Science in policy-making to protect public and environmental health

ENSSER webinar

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Questions:

In public policy-making on technological risks, what are the roles of science and politics, of experts, evidence and interests in systems of governance?

Can there be a separation of tasks, between science and politics, and what should be the division of responsibilities?

Should ‘benefits’, needs and alternatives also be assessed?

Are scientists and risk managers keeping us safe?

Ideas about the role of scientific advisors in public risk policy-making have evolved and they remain contested.

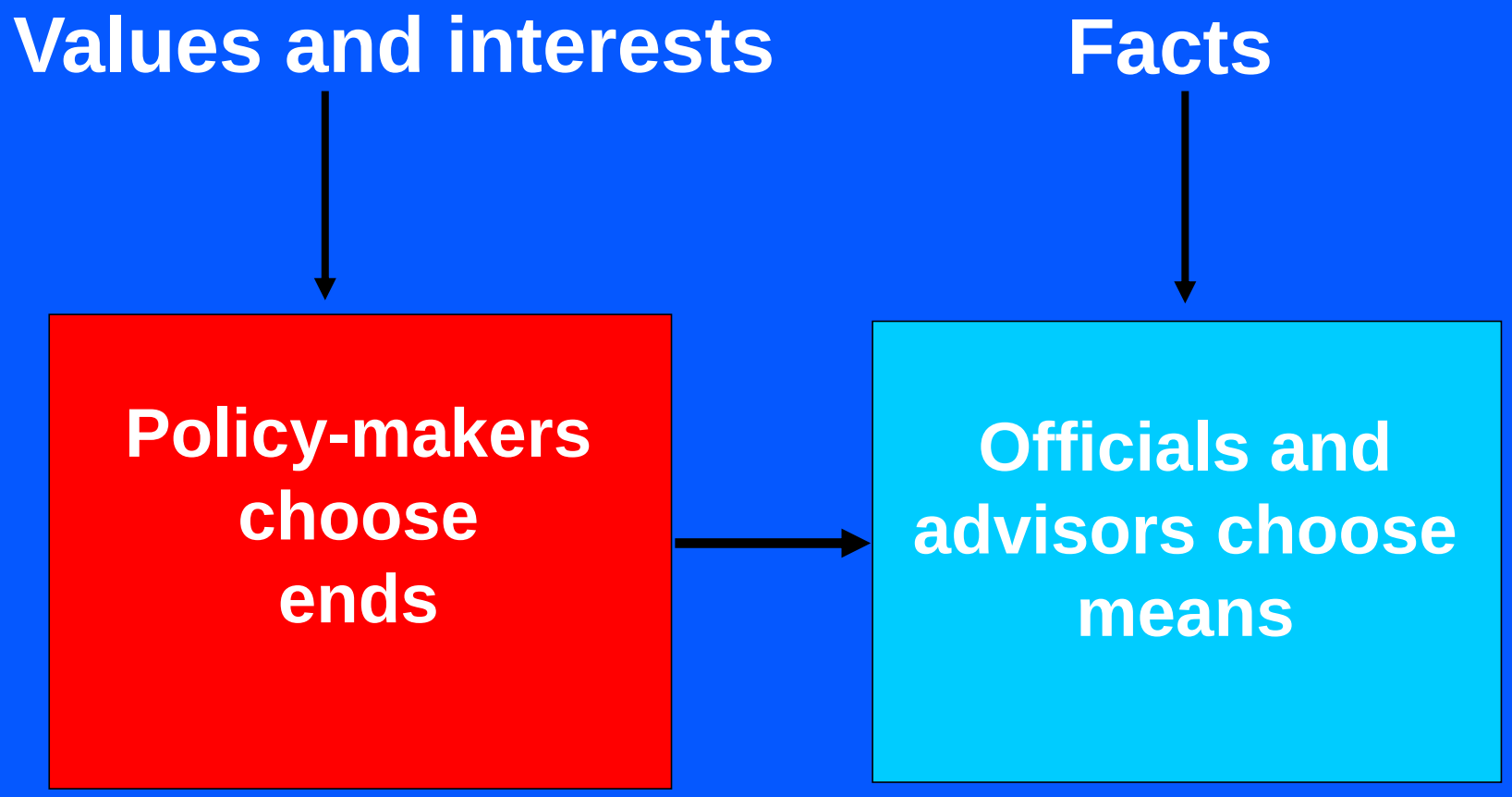
The ‘rules of the game’ have changed, with major implications for the scientific and democratic legitimacy of policy decisions, and for public and environmental health.

