



Persatuan Pengguna Pulau Pinang
Consumers Association of Penang

檳城消費人協會 பினாங்கு பயன்பட்டாளர் சங்கம்

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Our Reference: CAP/RS/GM/MON15985/20/Mgs
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Director General,
Department of Biosafety
Ministry of Environment and Water
Level 1, Podium 2, Wisma Sumber Asli
No. 25, Persiaran Perdana, Presint 4,
62574 PUTRAJAYA

Dear Sir/Madam,

Comments on application for approval for release of genetically modified products of MON 15985 cotton (*Gossypium hirsutum*) for the purpose of supply or offer to supply for sale/placing in the market
NBB Reference No: JBK(S) 600-2/1/15

Please find below comments by the Consumers' Association of Penang (CAP) on the above application submitted by Monsanto Malaysia Sdn Bhd to the National Biosafety Board (NBB).

As stated in the factsheet, the purpose of the import and release is to supply or offer for sale/ placing on the market -- for direct use as food, feed and for processing (FFP) of MON 15985 cotton. This means that MON 15985 cotton may enter Malaysia as cottonseed, food ingredients for processing or packaging or as finished products ready for distribution, or as feed meal for animals.

MON 15985 is a stacked event resulting from the genetic engineering of an already existing GM variety MON531. MON531 was genetically engineered to carry the insecticidal Bt toxin Cry1Ac and the antibiotic resistance gene *NPTII*. It was then subsequently modified further by introducing an additional insecticidal Bt toxin Cry2Ab2, and selectable marker gene *uidA*.

GM proteins may be present in edible oils

Considering that GM cotton is used for edible cottonseed oils in Malaysia, this raises health risks to the consumer that need to be ruled out by adequate safety testing.

It is often claimed that adverse health effects are unlikely for oil products such as edible oil derived from cottonseed, because GM proteins are not present in oils. However, recent scientific evidence has shown the presence of proteins in refined, processed oils¹. Refined peanut oil was shown to have two proteins that were sufficient to induce an immunogenic response in blood serum from people allergic to peanuts.

Insecticidal toxins linked to adverse health effects

Bt toxins have repeatedly been associated with adverse health effects. Animal studies on other Bt crops report a variety of health effects including stomach, uterine and gastric problems in mammals². Farmers' testimonies also report problems including deaths of livestock as a result of consuming Bt crops³.

Another variety of maize, that carries both the *Cry1Ac* gene and a different version of the *Cry2Ab2* gene, was reported to cause kidney disease and bladder stones in rats in industry tests⁴. *Cry1Ac*, the toxin present in MON 15985, has been associated with inflammatory responses in mammals, and shown to enhance immune reactions to other substances^{5,6}, increasing potential allergenic reactions to the GM cotton.

A new analysis of industry data on Bt toxins further reveals they may be 20 times more toxic than previously known⁷. The production of specific enzymes in plants such as cotton, maize and soybean enhances the toxicity of Bt toxins by protecting them from breaking down, such that their effects are amplified and prolonged. Concerns have been raised by independent scientists that such toxic and immunogenic effects may occur in mammalian guts, including those of humans. Regulatory bodies have however failed to assess such concerns in risk assessment protocols despite knowledge of this biosafety risk.

Toxicology study indicates potential adverse health effects

A summary of a sub-chronic toxicology study of MON 15985 on rats has been published by European regulatory bodies.⁸ The summary provides no data, but states that 'Several significant differences were observed between the test and the control group in haematology, clinical chemistry and urine analyses.'

It is vital that data on such differences are made publicly available for independent scrutiny, and most fundamentally, further interrogated with more detailed investigation, in order to ensure that the health of the public and of animals is protected from any adverse health risks of MON 15985.

Differences in composition indicative of unintended effects of genetic engineering

Genetic engineering is an inherently unpredictable process associated with unintended effects such as disrupted gene expression and subsequent changes in levels of proteins, or indeed nutrients or allergens. To assess this potential, crude nutritional data is analysed to see if the process has altered the composition of the plant in terms of levels of nutrients, anti-nutrients, toxins and allergens.

The factsheet states that levels of four analytes out of 52 are statistically significantly different in the GM cotton compared with conventional counterparts. Such findings are dismissed in the factsheet, which claims that MON 15985 is compositionally 'equivalent' to conventional cotton. However, such differences should be further investigated.

Indeed, more detailed techniques such as those that perform unbiased profiling of hundreds or thousands of genes, proteins and metabolites, termed 'omics' profiling techniques, have found alterations in GM plant analytes that were not observed in the basic tests performed for risk assessments⁹. It is vital that differences are analysed and not dismissed to ensure safety of MON 15985.

Risk assessment not sufficient to rule out other adverse health risks

The Bt toxins produced in MON 15985 cotton do not occur naturally. Bt toxins derive from bacteria and are subsequently modified and introduced into a new species where it can behave differently, as detailed above. Further, including numerous Bt toxins into one plant risks combinatorial effects of these toxins. However, none of these risks appear to have been assessed, which is even more important given the indications of unintended effects in the single toxicology and compositional assessments. Only bacterial versions of the Bt toxins were assessed, which are of limited relevance to those produced by the plant, which have been modified to enhance their effectiveness. Further, toxicity was assessed for each toxin individually, and not in combination.

Considering all the above concerns, the safety claims of MON 15985 cotton cannot be verified. Evidence of unintended effects on experimental animals cannot be dismissed. Instead, further assessments of the whole plant, including long-term toxicology assessments and more detailed profiling techniques need to be conducted.

In light of the foregoing, we strongly urge the National Biosafety Board not to approve MON 15985 cotton.

Thank you.

Yours sincerely,



MOHIDEEN ABDUL KADER
President
Consumers' Association of Penang

References

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