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# GM maize MON863, oilseed rape Ms8, Rf3, Ms8xRf3, oilseed rape GT73
# Statement on toxicological risk assessment
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Genetically modified (GM) maize MON863 has been approved by the European Union (EU) in 2005 for import and processing and in 2006 for the use as food, food additive, feed, and feed additive. In July 2008, Austria issued import bans against GM maize MON863 and derived products.
GM oilseed rape Ms8xRf3 has been approved by the EU in 2007 for import and processing and feed use. In July 2008, Austria issued import bans against GM oilseed rape Ms8xRf3 and derived products.
GM oilseed rape GT73 has been approved by the EU in 2005 for import and processing and feed use. In April 2006, Austria issued import bans against GM oilseed rape GT73 and derived products.

## Prolongation of Importbans

Current import bans have been justified, amongst other reasons (e.g. environmental risks), because of shortcomings in the toxicological risk assessment and therefrom deficits in assessing potential risks for humans and animals via exposure to food and/or feed derived from these GMOs.

Regarding GM maize MON863 the main critical points are the following:

- The 90-day toxicity study in rats is based on an OECD test design outdated at the time of planning and realisation of the study (thus, certain neuro-/immunotoxic endpoints being already state-of-the-art were not investigated)

- Significant differences are not classified as biologically relevant (arguments: within statistical bandwidth, no dose-related effects, no effects in both sexes, etc.) Further tests to investigate potential adverse effects were not carried out (long term studies, developmental/reproductive toxicity studies)

- No rationale is given whether 33% is indeed the highest possible level for maize in the diet of rats (accordingly, higher dosages may have been used).

Regarding GM oilseed rape Ms8xRf3 and GT73 the main point of criticism is that no subchronic oral toxicity studies with the whole GM plant were conducted.

In addition to the points mentioned above:

- studies in broiler chicken are mainly designed to investigate efficacy and tolerance and cannot be a substitue for *lege artis* toxicity studies,

- the intravenous administration of the transproteins does not reflect the natural route of exposure, and

- there are some deficits that become apparent in studies performed by the applicant and cited by Hammond et al. (2006):
    - The study design provided a majority of reference groups (60-80%), and thus the data of the *verum* group were potentially masked by comparing to broad ranges in their statistical relevance.

- Rules of good practice require examination of histo-pathological endpoints. However, these requirements were not fully met.
- Significant differences which had been observed were downgraded using arguments such as "no dose-related trends", "within historical control", and "pathologically irrelevant".

However, before maintaining the Austrian arguments the possibility has to be scrutinised if new scientific data had been published or had been submitted by the applicant since the entry into force and the prolongation of the import bans.

A comprehensive online search including all relevant information (EFSA Extranet, Website EFSA, Website DG Sanco, etc.) has proven that regarding toxicological and immunological risk assessment of MON863, Ms8xRf3 and GT73 no new data or studies are available or have been submitted since the prolongation of the import bans in autumn 2010.
The only exceptions were updates of database analyses (*in silico* analyses). These analyses, however, have no relevance regarding the arguments for the Austrian import bans.

**Austria has underlined a number of deficiencies and shortcomings as to the food and feed risk assessment of these three GM crops (MON863, Ms8xRf3 and GT73) made by the applicant. These deficits are still apparent. Therefore, the arguments for the Austrian import bans remain valid.**