I will firstly outline the historical evolution of ideas about the role of science in risk policy-making.

Those ideas have influenced the design and operation of regulatory regimes, and had practical consequences for public and environmental health.

The second part of this presentation, and the second webinar, will focus on some consequences.

Model 1: late 19th century decisionist model (eg Weber & Durkheim)

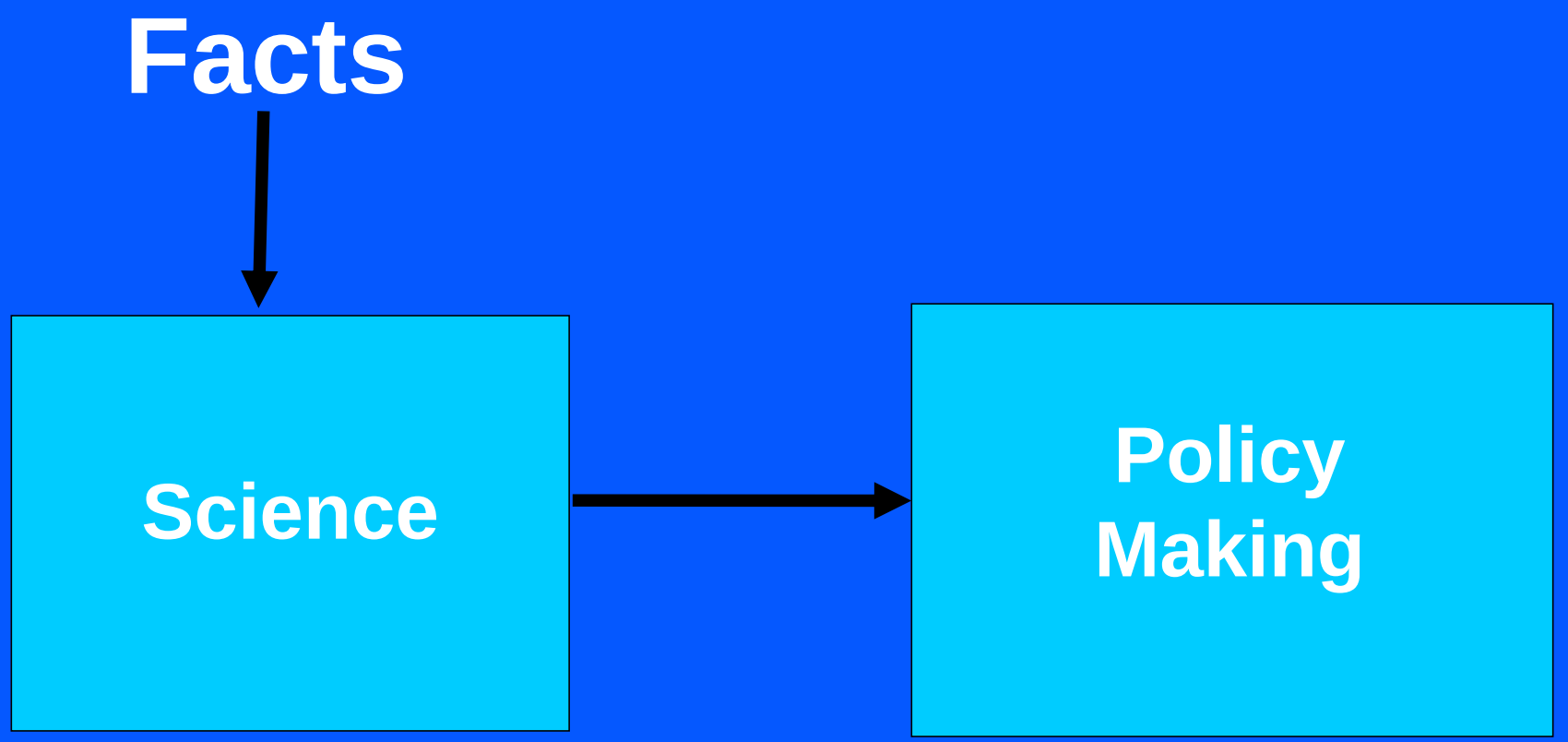


In response ‘positivists’ and ‘technocrats’ argued that policy-makers often cannot select the ‘ends’ without first obtaining information and advice from the experts.

