The Bioscience Resource Project
Fundamentals in Food and Agriculture

GM FREEZE
the campaign on
GM food, crops and patents

Gene VI in GM Crops: What's happening and why you should know

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1. What's been discovered and by whom?

In the course of a retrospective analysis to identify potential allergens in GMO crops, the European Food Safety Authority (EFSA) has belatedly discovered that the most common genetic regulatory sequence used in commercial GMOs (called the CaMV 35S promoter) also encodes a significant fragment of a viral gene.

This viral gene (called Gene VI) comes from the cauliflower mosaic virus (CaMV). The discovery of the genetic overlap was published in the scientific journal *GM Crops and Food* in late 2012.[i] The authors are Nancy Podevin, an EFSA employee, and Patrick du Jardin, Vice Chair of EFSA's GMO panel, which is responsible for the scientific assessment of GMOs by the EU.

Most GM crops approved by the EU contain the CaMV promoter and thus fragments of Gene VI.

2. Was Gene VI missed before or ignored?

The existence of Gene VI has been known scientifically since 1980, and it has been quite extensively studied. The existence and overlap of Gene VI is also described in original patents referring to the CaMV 35S promoter.[ii] Applicants must have known of its existence. However the publication by Podevin and du Jardin, together with the fact that Gene VI has never been mentioned by GM regulators around the world (eg, EFSA, the UK Advisory Commission on Releases to the Environment (ACRE), New Zealand Food Standards Australia), or noted in specific commercial applications themselves, indicates that regulators up to now have been unaware of the presence of Gene VI.

3. Why worry?

Gene VI encodes the protein of a viral pathogen. There are a number of concerns including:

- No viral protein has ever (knowingly) been approved for food or commercial use in the EU.
- Gene VI is a plant toxin and known to interfere with host plant defences. This may cause problems in agriculture.
- Gene VI interferes with the basic mechanism of protein production, which is common to humans and plants.
- Gene VI is known to disrupt RNA silencing, which is a conserved pathogen defence mechanism shared by animals and humans.

These properties of Gene VI are clearly established in the scientific literature and raise the possibility that Gene VI could be a human toxin.

It is true that the whole of Gene VI has not been approved by regulators, but even the shortest commercial versions of the CaMV promoter contain a third (lengthwise) of the Gene VI coding sequence. Gene fragments are often functional.

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4. We have been eating Cauliflower Mosaic Virus for centuries, so what's the problem?

There are three main concerns:

- Cauliflower mosaic virus has never been shown to be safe.
- A viral gene expressed from a transgene presents a very different risk scenario than do transient viral infections.
- We have not been eating FMV.

5. Aren't Gene VI and its protein broken down during digestion?

Many food items are only partially digested before they enter the body. Many pass through the gut and into the bloodstream directly, including vaccines, allergens, pharmaceuticals, DNA and caffeine. Furthermore GM DNA has been found to pass from gut to bloodstream in laboratory tests, and the Bt in GM insect resistant crops was reported found to pass into the blood of women in 2011.

6. Who is to blame for failing to assess the possible risks associated with Gene VI?

GM crops containing Gene VI have been approved wherever GMOs have been approved. This means EFSA, ACRE and ACNFP, which all contribute to risk assessment, have all unknowingly approved transgenes containing Gene VI fragments.

7. Does this reveal flaws in the GM regulatory system?

Yes. There are three flaws revealed:

- The inadvertent approval of GMOs containing Gene VI indicates that regulators are not incorporating information from the scientific literature into the approval process.
- The belated discovery of Gene VI also suggests that the "detailed examination of the inserted sequence" claimed by regulators appears not to have occurred.
- Regulators are over reliant on industry to tell them what is in GMOs.

8. What should happen now to ensure Gene VI is safe?

Given the uncertainty over the harmful nature of Gene VI the only response compatible with protecting public safety is to recall all GMOs containing the CaMV 35S promoter while its safety is established. This should also apply to all GMOs containing the figwort mosaic virus (FMV) 35S promoter (the presence of which in many of the same crops regulators have yet to acknowledge).

9. Who should take responsibility for dealing with this problem?

The direct responsibility for this failure to ensure the safety of approved GMOs lies with regulators, but governments are responsible for tolerating lax and complacent regulation.

Responsibility also lies with applicants. The biotech industry has pushed for a lax regulatory system in part by arguing they would never place the public at risk. This vested interest should never have been permitted to influence either the design of the approval system or its operation.

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[i] Podevin N and du Jardin P, 2012. "Possible consequences of the overlap between the CaMV 35S promoter regions in plant transformation vectors used and the viral gene VI in transgenic plants". *GM Crops and Food* 3: 1-5

[ii] US patent for CaMV 35S promoter – see paragraph 00015
www.patentlens.net/patentlens/patents.html?patnums=US_5530196&language=en&query=%28US_5530196%20in%20publication_number%29&stemming=true&returnTo=structured.html%3Fquery%3D5530196#tab_1