

Getting EU risk assessment protecting environment and health to achieve its legal objectives.

Escaping reductionist fallacies

CASE EXAMPLE GMOs (& pesticides)

Based on this paper

Hilbeck et al. Environ Sci Eur (2020) 32:54 https://doi.org/10.1186/s12302-020-00325-6 Environmental Sciences Europe

REVIEW

Open Access

GMO regulations and their interpretation: how EFSA's guidance on risk assessments of GMOs is bound to fail

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KEY ISSUE: Reductionism

Begins with the FRAMING of Environmental Risk Assessment (ERA) from the start







'Comparative Safety Assessment' is in essence ...

The concept of substantial equivalence has never been properly defined; the degree of difference between a natural food and its GM alternative before its 'substance' ceases to be acceptably 'equivalent' is not defined anywhere, nor has an exact definition been agreed by legislators.

Millstone et al. 1999, p. 525

Concept of Familiarity - No Recognition in GMO ERA



Cartagena Protocol on Biosafety:

Concept of Familiarity was introduced in 1996 (BSWG-1), discussed in BSWG-2 and BSWG-3, finally rejected in 1998 (BSWG-4)

Directive 2001/18/EC:

no mentioning of the Concept of Familiarity



Problems of this FRAMING:

In the 'comparative assessment' (aka substantial equivalence) step, the GM plant (=organism) is reduced to its chemical components:

Instead of assessing the GMO within its complex network of ecological interactions in the real world, EFSA:

- limits the focus on the 'added' chemical substances 'coded' for by the transgene, i.e. Bt-toxins
- arrives at its conclusions regarding risks based on data produced with Bt toxins isolated from an artificial bacterial surrogate system – not the GM Bt plant.







CASE EXAMPLE 1:

GM Bt plants







THE REALITY



THE REALITY



POSSIBLE SPREAD & EXPOSURE ROUTES



AQUATIC ECOSYSTEMS



EFSA Hazard ID builds on narrow narratives that are undocumented and outdated:

Mode of action \implies Specificity \implies efficacy (target effects) \implies nontarget effects

Paradigm	Outdated	Updated
GM plant- vs microbe- produced toxin	Identical	Different
Mode of action	Single	Multiple
Specificity	High (few insect taxa)	Broader (many taxa)
Nontarget effects	Few if any	Many



OPEN ACCESS Check for updates

The distinct properties of natural and GM cry insecticidal proteins

Jonathan R. Latham^a, Madeleine Love^b 💿 and Angelika Hilbeck^c

GM plant- vs microbe-produced Bt toxin – significantly different

Truncations, mutations, additions create novel toxins unknown in nature

Goal: Impact new target pests, increase toxicity to target pests, new patents

"... common industry and regulator narrative maintains that none of these alterations matter much when it comes to environmental and human and animal health safety issues, while they do induce significant novelties and changes with regard to patents and efficacy." RAGES Report 2019

In EFSA ERA: 1 concept of mode of action



Classical model

Published: Many different concepts for modes of action



adapted from Vachon et al., 2012.

Published: Many different concepts for modes of action



adapted from Vachon et al., 2012.

Exposure of NTOs in food webs is clearly underestimated

Bt toxins:

a) persist longer in the food web than commonly declared which increases the likelihood of exposure of NTOs,

b) occur in different biochemical forms than in microbes

- c) their presence can extend beyond the presence of the Bt toxin source, i.e. through pollen and plant residues it can reach both other terrestrial and aquatic ecosystems
- d) they can further spread through as of now unrecognized processes like intergenerational transfer (as published by Paula/Andow team)

We found 39 peer-reviewed publications that report significant, diverse, UNPREDICTABLE (adverse) effects of Bt toxins on many 'out-of-range' species, including representatives from non-arthropod taxa, like snails or crayfish or bacteria.

A selection of reportedly adversely affected nontarget beneficial organisms to illustrate diversity of taxa – often only when using plant material













ADVERSE EFFECTS

Growing diversity of affected species reported, most of which cannot be detected in shortterm acute direct toxicity tests that follow first tier OECD toxicity protocols.



Continued Bias and Double Standards in EFSA assessment

ALL studies reporting unexpected adverse effects on NTOs are dismissed

While almost all studies confirming no effects are accepted – with rare recent exceptions

Arguments for dismissal continue to be:

- out-of-range paradigm/not meeting expectations
- double standards bridging data to show safety but not risks



Notorious double standards

... the GMO panel argued that the findings reported by Paula et al. 2015 and Paula and Andow 2016 'have no direct relevance for the environmental risk assessment of maize MON810 because none of the Cry proteins evaluated ... correspond to the protein expressed in maize MON810, i.e. Cry1Ab.'