Policy-makers may otherwise be ignorant of the risks that may need to be assessed or managed.

So they proposed a different model of science-based policy-making, omitting the ‘politics’.

Model 2: the technocratic model
policy is based (only) on sound science



Technocratic narratives can be very appealing to both policy-makers and their expert advisors.

Ministers and Commissioners often enthusiastically try to shelter behind their expert advisors.

Eg ‘we are following the science’ or ‘we are doing what our expert advisors tell us we should do’.

The technocratic model has been torpedoed by the obvious fact that scientific evidence is often incomplete, equivocal and uncertain.

Extra cancer cases from saccharin in the USA were estimated by US NRC in 1978 to range from
0.22 to 1,144,000 from ~70 mg/cap/day.

Uncertainties and disagreements are often not temporary.

Science in policy often does not speak with certainty or with one voice.

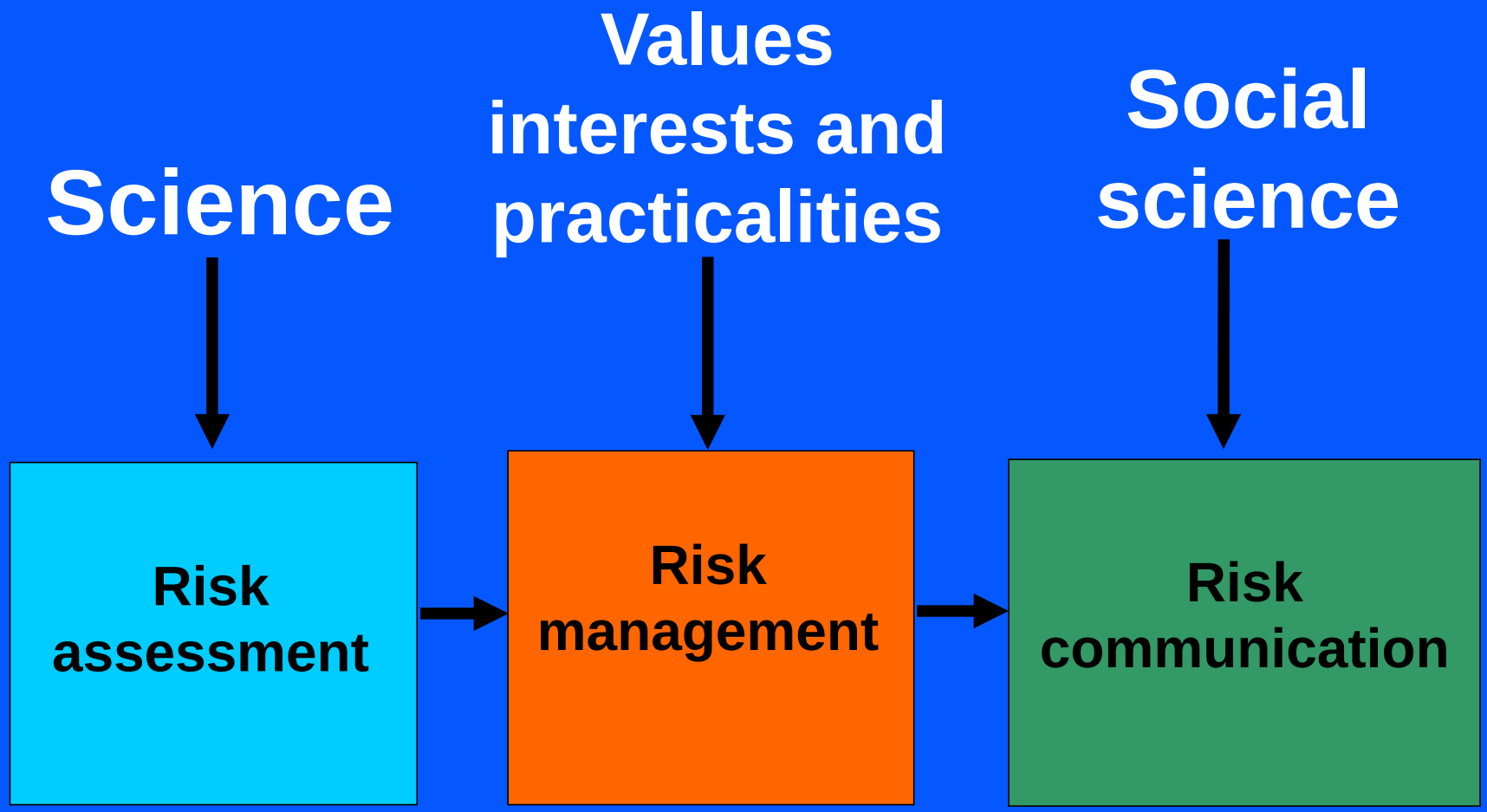
Even if *per impossibile* all scientific uncertainties were eliminated, science still could not decide eg food or environmental safety policies.
(You cannot derive an ‘ought’ from an ‘is’.)

