MON89034 for food/feed

MON89034 is a Bt maize with two Bt toxins Cry1A.105 and Cry2Ab2 against lepidopteran pests, whereby Cry1A105 is a protein compromising several Bt toxins [1].
Even before MON89034 was authorized on 30 October 2009 by the EU Commission after failing to get a qualified majority, at least 7 applications have been submitted to the EU for MON89034 hybrids for food/feed.

In 2007, the Dutch authority COGEM had advised *against* approving of MON89034 for feed/food, mainly because of lacking information, and because the monitoring plan was considered insufficient. However, COGEM points out that the molecular analysis of maize line MON89034 is incomplete. In view of the incomplete molecular data, COGEM cannot advice positively on the application for import and processing of MON89034.
In 2008, COGEM accepted the revised monitoring plan as sufficient, and did not comment on some other issues anymore due to a change in policy.

Comments on the opinion of the GMO Panel:
As with other opinions, the GMO Panel only assessed MON89034 only for its 'intended purposes' therefore excluding effects of accidental cultivation.
The **molecular analysis** explains why nptII was part of one of the two transgenic inserts, but nevertheless nptII is missing in the transformed plant. No explanation is given for this.
In contrast to other applications detailed information is given about Bt concentration in different tissues, including roots. However these data only comes from locations in Argentina (where MON89034 is not approved for cultivation) and the US, during two years.

For **compositional analysis** MON89034 was *not* compared to its isoline, but to the maize hybrid LH198 x LH172 which is described as a "conventional maize hybrid with background genetics similar to maize MON89034". Three commercially available maize hybrids were used as additional comparators.

The EFSA opinion admits that "when the compositional data on materials from the 2004 field trials in the USA were analysed for each separate site, 44 statistically significant differences were observed." However, in the end the GMO panel concludes that none of these statistic significant differences had "biological relevance" and that - except from the Bt toxins - MON89034 would be "compositionally equivalent to the control maize
and commercial maize hybrids."

For the assessment of **agronomic traits and GM phenotype**, Monsanto provided data from studies that took place in the US in 2004 and/or 2005, with two different maize hybrids as comparator, depending on where the cultivation took place.

Food/feed safety was assessed in studies with mice (acute toxicology, single dose of bacterial Bt toxin, 2 times 20 mice), rats (90 days feeding study, 60 rats) and broilers (42 days, nutritional assessment, 100 broilers).
The GMO Panel comes to the conclusion "that post-market monitoring of the GM food/feed is not necessary"

Because the 'intended use' of MON89034 is food/feed import but no cultivation, the environmental risk assessment only included potential effects of the Bt toxins when excreted in manure and feces of livestock feeding on it. The GMO Panel therefore concluded that "exposure of potentially sensitive non-target organisms to the Cry1A.105 and Cry2Ab2 proteins is likely to be very low and of no biological relevance."

Related events: Event MON89034 [1]

Related application(s): MON89034 x NK603 for food/feed [2]
Question number: EFSA-Q-2007-042
Application number: EFSA-GMO-NL-2007-37
Application date: 31.01.2007
Type: new application
Aplication accepted: 24.08.2007
Status: opinion adopted
Deadline: 10.03.2009
Links & resources: Negative advice from Dutch authority COGEM (2007) [3]
EFSA registration [4]
Petitioner: Monsanto Europe BV
Applicant/Requester: The Netherlands
Opinion number: ON-909
Opinion adopted: 03.12.2008
Opinion of the GMO Panel [5]
EU consultation form or comments [6]
Consultation deadline: 18.01.2009
Application status at EU level: authorized
EU authorization status [7]
Authorisation date: 30.10.2009
Authorisation expiration date: 29.10.2019

Links
[1] https://www.testbiotech.org/node/133 [2] https://www.testbiotech.org/content/mon89034-x-nk603-foodfeed [3] http://www.cogem.net/ContentFiles/071022-02, advies import mais MON89034 eng.pdf [4] http://registerofquestions.efsa.europa.eu/roqFrontend/?wicket%3Ainterface=%3A3%3A%3A%3A%3A%3A [5] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902216540.htm [6] http://ec.europa.eu/food/food/biotechnology/authorisation/comments_mon89034.pdf [7] http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=34