No RISK conclusions can be drawn from studies using Cry1Ac or any other Cry toxin for Cry1Ab (i.e. MON810)

Notorious double standards



'Based on the known spectrum of activity of **Cry1Ac and Cry1F proteins** and its selectivity to lepidopteran species and the phylogenetic distance between ladybird beetles and target species (pests of the order Lepidoptera), susceptibility of H. axyridis to **Cry1Ac and CryF** proteins is **not expected at field concentrations**'

'Similar findings (no adverse effects) have been reported in the scientific literature for **Cry1F** and other Bt-proteins on this ladybeetle. In direct feeding assays, ingestion of biologically-active purified **Cry1Ac, Cry2Ab, Cry1Ca, Cry1F or Vip3A** proteins by H. axyridis larvae did not negatively affect their development, survival or weight (Ali et al. 2016).' EFSA GMO Panel 2019

No Cry1Ab (i.e. MON 810) tested!

SAFETY conclusions can be drawn from studies using any other toxin from the Cry1 class – **Bridging ok**!

Notorious double standards



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Additionally, lack of scrutiny in studies that confirm safety: EFSA did not critically assess this study by Ali et al. 2016 because no adverse effect

Ali et al. used flawed protocols with unexplained excessive amounts of antibiotics known to significantly alter (=MASK) the impact of Bt toxins!



CASE EXAMPLE 1:

GM HT plants

REDUCTIONISM



REDUCTIONISM



GMO regulations = known enzyme, **no** testing



CONCLUSIONS and CORE PROBLEMS

Narrow ERA model

effectively denies relevant biological complexity and contingency, such as interactions between Bt-toxins, GM plants and ecological communities in the environment.

Consequences

EFSA is relieving the applicants from their obligation to prove the safety of their products based on new data and the most recent science and is placing the burden of proof on independent scientists with extremely limited funding.

Reversal of the Precautionary Principle

What we want!



All-inclusive Benefits





Better ERA model available – New Species selection procedure embedded in ERA components

Improved alternative concept needed, designed for a GMO rather than a **pesticide**

In a 6-year project funded by SDC and local partners, public sector scientists developed an improved concept, tested it in 4 GM crop cases in 3 countries: Kenya (maize), Brazil (cotton) Vietnam (cotton). Published in a CABI book series....

Major Publications CABI Book Series: 'Environmental Risk Assessment of Genetically Modified Plants'



Kenya Vol 1 2004



Brazil Vol II 2006



Vietnam

GEF-STAP sponsored publication



HANDBOOK on Problem formulation & Options Assessment

http://www.gmoera.umn.edu/pu blic/publications/index.html

While the ecotox model is

prescriptive with regard to species and protocols – starts narrow and considers other (e.g. longterm, cumulative) effects only if acute, short-term effects of a plant-produced novel protein occur.

The GMO ERA Model is

prescriptive with regard to the selection procedure for testing species from the receiving environment

Whole Plant - GMO ERA Model

- Based on a biodiversity function approach
- Starts broad reducing species number through a transparent process based on ecological criteria like: abundance, phenology, ecological significance, exposure
- Aim: Filtering out those that are associated with highest potential risk (= exposure x ecol. significance)
- Selection process informs: potential adverse effect scenarios -> formulation of risk hypotheses -> design of proper experiments and protocols







"The problems highlighted ... indicate that substantial changes are required both at EFSA and in the European Commission, and in their interactions.

At a minimum, the Commission should properly research, understand, and then deliver on the commitments concerning explicitly articulating risk assessment policies, in advance of risk assessments, and in accordance with the inclusive and accountable procedure stipulated in the Codex provisions on risk assessment policy-making.

It should have done this some years ago.

(Hilbeck et al. 2020)

"Then we might ... discover two major all-round benefits: that EFSA's science is able to support and comply with EU democratic legislative and regulatory objectives, rather than to undermine them; and that EFSA's repeated failure to achieve European public and Parliamentary respect [83, 84] might begin to reverse itself."

(Hilbeck et al. 2020)

THANK YOU

More information and details: https://www.testbiotech.org/en/content/research-project-rages