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Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001

RE: Docket Identification Number: EPA-HQ-OPP-2006-0642

Exemption Under the Federal Insecticide, Fungicide, and Rodenticide Act for Certain Plant-Incorporated Protectants Derived From Plant Viral Coat Protein (PVCP-PIPs) Gene(s)

Center for Food Safety appreciates the opportunity to submit the following comments.

The proposed rule should be amended so that the exemption applies only to transgenes that cannot express viral coat proteins.

There are several reasons this amendment is needed.

First, some viral coat proteins of wild-type viruses are known to inhibit gene silencing in the crop as a means of overcoming the plant's defense mechanism and infecting the crop. If a coat protein expressed by an integrated transgene had the same effect, the result could be a host plant that is more susceptible to a range of plant pathogens. One example is provided by Carmovirus coat proteins, which the proposed rule would exempt. Several carmoviruses are known to infect plants in the United States, for example Nootka lupine vein-clearing virus (see Robertson 2004; Liu et al 2003). The coat protein of one carmovirus (turnip crinkle virus, TCV) is known to inhibit host plant defence mechanisms by neutralising gene silencing (Thomas et al 2003; Qu and Morris 2003). Insertion of the transgene for this coat protein, assuming it functions as a transgene as it does in the wild-type virus, would most likely result in the crop species into which

it was inserted becoming susceptible to a wider range of plant viruses. Nearby crops could also be affected. Plant-incorporated protectants are supposed to decrease, not increase, disease susceptibility.

Secondly, a protein that inhibits gene silencing in food crops may also present risks to the health of humans and animals that consume the crop. This is because the pathways of gene silencing are significantly conserved between plants and animals. For example, the NS1 protein of Human influenza virus inhibits gene silencing in plants (Delgadillo et al 2004). Humans and other animals rely on gene silencing as a primary defence against viral infections in general, and the gut is a primary entry point for these pathogens. If they are consuming inhibitors of this defence system along with their food, these defences may be compromised.

Third, such an amendment to the rule would prevent potential problems with heteroencapsidation and also recombination with superinfecting viruses.

Finally, the amendment is necessary in light of our still vast ignorance of the properties of viral coat genes and proteins. It is worth noting that the additional function of the TCV coat protein discussed above was discovered only in 2003. It is entirely possible, and indeed likely, that coat proteins of other viruses have yet unknown, additional functions that make them inappropriate, or even hazardous, as plant protectants. Given our inadequate knowledge of the properties of many plant viruses, all transgenes that express viral coat protein should be excluded from the proposed exemption.

We note that this reasonable amendment would not prevent the development of virus-resistant transgenic crops, and is consistent with the recommendations of many scientists who have considered this issue (Tepfer 1993; Hammond et al. 1999; Tepfer 2002; Power 2002).

Sincerely,

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