Policy judgements are concerned with the ***acceptability*** of possible risks (and uncertainties) in exchange for anticipated benefits, and those are socially variable value judgements – they are policy matters, not scientific issues.

In 1983 the US government introduced a new narrative and model. It emerged in a publication from the US National Academy of Science entitled *Risk Assessment in the Federal Government.* It was published with a bright red cover, and has become known as the *Red Book Model*.

A graphic representation is:

Model 3 – The *Red Book* ‘decisionist’ model



That model was a step forward because it acknowledged roles for both facts and values, and acknowledged (some) uncertainties but it is incomplete because it ignores that, and how, *non-scientific considerations frame scientific representations of risk*.

For example, normative questions about eg what is deemed a ‘risk’ (bio-physical &/or socio-economic), and what is to be protected?

Studies of science-based risk policy-making show that the science is rarely certain or complete, and that often only some, but not all, possible risks are assessed.

Typically those risks are those on which data can be readily assembled, while the harder or more complex questions are ignored or discounted.

We also find that the selection and interpretation of the evidence has often been ‘asymmetrical’ and antithetical to the protection of public and environmental health.

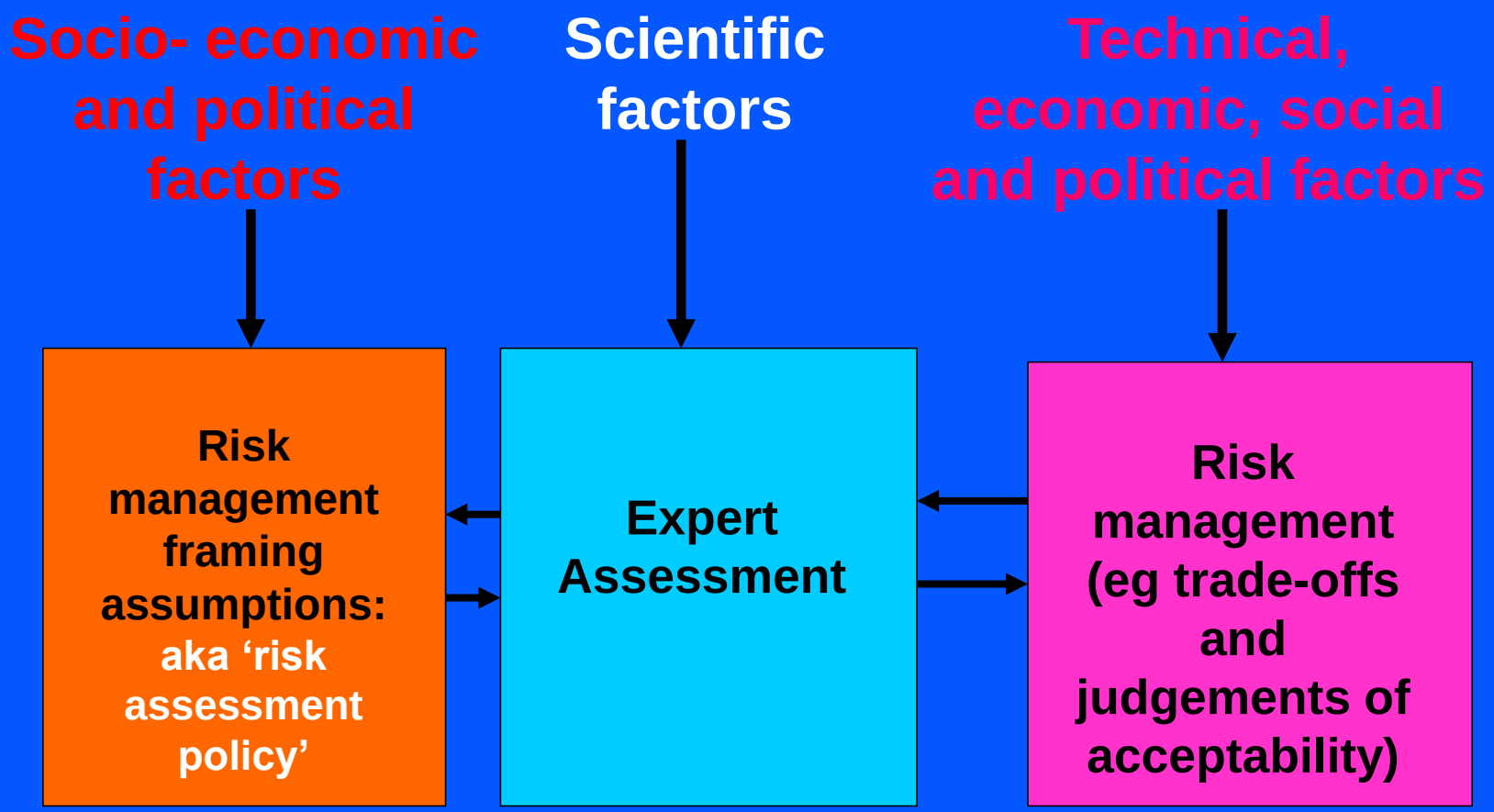
The source of many of the uncertainties, and conflicting risk assessments, are: ***non-scientific framing assumptions*.**

