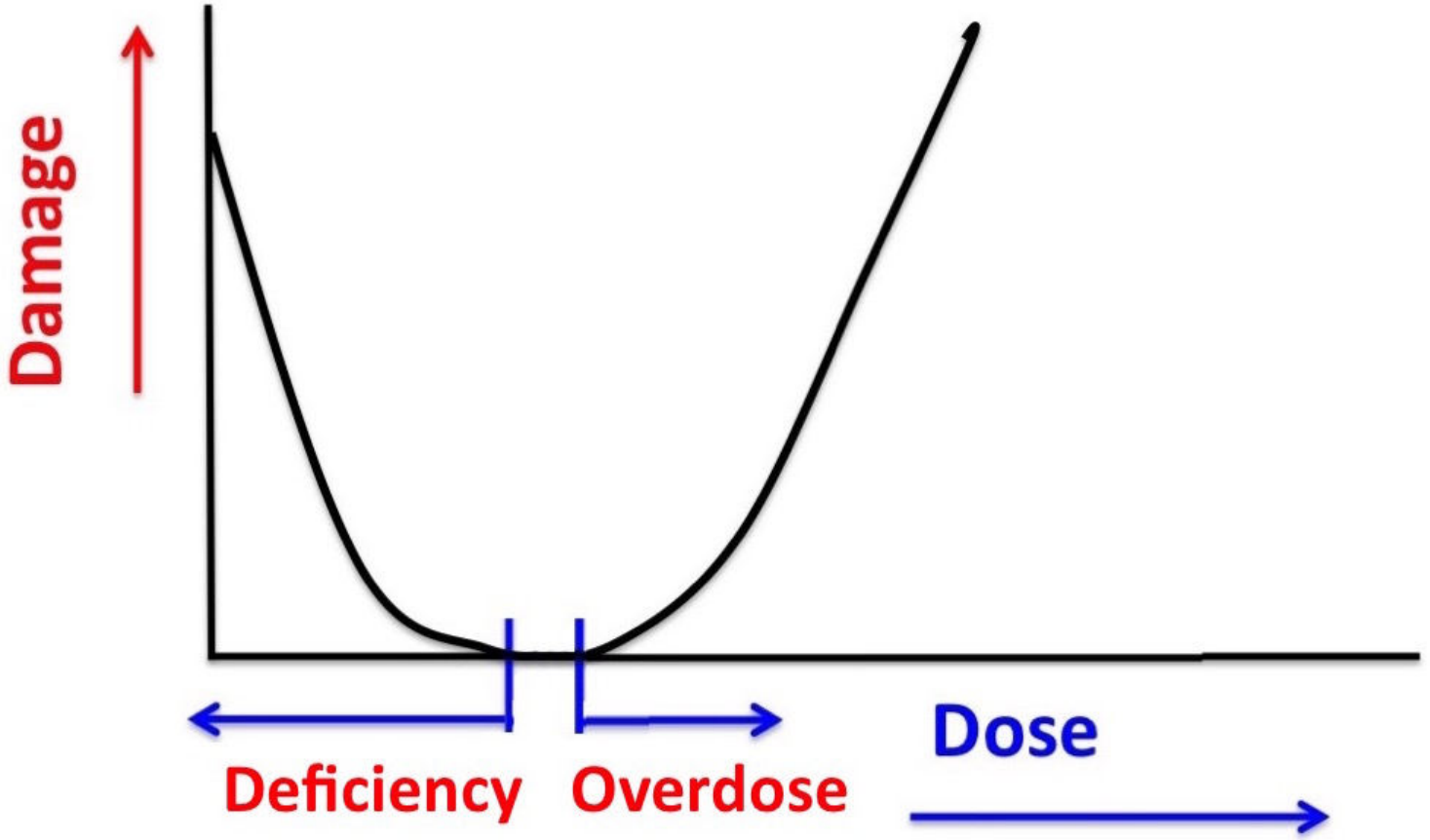


# Example with actual data- Synthetic pesticide

Effect of DDT on formation of pre-cancerous lesions in the presence of a carcinogen




From http://www.ufrgs.br/imunovet/molecular_immunology/generaltoxicology.html




Many substances are harmless or beneficial in the right amounts but harmful if **too much** or **not enough**

# Vitamin A

Adults: needed 1 mg per day
harmful at 3 mg per day

## Selenium


Adults: needed 50-150 µg per day
harmful at 300 µg per dag

*(Netherlands Health Council)*

# Development of improved methodology

## GHI: WG Genetic toxicology

### Chair: Firouz Darroudi

Currently evidence of safety of new food products, new ingredients and new technologies is typically obtained by animal testing.

