From: Legris, Gaston (G)

Sent: Tuesday, April 10, 2012 3:31 PM

To:

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Cc:

Subject: presentations for IPTS workshop "New Plant Breeding Techniques: Adoption and Economic Impact"

please find attached the written notification received by Dow AgroSciences from USDA-APHIS following the review of plants with targeted deletions on the IPK1 gene, produced by using one of the applications of Zinc Fingers technologies - referred to in the EU as ZFN1.

In the letter, the APHIS concluded that "plants containing targeted deletions, caused by naturally-occurring DNA repair after the targeted break is made by zinc-finger nucleases, and in which no genetic material is inserted into the plant genome, are <u>not</u> regulated articles under CFR part 340".

This statement implies that as long as the construct used to deliver the ZNFs into the plant cells does not integrate or remain in the final product, the USDA will not regulate plants with targeted deletions; hence, the <u>maize plants with targeted deletions on the IPK1 gene</u>, were exempted, in the <u>United States</u>, from the <u>GMO status</u> and are treated as conventional maize varieties.

Be aware that the USDA only reviewed ZFN1 because we had, at the time we engaged with the regulators in the US, maize plants with targeted deletions on the IPKI gene produced using ZFN1 technologies; hence, ZNF applications 2 and 3 were not part of this reviewing process. Kind regards,

Gaston LEGRIS Ph.D.

Regulatory Affairs Leader (Seeds, Traits and Oils) European Trade Area

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