

**Comments by GeneWatch UK to 2001/18/EC marketing application
reference GB/02/M3/03.
(March 2004)**

1 Reference to internal documents and lack of supporting data.

There is very little data actually presented within the dossier itself or the appendices. Monsanto either simply do not provide data, as in the case of section D4 (page 40) or reference 'Monsanto internal documents'. An example of this later case is shown in section D7(a) (page 48) where a number of statements are made about the safety of the Cp4 EPSPS gene. The dossier states that a full description of the safety assessment of the Cp4 EPSPS gene is given in the dossier C/ES/00/01. When looking at this dossier, it is found that whilst the general methods and used to undertake this safety assessment are described details of the work and the results are contained in 'Monsanto internal documents'.

It is of great concern to GeneWatch that ACRE has not had access to the details of many of the experiments carried out by Monsanto on MON810 x NK603 or on the individual dossiers for MON810 or NK603 to which much reference is made. Without access to these details GeneWatch do not believe ACRE can make a full assessment of the safety of NK603xMON810.

2 Use of the argument that lack of evidence of harm is equivalent to evidence of the lack of harm.

Monsanto argue that because people in the United States have been eating an amount of these the CP4 EPSPS and Cry1Ab proteins for a long time, and that there have been no reports of problems, therefore the proteins must be safe (Page 48 & 49). However, there have been no studies undertaken to look specifically at the long term effects of digestion of either of these proteins, whether singularly or together on human beings and therefore this assumption is not valid.

3 Compositional analysis.

3.1 Data taken from very limited source material.

Compositional data was obtained from three French trial sites grown over one year. The compositional variation of any given species or variety arises from both genetic and environmental variation. To provide an assessment of safety for health and environment, it is necessary to find the compositional variation under the full range of likely growing conditions. Monsanto acknowledge that NK603xMON810 could be imported into the EU from Africa, North America, Asia, and Central and Eastern Europe. Three sites in one country during one growing season cannot provide this range. Additionally this application is for import into the EU and, therefore, the use of France as the site for the trials is not appropriate. The trials should have been carried out in the countries and habitats likely to grow this GM line.

This issue is highlighted when, on page 55 of the dossier C/GB/M3/03, Monsanto indicate a significant difference in phosphate levels at one of the sites. Part of their argument is that this difference is only at one site and therefore not biologically significant. However, due to the sample size this is also a third of the sites.

3.2 Analysis deviates from OECD Consensus Document on Maizeⁱ.

- a) It is unclear why Monsanto did not analyse Vitamin A, Vitamin B6, niacin or Selenium content for the maize grain, despite these being part of the OECD consensus document.
- b) The OECD consensus document identifies 16:0 Palmitic , 18:0 Stearic 18:1 Oleic, 18:2 Linoleic and 18:3 Linolenic as the fatty acids found in maize kernels. Monsanto's analysis covers these and many more. However, the OECD figures give fatty acid composition of refined maize oil where as for NK603xMON810, Monsanto give composition of total fatty acids. Therefore it is impossible to make comparison with the OECD document.

4 Animal Studies

There are five main animal studies referred to in the dossier;

- Chicken broiler study carried out using NK603xMON810 (page 56-60)
- Acute mouse gavage study using trypsin resistant core of Cry1Ab produced in E. coli (C/F/95/12/02 page 47)
- Acute mouse gavage study using CP4 EPSPS protein produced by E. coli (C/ES/00/01 page 72)
- Broiler chicken feeding study using NK603 (C/ES/00/01 Page 77)
- Rat feeding study using NK603 (C/ES/00/01 Page 82)

Only one has been carried out on the actual GM crop in question, NK603xMON810, two have been carried out on the parent line NK603, whilst two are carried out on copies of Cr1Ab and Cp4 EPSPS produced by a bacteria and not by a plant and not in the plant in question.

The trial actually carried out on NK603xMON810 used chickens which have very different digestive systems to the wide range of species which may come into contact with this crop either deliberately or via spillage, accidental contamination etc. and eat it.

5 Allergens.

The OECD Consensus Document on maize states "*Maize is not a common allergenic food, although in some case-studies, allergenic reactions were reported (Helfe, 1996) These reported allergic effects for maize include skin - gastrointestinal -, and respiratory complaints*". The accompanying note states that some research has been carried out to identify the allergenic proteins but results so far conflicting and uncertain. Nowhere in the documentation do Monsanto refer to this and do not explore the possibility that NK603xMON810 may exacerbate the level or amount of allergen produced in the maize and allergic reactions to it.

6 Overall food safety testing.

The overall safety of NK603x MON 810 cannot be assessed by simply looking at the constituent parts. The evidence supplied by Monsanto relies heavily on one two week chicken study. Maize line NK603xMON810 may be eaten by both humans and all types of live stock. GeneWatch would wish to see studies carried out on a wider range of farm animals and specifically to include ruminant animals

7 Environmental safety.

The environmental safety assessment report given by Monsanto relies heavily on the idea that NK603xMON810 is substantially equivalent to conventional maize except for the production of Cp4 EPSPS and Cry1Ab. In an environmental context Monsanto's evidence for this seems to be based on field trials carried out in the US and EU on NK603 and on MON810 during the 1990's and from unspecified 'observations of conventionally bred NK603xMON810' (page 75). Monsanto clearly state that no phenotypic differences were observed. Furthermore, in previous sections of the dossier (D4, page 40 and D6 page 48) Monsanto claimed to have monitored plant morphology, seedling emergence and vigour, disease susceptibility and insect damage. At no point do Monsanto provide details about how these observations were made nor any data or references to data on the outcome of these observations.

GeneWatch is hopes that ACRE will either ask Monsanto for further details to support these claims of substantial equivalence or disregard that claims made.

8 Measures to be taken in case of unintended release misuse

In this section (B.1, page 73) Monsanto do not provide the information asked for. Instead, they explain why in their opinion there will not be any unintended release or misuse.

9 Consent should not be given until;

- the above issues have been resolved.
- Monsanto have provided the detailed arrangements for the post release monitoring plan as asked for by ACRE.
- NK603xMON810 has obtained authorisation for human food and animal feed use are required by Regulation (EC) 1829/2003.

ⁱ OECD Series on the Safety of Novel foods and Feeds No.6. Consensus document on the compositional considerations for new varieties of maize (*Zea mays*): Key food and feed nutrients, anti-nutrients and secondary plant metabolites. (2002)