Failure of EFSA in GMO risk assessment - case studies.

Christoph Then, Greenpeace Germany,

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Part 1: risk assessment and health: MON863

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MON863: findings from independent experts

"The following findings clearly indicate major failures of statistical analyses as performed by Monsanto:

→introduction of irrelevant variability sources as use of additional animal groups likely to dilute biological effects,

→methodological errors such as wrong test system in general which is not suitable to detect very important effects,

→statistical techniques not performed properly; such as the Student test with too small animal groups (...)."

(*D. Cellier and G.E. Seralini. CRIIGEN)*

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MON863: findings from independent experts

„Significant differences were indeed found in the study, and afterwards were classified as irrelevant. (This is as if a marksman had shot at a wall and the rings of a target were then drawn around where the shot had made a hole, and it was then maintained he had hit the target dead centre.)“

Professor Wegscheider, University of Hamburg

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MON863: some specific conclusions

Significant findings were assumed to be “not of biological relevance” by EFSA without sufficient statistical investigation. Statistical methods were not checked, failures were not detected

Definition of, and assumption made during assessment of “biological relevance” are scientifically not valid

The risk assessment has be restarted: Full revaluation of the data is necessary, new investigations have to be started

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MON863 and GMO guidelines of EFSA

So far there is no clear regulation for sufficient mandatory testings in the guidelines

- even listed standards were disregarded:

GMO guidelines, Annex 1, Part 1:

"Data provided in support of an application should be of at least the quality expected of data submitted to a peer review journal. Particular attention should be paid to the sensitivity and specificity of methods employed and to the adequacy and appropriateness of controls."

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MON863: some general lessons learned

The material produced by industry has to undergo a comprehensive quality review before use in EFSA opinions.

The Precautionary Principle has to applied in a way that significant findings in health tests makes further investigations mandatory and no positive opinion can be forwarded.

Allergenicity tests as well as toxicity and antinutrition tests have to undergo a detailled, comprehensive and mandatory testing regime. (Testing regimes for toxicity should at least follow pesticide regulations, as raised by several experts.)

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Part 2: risk assessment and environment: Bt11 and maize 1507

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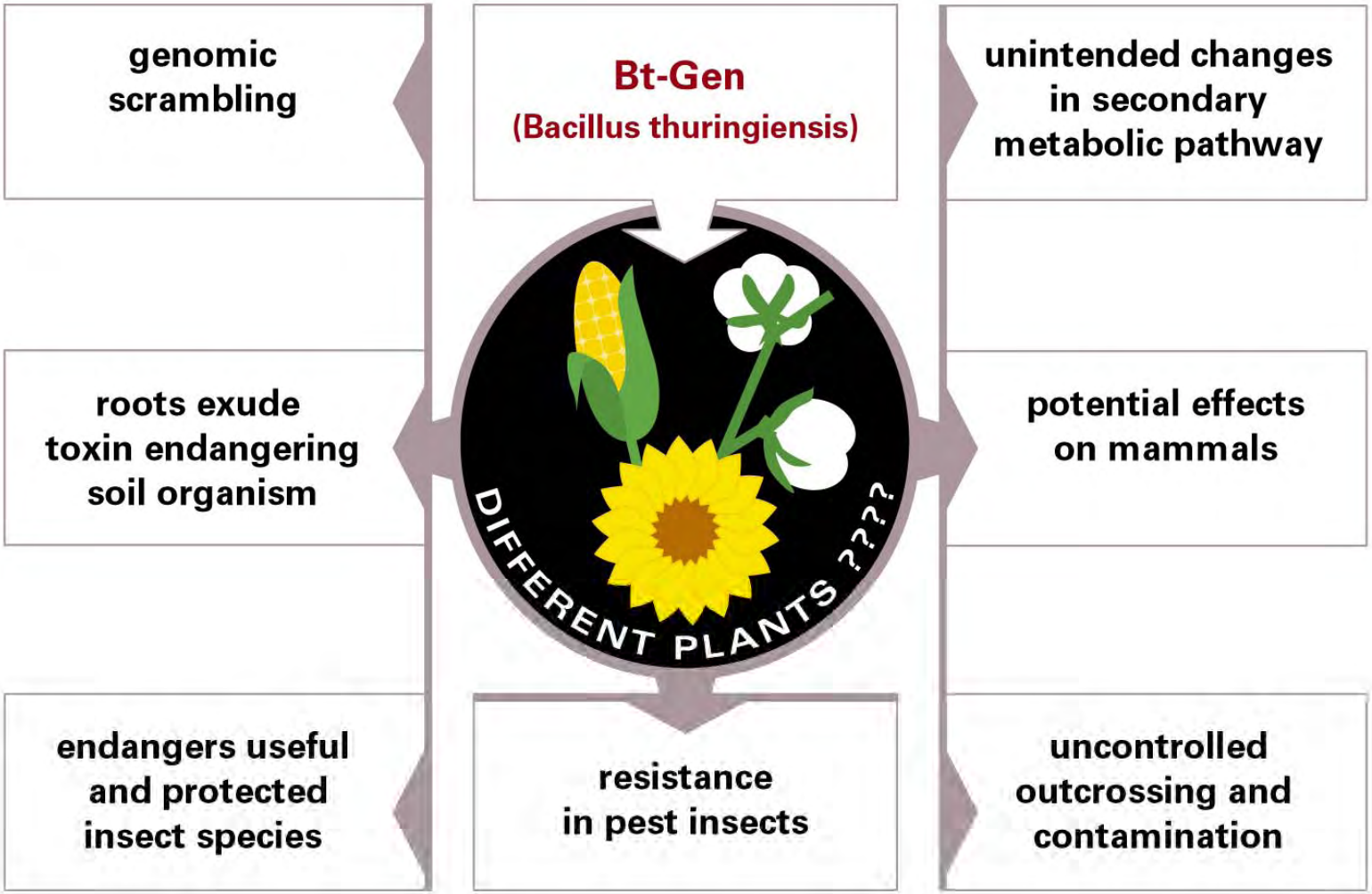
Example: Inserting **Bt-gene in plants**