The WHO-FAO Codex Alimentarius Commission's innovation was recognising those assumptions, and calling them:

'risk assessment policy'.

The CODEX Alimentarius Commission (in 2003) and all its 189 Member States (in 2007) implicitly rejected the Red Book Model in favour of what science policy analysts called a *co-dynamic* model – ie a model in which science and policy-making mutually influence each other.

Model 4 - the co-dynamic model:
reciprocal links between **science** and **policy**



The Codex *Procedural Manual* says:

"Determination of **risk assessment policy** should be included as **a specific component of risk management**.

Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and *all other interested parties*…

The mandate given by risk managers to risk assessors should be as clear as possible." (emphases added)

There are at least 3 main types of risk assessment policy (RAP) judgements:

- **substantive**
- **procedural and**
- **interpretative.**

and they are inter-dependent.

In these webinars our main focus is on a set of **substantive** RAP judgements. They are concerned with selecting the risks to be assessed.

Do the scientists assess:

1. One possible risk?
2. A few possible risks?
3. Many possible risks? or
4. All possible risks?

We will review a set of examples in which official expert advisors have only reviewed a few risks, or a few types of risks, and ignored or discounted several, or even many, others.

We will show that official expert scientific advisory bodies, such as EFSA, have been providing incomplete and inadequate assessments of risks posed by eg agricultural biotechnology, pesticides and food additives.
We maintain that they have adopted overly-simplistic ‘reductionist’ approaches, that can and should be replaced by more comprehensive approaches.

RAP judgements are policy judgements about science; they contribute to framing scientific deliberations and advice, and also research.
They should be set by policy-makers in advance of a scientific risk assessment, not by scientists.

Instead, too often, policy-makers choose to leave it to scientific advisors to select their own framing assumptions, despite the fact that they are neither competent nor accountable for policy matters.

Consequently vital policy judgements masquerade as if they were only and purely scientific.

Some RAP judgements are embodied in **legislation**.

Under EC Directive 90/220 risk assessments of the environmental release of GMOs covered adverse effects on flora and fauna irrespective of their commercial significance, while those in the USA only included changes that could cut farm incomes.

The revised EU Environmental Release Directive 2001/18 extended the scope of risk assessments to include **indirect** as well as **direct** effects on flora and fauna and the environment, and to **long-term** effects as well as **short-term** ones.