Testing using animals is not popular, it is slow and expensive.

The alternative, developed in the past three decades is in vitro testing, using intact human liver cells. It is:

- more accurate
- relevant to humans (not test animals)
- cheap
- fast

**But it is NOT IN CURRENT REGULATIONS**

By Larry Keener & Huub Lelieveld

# Global harmonisation of food legislation: the way forward

There have been many food scares during the past 10 years. Examples are BSE, Salmonella in eggs, acrylamide, *Escherichia coli* O157:H7, avian influenza and foot-and-mouth disease. These scares have urged governments to tighten legislation. In the EU it led to Regulation (EC) 178/2002 (amended by (EC) 1642/2003) of which implementation started in 2002 and must be completed before 2007.

Although governments work together in organisations such as Codex Alimentarius and the World Trade Organisation (WTO), regrettably there are often differences in regulation between countries. The WTO recommends using international standards where they exist but also allows tougher standards if there is scientific justification. Serious concerns apply to the phrases 'where they exist' and 'scientific justification'. In such cases decisions may easily err on the extreme safe and may lead to undue destruction of large amounts of food or provide serious barriers to trade.

In an attempt to eliminate these problems, the Food Science and Technology organisations in the USA and Europe, viz. the International Division of IFT, EFFoST and the Food Chemistry Division of FECS, intend to make an inventory of significant differences in legislation between countries on all continents and to produce recommendations to remove these differences, based on sound science and technology.

During IFT's Annual Meeting in July 2004 in Las Vegas, a symposium was devoted to the subject, covering food legislation in Asia, Europe, North America, South America, and Australia. Speakers explained the good intentions of governments and international organisations and the consensus among all of them on issues identified. The second task therefore is to identify issues that need to be prioritised. Subsequently, working parties will be formed to deal

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Trends in Food Science & Technology 20 (2009) 582–584

TRENDS IN FOOD SCIENCE & TECHNOLOGY

Review

## Progress with the global harmonization initiative☆

**Huub Lelieveld***

**Enahlaan 11, 3723 HT Bilthoven, Netherlands (Tel.: +31 30 225 3897; e-mail: huub.lelieveld@etor.nl.net)**

The need for global harmonization of food safety regulations is growing with every new food safety incident. To be able to control food safety adequately, there must be a sound legal basis. Regrettably, often that basis has not been well developed or is not in existence. With regulation based on sound science, it is unlikely that incidents will be eliminated, but it will help to reduce the number and severity of food safety incidents. Regulations, however, will never stop incidents that have been created with criminal intent, although some legal measures may help. An example may be a global regulation for tamper-evident packaged food. Currently, as a direct result of the threat of bio terrorism, countries have been developing regulations on tamper-evidence for example for baby food and products sold at airports.

### GHI association

To give GHI a legal existence, in October 2007, the GHI Association was registered in Vienna, Austria. The goal of GHI remains "Achieving consensus on the science of food regulations and legislation to ensure the global availability of safe and wholesome food products for all consumers". This has been carefully incorporated in the constitution, which is entirely based on the Charter of GHI. To comply with the Austrian law, however, the Charter had to be translated into German and the text had to be adapted to meet legal requirements. The Executive Committee of GHI has painstakingly ensured that the translation and necessary changes did in no way alter the goal and objectives as described in the Charter. The German "Vereinssatzung" (constitution)" can be found on the GHI website (http://www.globalharmonization.org/constitution-german-2008.pdf). An English translation will be posted on the website shortly. The Austrian law also required to have instead of "Co-Chairs" a President and a vice-president. The Founders of the Association are Huub Lelieveld (Netherlands), Larry Keener (USA), Gerhard Schleining (Austria), Sangsuk Oh (Korea), Vishwesh-waraiah Prakash (India), Christine Boisrobert (USA) and Roland Poms (Austria). The Executive Committee consists of the same persons, with the exception of Roland Poms, who is the Chair of the Supervisory Board. Currently, Huub Lelieveld acts as President and Larry Keener as Vice-President.