Grafik: Nicole Krohn, 10/05

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Bt 11 for cultivation: Syngenta´s data and EFSA´s opinion

Genomic data:

Information about the insertion site and the insert are classified as confidential. Independent assessments are therefore impossible.

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Bt 11 for cultivation: Syngenta´s data and EFSA´s opinion

Health:

Syngenta provided the results of only short term feeding studies which were not intended as toxicity or allergenicity studies.

! EFSA is of the opinion that no long term studies should be performed because no drastic effects where seen in short term experiments.

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Bt 11 for cultivation: Syngenta´s data and EFSA´s opinion

ERA:

Adverse effects of Bt11 on non-target organisms such as multitrophic interactions between plants, herbivores and pests where not investigated in ERA and are not even included in monitoring or general surveillance.

Effects on soil organisms, for example potential *Bt* accumulation were not investigated in ERA and are not included in monitoring or general surveillance.

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Maize 1507 for cultivation: Pioneer´s data and EFSA´s opinion

Genomic data:

Several unintended additional fragments were observed. These unintended fragments result in two open reading frames, a faint signal was seen is indicating the presence of unintended RNA, but this was not investigated further.

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Maize 1507 for cultivation: Pioneer´s data and EFSA´s opinion

Compositional data:

Many statistically significant differences are seen in the compositional analysis of GM maize 1507. Despite this, EFSA states that there is "*No indication that such a [DNA] deletion produces any phenotypic effect in the transformed maize line.*"

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Maize 1507 for cultivation: Pioneer´s data and EFSA´s opinion

Health:

Several significant differences with feeding studies were observed, but dismissed without sound scientific arguments (like being observed only within one sex).

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Maize 1507 for cultivation: Pioneer´s data and EFSA´s opinion

ERA:

•The toxicity of 1507 to non-target lepidoptera is, in general, unknown. There have been no studies of the toxicity of this GM Bt maize to European lepidoptera.

•No relevant long term studies, either of exudation by the roots, on persistance, on accumulation nor the toxicity of Cry1F have been undertaken.

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Maize 1507 for cultivation: EFSA´s opinion and Pioneer´s data

Monitoring:

no case-specific monitoring is requested by EFSA for:

- the exudation of *Bt* toxins into the soil
- the accumulation and persistence of *Bt* toxins in the soil
- the possible effects on non-target soil organisms
- EFSA justifies even the exclusion of lepidoptera from the case-specific monitoring because they consider it too expensive.

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Bt11 and 1507: Some lessons learned

- EFSA´s opinions lack scientific rigour, being based more on assumptions as on science. Scientific evidence has not been assessed adequately. Uncertainty not made clear.

- For example, the fate of the Bt toxin from GM Bt plants such as Bt11 and 1507 and its lifecycle in the farming environment or its ecological surroundings has to be taken into account in terms of the multi-trophic and multi-layer effects on the ecological food web.

- EFSA´s opinions on Bt11 and 1507 have to be withdrawn

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Bt11 and 1507: Example for failures of GMO guidelines

EFSA guidelines are clearly not in accordance with complexity of food web and multitrophic effects:

“If first tier tests do not identify sensitivity in exposed species then second and third tier test may not be required.”

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Bt11 and 1507: Example for failures of GMO guidelines

EFSA is not even adressing the most basic questions in a mandatory way:

“The applicant should address, where appropriate, the potential impact on biogeochemical processes as these influence ecosystem function, e.g. in relation to soil microbial communities.”

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Part 3: Conclusions

Some General conclusions (1)

Work of EFSA´s GMO panel has to reorganised, its published opinions have to be withdrawn.

A new comprehensive, coherent and mandatory regime is needed necessary risk assessment of GMOs. This is relevant for the quality and amount of data to be presented by industry and as well as the way how these data are assessed. The material produced by industry has to undergo a much more comprehensive quality check before used in EFSA assessments.

Monitoring and general surveillance has to take into acount all levels of complexity, interactions and possible effects regarding human health and environment.

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Some General conclusions (2)

Full and free access to data has to be provided

The opinions presented by GMO panel of EFSA have to reflect all open questions and uncertainties without prejudice.

Precautionary Principle has to be applied in a way that uncertainties regarding safety are seen as an obligation for further investigations and no positive opinion can be filed.

No further delivery of any opinion is possible as long the basic principles of GMO risk assessement are not defined.

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