In relation to pesticides in the EU, Regulation 1107/2009 aims: “…to ensure a high level of protection of both human and animal health and the environment…” but also to safeguard “…the competitiveness of Community agriculture”.

Recognising that some population groups are more susceptible to pesticide exposure than others, it calls for particular attention to be paid “…to the protection of vulnerable groups of the population, including pregnant women, infants and children”.

It emphasises that the precautionary principle must be applied when there is a potential risk in the authorisation of a pesticide substance, even if there is no scientific consensus on the issue.

Annex II of Regulation 1107/2009 says: “…an active substance, safener or synergist” cannot be approved if it is “…carcinogenic, mutagenic, toxic to reproduction, or endocrine disruptive for humans.”

For the environment, it cannot be a POP (persistent organic pollutant), PBT (persistent, bioaccumulative, and toxic), endocrine disruptive to non-target organisms or toxic to bee colonies.

These are called hazard ‘cut-off criteria’, because if a substance has any of these properties, as revealed in scientific tests, it should just be banned.

The regulation also refers to other toxic effects, such as the ability of the substance to cause neurotoxicity or immunotoxicity during the early life stages of mammalian development, or other critical effects of “particular significance”.

But in relation to pesticides PAN Europe found that:

“Frequently, academic studies on effects of formulated products are dismissed completely from the assessments and are not taken into consideration at all, even in the overall evaluation of the active substance. Moreover, most co-formulants are considered to be proprietary secrets and remain undisclosed.”

(PAN Europe, *Ensuring a Higher Level of Protection from Pesticides in Europe*, *See https://citizens4pesticidereform.eu/wp-content/uploads/2018/12/White-Paper_Dec2018.pdf*)

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MDPI

Review

Glyphosate's Synergistic Toxicity in Combination with Other Factors as a Cause of Chronic Kidney Disease of Unknown Origin

Sarath Gunatilake [1], Stephanie Seneff [2,*] and Laura Orlando [3]

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Glyphosate and its formulation Roundup impair pig oocyte maturation

Marcella Spinaci✉, Chiara Nerozzi, Car lo Tamanini, Diego Bucci & Giovanna Galeati

Roundup at the same glyphosate-equivalent concentrations was shown to be more toxic than pure glyphosate, altering steroidogenesis and increasing oocyte ROS levels, thus confirming that Roundup adjuvants enhance glyphosate toxic effects and/or are biologically active in their side-effect and therefore should be considered and tested as active ingredients.

www.nature.com/scientificreports

SCIENTIFIC REPORTS
natureresearch

SCIENTIFIC REPORTS | (2020) 10:12007 | https://doi.org/10.1038/s41598-020-68813-6

Carcinogenicity of glyphosate

International Agency for Research on Cancer

World Health Organization

- **Probable human carcinogen**
  - Limited evidence in humans
  - Sufficient evidence in experimental animals
  - Strong mechanistic evidence

✓ Only published studies
✓ Included studies on product
✓ Strict rules on conflict of interest

