GMO Feeding Studies and Rodent Cancer Bioassays

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PETA INTERNATIONAL SCIENCE CONSORTIUM LTD.

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Promote reliable, relevant non-animal testing methods

Promote international acceptance of non-animal methods

Conduct retrospective analyses

Fund and organise method development and validation efforts

Provide regulatory staff with training opportunities

Organise and participate in workshops and webinars

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Overview

The PETA International Science Consortium

Rodent Cancer Bioassays

GMO Feeding Studies
Rodent cancer bioassay background

- Glyphosate debate + EU reauthorisation in 2017
- European Parliament's Special Committee on the European Union's authorisation procedure for pesticides (PEST)
- Regulation (EU) 283/2013 setting out data requirements for pesticide active ingredient (AI)
- Rat bioassay is required; mouse bioassay can be waived
- 400 animals per test. Multiple tests per AI.
Rodent cancer bioassay background

• Why are validation standards important?
  • Reliable
  • Reproducible
  • Relevant

• Rodent studies are poorly reproducible.

• Glyphosate: 14 rodent cancer bioassay = 3,500 animals. No reproducible results. Low concordance

• Human carcinogens ≠ Rat carcinogens
Non-animal methods

Assessing chemical carcinogenicity is complex, but scientists are rapidly establishing new strategies for identifying potential human carcinogens.

- Carcinogen screening: using human tissues
- Carcinogenic chemical signatures: advanced computational models
- Long-term human population studies: collecting decades of data - correlation between pesticide application and cancer.

The focus must be on human-relevant data.
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GMO Feeding Studies
GMO feeding studies requirements

Commission Implementing Regulation (EU) 503/2013

- 28-day repeated-dose study using rodents required for newly expressed proteins
- 90-day feeding study using rodents required for whole GM food/feed product
GMO 90-day feeding study

- Used to characterize gene-influencing alterations in the food/feed matrix
- No formal guideline so OECD 408 was adapted to a comparative limit-test design with no hypothesis to test
- Roughly 80 rats/mice per study
GMO feeding studies provide “little additional value”

“where molecular, compositional, phenotypic, agronomic and other analyses have demonstrated equivalence between the GM plant and derived food and feed and its comparator, ... the performance of animal feeding trials with rodents or other (target) animal species (e.g. broilers) is of little additional value if any, and is therefore not deemed necessary on a routine basis.”

“This subchronic testing paradigm has been applied to the safety assessment of food and feed from GM crops for over a decade with no evidence of adverse effects reported to date.”
Do we need the 90-day feeding study?

Recital 12: “The **current uncertainties** in relation to **the need** and design of 90-day feeding trials will be addressed by a large research project under the 2012 work programme of Theme 2 ‘Food, Agriculture and Fisheries, and Biotechnologies’ of the seventh Framework Programme for Research (FP7).”

Commission Implementing Regulation EU 503/2013
Assessing short- and long-term feeding studies

**GRACE and G-TWyST studies**

| [a]nimal feeding studies **add limited value** to GM plant risk assessment | [n]o health risks, including no carcinogenicity, were found for the GM maize tested |
| [t]he mandatory requirement to conduct untargeted animal feeding studies for each novel GM plant **should be discontinued.** |

“...[T]he Commission considers it is appropriate to **maintain the requirement for the submission of a 90-day oral toxicity study in rodents** for each single GM event as part of the application data package...”

“The requirement for the 90-day oral toxicity study will be **reviewed in the future** in light of progress made in the development of validated in vitro methods.”

European Commission. Review of the requirement to perform 90-day feeding studies in rodents. 2017
Feeding studies are required in every assessment, not case-by-case.

*Contradicts* Directive 2010/63/EU to minimize the use of animals in research

Regulators must accept tiered strategies that test specific risk hypotheses.
Points for discussion

Rodent cancer bioassay:
• How often is testing on two species carried out, and what is the added value?
• What do risk assessors need in order to replace this test?
• Would risk assessors consider waivers containing subchronic and mechanistic data in place of the rodent cancer bioassay?

GMO feeding studies:
• What action is being taken following publication of the GRACE and G-TWyST studies?
• When will changes to animal test requirements be proposed?
Thank you for listening!

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