On Feb 23, 2012, at 3:24 AM, "Henk Schouten" <henk.schouten@wur.nl> wrote:

Dear Dr. Gregoire,

I received your name and contact information from the Netherlands Embassy in Washington DC.

Let me shortly introduce myself: I am a researcher at Wageningen University and Research Centre, the Netherlands, and work on disease resistance in apple. The aim is strong reduction of fungicide applications in fruit production, in view of cost reduction and environment. Apple scab, caused by the fungus Venturia inaequalis, requires in our country 20 to 30 chemical sprays per seasons. In view of the scab problems, classical apple breeders have been working on introgression of the Vf-gene into commercial cultivars already for more than 50 years. However, the quality of these cultivars is still not optimal, due to genetic drag. Therefore, the Dutch companies Inova Fruit and TreeQuattro have asked Wageningen University and Research Centre to speed up the breeding by innovation. We have decided to enrich current well-known apple cultivars with resistance genes from apple, without introduction of any foreign gene, i.e. by means of cisgenesis. The introduced gene is under control of its native promoter, and the expression level is similar as in conventionally bred selections. Cisgenic plants do not contain foreign genes, such as bacterial selection genes.

We developed and introduced the cisgenic approach, together with several colleagues, and wrote about it in Nature Biotechnology, EMBO Reports and other journals several years ago. In the meantime we have developed cisgenic apple trees, by adding the Vf scab resistance gene from apple to the highly susceptible apple cultivar Gala. The cisgenic cultivar requires only two sprays against scab. We intend to add also resistance to fire blight, using natural resistance genes from apple.

In 2011 we set up the first test orchard with cisgenic, scab resistant Gala in our country. The development and commercial introduction is a collaborative effort with Inova Fruit and TreeQuattro. We would also like to introduce our cisgenic cultivars into the United States too, for production of disease resistant, high quality trees and apples in the USA. We are convinced that this will reduce chemical input in apple production in the USA, and therewith save money to fruit growers. Further, this is beneficial to the environment, to labor conditions of fruit growers and nurserymen, and it can reduce chemical residuals on fruits.

With respect to the cisgenic technology, we have been very pleased when Science and Nature Biotechnology announced that the EPA is discussing to exempt cisgenic crops with disease resistance from the GMO registry in the USA.

Last week, the European Food Safety Authority (EFSA), published its report on safety of cisgenic crops. It concludes that cisgenic crops are as safe as conventionally bred crops for food, feed and environment (http://www.efsa.europa.eu/de/efsajournal/pub/2561.htm). Further the European Commission established a working group on novel breeding technologies. That working group finished its report in December 2011, and recommends excluding cisgenic plants from the GMO Regulation in the EU. Thepolitical decisions about the legal status of cisgenic plants have still to be made in the EU. Both EFSA and the working group regard phenotypic traits of intragenic plants (that contain new combinations of promoters and coding regions from native genes) as being outside the normal range of conventional breeding, and recommend treating these plants as plants that contain foreign genes, so like transgenic crops that are covered by the GMO Regulation. This is completely in agreement with the EPA proposal.

As you belong to the experts in GMO Regulation in the United States, we would very much appreciate an opportunity to meet with you, yourstaff and possibly representatives of FDA and EPA, to learn how disease resistance cisgenic plants are currently regulated in the United States and what our next steps should be to introduce cisgenic Gala plants that contain the *Vf* gene for scab resistance into the United States. Your opinion and judgment are very important for us, and are the basis for our commercial market introduction strategy of disease resistant varieties. We would appreciate indeed a joined meeting with APHIS, EPA and FDA. During the meeting we can provide detailed background information about the cisgenic lines we have developed.

We would be available to come to the United States to meet with APHIS, FDA and EPA on April 17, 18, 19 or 20 in a joint meeting to discuss this topic. During that time we also plan to visit possible test sites in the United States and Canada, and Canadian regulators. Probably, our Vf-Gala is not novel food according to the Canadian Regulation, and therefore not under the GMO registry in Canada. The Netherlands Embassy in Washington, DC has offered to coordinate the visit.

Thank you very much for your consideration. I look forward to hearing from you.

Yours sincerely,

Dr Henk Schouten

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