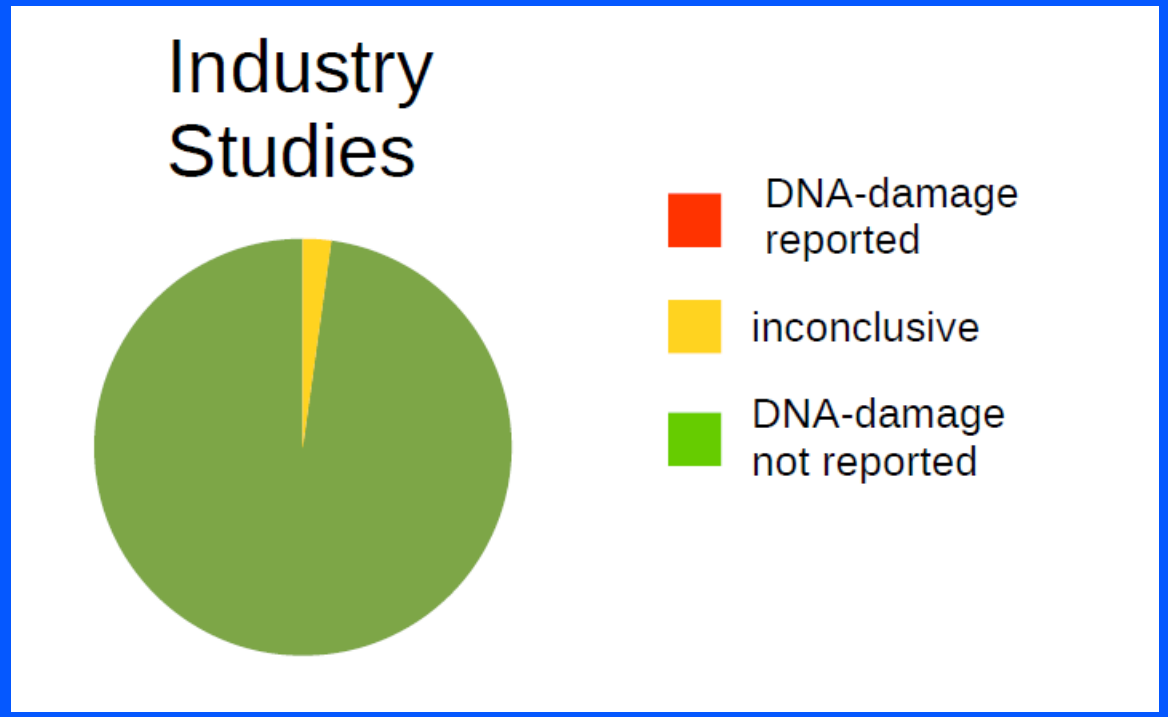
efsa European Food Safety Authority

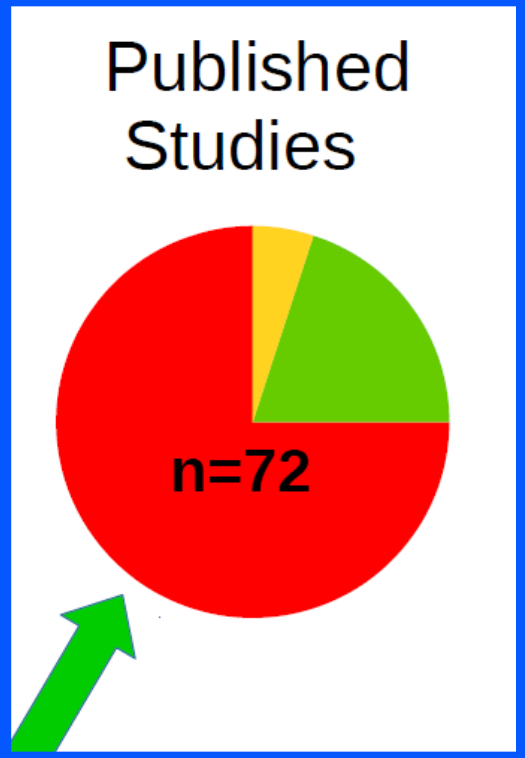
ECHA EUROPEAN CHEMICALS AGENCY

- **Not a human carcinogen**:
  - Evidence in humans not enough
  - Tumours in experimental animals not significant
  - Mechanistic data not relevant

✓ Weak arguments/data gaps
✓ Studies on products not relevant
✓ Undisclosed/confidential studies
✓ Ghost-written scientific papers

Published Vs industry studies (glyphosate genotoxicity)





Source: Helmut Burtscher (Global2000), European Parliament, PEST Committee hearing 2018

The reductionist approach has not just been adopted by EFSA panels, it has also been endorsed by EFSA : panels are obliged to use it.

SCIENTIFIC REPORT OF EFSA

International Frameworks Dealing with Human Risk Assessment of Combined Exposure to Multiple Chemicals[1,]

European Food Safety Authority[2,3]

European Food Safety Authority (EFSA), Parma, Italy

EFSA Journal 2013;11(7):3313

2.4.1. Dose Addition

Dose-addition (also known as simple similar action, similar joint action or relative dose-addition, concentration addition) is the most common approach for the assessment of combined exposure to multiple chemicals and assumes that all components of a “mixture” behave as if they were a simple dilution of each other (Bliss, 1939; EFSA, 2013) and have a similar MOA [Mode of Action].”

