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EFSA activity on 3Rs approach Animal studies in GMO risk assessment

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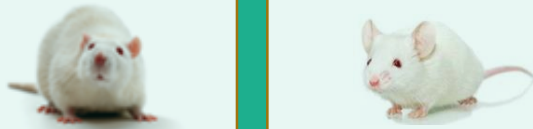
Senior Scientific Officer, GMO Unit

Trusted science for safe food

Animal studies in GMO risk assessment

28-day toxicity studies on new proteins

OECD TG 407



If needed

NP/EFSA/GMO/2018/01
“Literature search –*In silico* protein toxicity”

Studies on the whole food/feed



Rodent

OECD TG

90-day

others



Reg. (EU)
503/2013

If needed



Target animals



If needed

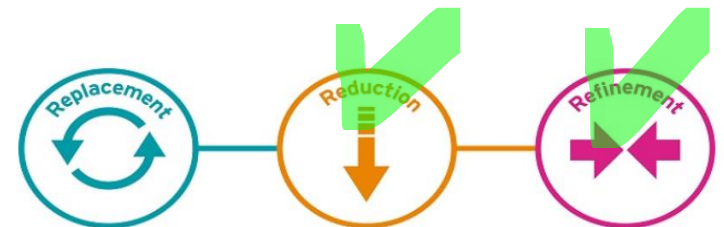
- (d) identify potential adverse effects on the whole genetically modified food/feed or address remaining uncertainties through the performance of 90-day feeding studies.

Issue

- OECD TG 408 adaptation needed (food/feed)
test item characterisation, control material, dose levels, cage effect, etc.

Risks

- inadequate studies (repetition)
- unnecessary use of additional animals
- unbalanced diets (welfare)



Solutions

- clear instructions by EFSA guidance documents
 - integrating OECD TG 408 on critical aspects
 - discouraging the use of additional controls (rather HCD)
 - balanced diets
 - social housing (with proper data analysis)
 - soft benefit: consistency, data homogeneity
- case-by-case assessment
 - analysis of deviations, clarification questions
- communication
 - applicants, MSs, public; ad-hoc (application specific)

- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2011. EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal, 2011;9(5):2150, 37 pp.
<https://doi.org/10.2903/j.efsa.2011.2150>
- EFSA Scientific Committee, 2011. EFSA guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed. EFSA Journal 2011;9(12):2438, 21 pp.
<https://doi.org/10.2903/j.efsa.2011.2438>
- EFSA (European Food Safety Authority), 2014. Explanatory statement for the applicability of the Guidance of the EFSA Scientific Committee on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed for GMO risk assessment. EFSA Journal 2014;12(10):3871, 25 pp.
<https://doi.org/10.2903/j.efsa.2014.3871>

Beyond 90-day studies:

- EFSA, 2013. Considerations on the applicability of OECD TG 453 to whole food/feed testing. EFSA Journal 2013;11(7):3347, 18 pp. <https://doi.org/10.2903/j.efsa.2013.3347>



GRACE

GMO Risk Assessment and
Communication of Evidence

<http://www.grace-fp7.eu/>

- EU FP7 research project with two key research objectives: Assessing health, environmental and socio-economic impacts of GM plants (risks and benefits) and testing various types of animal feeding trials and alternative in-vitro methods for health risk assessments of GM food and feed.



G-TWYST

GM PLANTS TWO YEAR SAFETY TESTING

<https://www.g-twyst.eu/>

- Collaborative Project of the Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (KBBE.2013.3.5-03).

- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 12.3.2001, p. 1–38. <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:32001L0018>
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23. <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32003R1829>
- Regulation (EU) No 503/2013 of 3 April 2013 on application for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 604/2004 and (EC) No 1981/2006. <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32013R0503>

Thank you!

Any questions?

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