### Supervisory board

From the start, the founders of GHI stated that impartiality of the scientific consensus process would be an essential requirement to be able to cooperate with scientists from all over the world and therefore, this impartiality should be carefully maint
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* Although in English the spelling is with an "s", as a result on its inception during a meeting in the USA, in the official name the spelling is "Harmonization", with a "z".
* Corresponding author.

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doi:10.1016/j.tifs.2009.07.005

in Vienna, Austria. The group is supporte
by nearly two dozen international scientif
organisations, academic research institu
and publishers, including IUFoST, the
India Central Food Technological Resear
Institute, the International Association
for Cereal Science & Technology, and
the Korean Food Safety Institute.

GHI furthers the opportunity for collabor
work among members and provides
educational outreach to key stakeholder
organising member meetings, worksho
and symposia throughout the world. GH
activities at the Cape Town conference

12 Food & Beverage International June 2010

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## The pressing need for global harmonisation of food regulations

By Huub Lelieveld (President of the Global Harmonization Initiative) and Professor Lucia Anelich (Director at Anelich Consulting, South Africa)

While the globalisation of world trade has created new pathways to economic growth for many nations, the trend toward a "one-world economy" has also exposed critical differences in international laws and regulations that are designed to protect the world's citizens. Nowhere is this more evident than in the global food supply chain, where gaps in the science used to justify international regulations not only create confusion for food producers trying to achieve compliance, but also create a world of barriers to achieving food security and effective food safety – and the technological advances that could ensure both. The need to harmonise global food regulations and laws has never been greater, considering the following challenges:

- **Food security and nutrition**

  Despite the fact that the world as a whole produces enough food for everyone, about half of the food produced does not reach those who need it. As a consequence, today about one *billion people* suffer from hunger. One of the major reasons is that a significant percentage of the food is destroyed during harvesting, transport and storage. Much is spoiled before consumption due to inadequate preservation, but food may also be deemed unfit for consumption – and consequently destroyed unnecessarily – without scientific justification due to inadequate or uninformed laws. In addition, food preserved to prevent microbial spoilage often has a significantly reduced concentration of essential nutrients. This leads to entire populations suffering from a dangerously reduced resistance to disease, especially affecting children during their growth phase. One way to address this is to promote the development of new technologies that preserve foods from spoilage and simultaneously retain vital nutrients; however, conflicting, non-science-based regulations act as barriers to the creation and adoption of these much-needed technological solutions.

- **Food safety**

  Nations enact food safety regulations to protect consumers from food poisoning. This is needed because some unscrupulous producers and tradesmen are more concerned about making a profit than safeguarding consumer health. Regrettably, significant differences in food safety regulations between nations can, and do, result in situations in which a food that is considered safe in one country is considered unfit for consumption in another country. This, in turn, leads to the destruction of imported foods that are safe but that do not meet regulatory requirements, or prevents countries from exporting food to areas where it is needed. Without globally harmonised, science-based regulations, rules intended to protect consumers from foodborne illness or death merely serve to erect trade barriers that inhibit technological advances that ensure public health.

If you are not a member, you are invited to join GHI, just go to

www.globalharmonization.net/user/register

and if you forgot, email

Info@globalharmonization.net

There is no fee, you only need to qualify as a food scientist

**You will influence the future**

# Development of improved methodology

## If the dose-response is actually hormetic:

Then it is not so important to know which doses are harmful, since they should be avoided anyway.
We just need to know which doses are beneficial!

- Most tests of harm are not suitable for measuring benefits.
- Most tests that are suitable for measuring benefits are not routinely applied to toxins.

**There is no scientific reason for this, and lots of options**
**Just get on with it and produce some data!**
**This will change the world as we know it!**

Thank you for your interest!
Any questions?