(EFSA, 2013 p 14)

Relative Potency Factors

“The Relative Potency Factor…approach uses toxicity data for an index chemical in a group of multiple chemicals to normalise the potencies of all chemicals in the mixture assuming similarity of MOA between individual chemicals in the mixture.”

That assumption is reductionist - and antithetical to precaution!

EFSA's Cumulative Risk assessment pilot study (2019)

EFSA pilot study on chronic effects on thyroid:

- Based on probabilities and assumptions,
- Uses industry-sponsored old studies (insensitive) to set the toxicity thresholds
- Uses uncertainty analysis to "correct" any identified risk
- Concludes "*Consumer risk from dietary cumulative exposure is below the threshold that triggers regulatory action for all the population groups covered*" – i.e. no action is needed. The single pesticide assessment is protective enough to cover exposure to mixtures of pesticides (!!)

Toxicity of pesticide mixtures is not addressed

“In real-life conditions, people are always exposed to several chemicals (including pesticides) at the same time. These chemicals may work through similar and/or interacting mechanisms, with both options bringing additional risks. In fact, farmers often use cocktails of pesticide products on their crops. Despite the political decisions (enshrined in Reg. EC 296/2005 and EC 1107/2009) to take combination effects into account, the potential effects of chemical mixtures are still ignored in risk assessment and in risk management policy-making.”

(PAN Europe, *Ensuring a Higher Level of Protection from Pesticides in Europe*, *See https://citizens4pesticidereform.eu/wp-content/uploads/2018/12/White-Paper_Dec2018.pdf*)

See: https://www.soilassociation.org/media/19535/the-pesticide-cocktail-effect.pdf

The petro-chemical industry is happy to claim ‘synergy’ to help sell its products, but not when the risks its products might pose are to be assessed.

Senior EC advisors have argued that:

"The PPP approval and authorisation process must better assess risks associated with PPP mixtures and long-term exposure, and keep pace with scientific and technological developments and the changing nature of PPPs, such as nanopesticides and the increasing shift to biological control agents."

EC Scientific Advice Mechanism, *EU authorisation processes of Plant Protection Products, 2018, see https://ec.europa.eu/research/sam/pdf/sam_ppp_report.pdf*

But EFSA has not responded by changing its practices.

In relation to **food additives**, their risks are only ever assessed individually, and never in combination.

A senior representative of the artificial sweetener industry asserted that while Aspartame and Acesulfame-K can together produce a stronger sweet taste than the sum of the individual sweetness, it is certain (without any experimental evidence) that toxicologically, their effects cannot be mutually reinforcing.

“For quantities [of different sweeteners in mixtures] as ingested by consumers no combination effects must be anticipated, as even under unfavourable circumstances ingested single doses remain far below a potential threshold for toxicological effects, and interactions of the individual sweeteners due to different kinetics must not be anticipated.”

Gert Wolfhard von Rymon Lipinski, ‘The blending of sweeteners – applications and safety issues’ Ch 14 of Grenby TH ed. *Advances in Sweeteners*, Chapman Hall, London 1996, p 271

In the late 1990s I interviewed a senior UK government official about food additive testing and safety. When I asked him why was there no requirement top test mixtures of additives, or mixtures of additives and foods, his reply was very revealing.

He said: “…because if we found an adverse effect, we would then need to test each ingredient separately to see which of them had been responsible.”

He just assumed that toxicological effects could not arise as a consequence of interactions between compounds.

EFSA's risk assessments of eg pesticides, additives and GMOs are incomplete and not 'fit for purpose'.

They are limited by a set of reductionist assumptions, which EFSA panels have adopted, despite the requirements of the legislation.

In summary:

EFSA is covertly making political judgements, and hybrid scientific & political judgements, which are misrepresented as if purely scientific.

That practice is contrary to the EU's democratic, legal and constitutional requirements of its scientific advisers.

The European Commission is complicit by failing to deliver on its responsibilities for providing EFSA with a set of risk assessment policies.

The Commission is also complicit in concealing EFSA's tacit policy choices, which have not been democratically legitimated, and by pretending that EFSA only provides impartial, comprehensive, sufficient and decisive scientific advice.

EFSA also fails to ensure that its advice contributes to achieving the health and environmental protection goals mandated in EU legal and constitutional authorities.