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## Report from meeting with Schuttelaar & Partners on new plant breeding techniques, 13th March 2012

Participants: [4.1(b)] (Schuttelaar & Partners), [4.1(b)] (TRADE )

*Context:* Since the 1980s, many new plant breeding techniques (NPBTs) have been developed. Many of these new approaches deploy biotechnology. Although the applied methodology and changes achieved in the genome of the crops differ from earlier transgenic approaches the question still arises (in countries where GMOs are regulated under specific legislation, including the EU) as to whether crops derived by these techniques should be classified as GMOs.

A working group established by DG SANCO with MS participation is currently evaluating whether certain new techniques constitute techniques of genetic modification and, if so, whether the resulting organisms fall within the scope of the EU GMO legislation. The following eight new techniques are being considered:

- Zinc finger nuclease (ZFN) technology (ZFN-1, ZFN-2 and ZFN-3)
- Oligonucleotide directed mutagenesis (ODM)
- Cisgenesis and intragenesis
- RNA-dependent DNA methylation (RdDM)
- Grafting (on GM rootstock)
- Reverse breeding
- Agro-infiltration (agro-infiltration "sensu stricto", agro-inoculation, floral dip)
- Synthetic genomics

It is estimated that the most advanced products derived from these technologies, e.g. herbicide resistance in oilseed rape and maize, fungal resistance in potatoes, drought tolerance in maize, scab resistant apples and potatoes with reduced amylase content, could reach the stage of commercialisation on the global market in 2-3 years time. Biotechnology companies and plant breeders are particularly concerned about the legislative uncertainty of the GMO classification of new plant breeding techniques. Regulatory costs for plants classified as GMOs are much higher than those for the registration of non-GMO plants, and public acceptance is lower.

**Schuttelaar & Partners** requested a meeting with TRADE in order to present the work of the New Plant Breeding Techniques (NPBT) Platform, which is a coalition of business and scientific sector striving for 1) legal clarity on whether NPBTs do or do not lead to genetically modified organisms, 2) having NPBTs excluded from the scope of the GMO legislation. Companies, including SMEs, and research institutes based in the EU play a prominent role in research and development activities in NPBTs. EU occupies the second place in the world for patent applications (within the EU, UK and NL contributes the most significantly). There is a serious risk that a possible classification of these techniques as GMOs would lead to competitive and technological disadvantages for plant breeders and research institutes in the EU and would jeopardize the breeding sector in the EU. It should also be stressed that crops resulting from most of the techniques cannot be distinguished from conventionally bred crops and detection is therefore not possible.

**TRADE** took note of the presentation and explained our work on trade-related biotechnology issues in general. With regard to NPBTs, the lead DG is SANCO, which is currently consulting MS on the problem of classification of these techniques. No COM line has been agreed so far. TRADE and other concerned

services will express their opinions during the formal ISC procedure. Asked for clarification on the benefits for consumers of these technologies.

*Schuttelaar & Partners* informed that the use of NPBTs makes the breeding process faster which lowers production costs, results in environmental benefits and more sustainable production methods. Some of the examples of NPBTs with tangible consumer benefits are drought resistant crops, crops with vitamin A content.

**Conclusions/next steps:** DG SANCO is chef de file on NPBTs. So far, no discussion has taken place on this subject between SANCO and other services, as work is sill ongoing on the classification of theses techniques and there is no agreed line yet within DG SANCO on the possible approach to be taken. I was reassured by my SANCO counterparts that the trade angle will be taken into account when deciding on the COM line to take. An inter-service consultation on this subject will be launched in the second half of the year. TRADE will have to ensure that any measure/solution proposed will not result in trade disruptions and that we avoid possible problems of asynchronous authorisations for NPBTs' derived products. The fact that detection is not possible for most of the techniques (except ZFN-3 technology, cisgenesis/intragenesis and floral dip) would make traceability impossible and could, in the worst case scenario, result in a similar situation we are facing on the animal cloning issue. I will keep you in the loop on future developments on this issue, together with a more detailed analysis of the problem once more data is available, including regulatory approaches taken by our trading partners (at this stage experience with the regulation of crops obtained by NPBTs is very limited globally).

Best regards,

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