Annex 2

EUROPEAN COMMISSION
Directorate-General for Trade

Directorate F - WTO Affairs, OECD and Food-related Sectors
Food-related Sectors

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NOTE FOR THE FILE

Subject: Report on the technical GMO meeting with US delegation – 28 Feb. 2007

Participants:
[redacted] (chair), [redacted], [redacted], [redacted], [redacted] (TRADE), [redacted] (SECGEN), [redacted], [redacted] (ENV), [redacted] (SANCO), [redacted] (Agri).

[redacted] (Chair), [redacted], [redacted] (USTR), [redacted] (USDA-FAS), [redacted] (US Mission)

Scene setting:

The main purpose of the meeting was to hold technical discussions with the US to identify their (economic) interests in the WTO dispute. [redacted] made it clear that in Washington DC people [redacted]. The final decision would depend on the outcome of the meeting. (1)

The concerns of the US were explained as follows: (1) normalisation of trade of biotech ag products, (2) lack of transparency in EU approval system, (3) delays in EFSA assessment (i.e. completeness check period), (4) lack of political will to operate EU approval systems of GMOs (MS opposition), (5) [redacted] (2)

Main products of US economic interests: maize (exports of corn gluten feed, possibly maize as well), cotton, sugar beet (for processed food), maize seeds. The US mentioned their interest not only in product approvals but also in the issue of adventitious presence of unapproved products.

Key issues discussed:

(1) Link between the absence of new authorisations since 2006 Commission orientation debate ([redacted]). (3)

(2) Increasing delays in EFSA to perform the so-called completeness check that according to the US could be connected to the criticisms of EFSA in the context of the orientation debate.

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: CHAR 9/145. Telephone: direct line (32-2) 2965891. Fax: (32-2) 2991046.

E-mail: [redacted]@ec.europa.eu

(3) Delays in risk management process (i.e. period after the release of EFSA scientific assessment and presentation of draft decision to the regulatory committee).

(4) "Zero tolerance and Adventitious presence in the following situations: (1) absolute zero tolerance for non approved GMOs (including those that have been favourably risk assessed by EFSA), (2) discontinued products that have been approved in the EU, (3) discontinued products that have never been approved in the EU.

(5) National measures ([redacted]). The US sought confirmation whether [redacted] (4)

(6) Absence of authorisation for cultivation since 1998 (i.e. in US term, EC continue to maintain a moratorium on approval for cultivation).

Overall, the meeting was constructive from both sides; the US drew up the following "positive" list to be reported back to DC:

- The Commission is determined to lifting national bans; [redacted] (5)

- The new EFSA procedure introduced after the 2006 orientation debate should increase MS confidence in the risk assessment process. If successful, this may decrease opposition to Commission approvals in absence of QMV in reg. committee and in Council.

- First approval in SANCO pipeline can be expected for Sept. 2007.

- The Commission will draw the attention of EFSA to economically important applications [redacted] (6)

- The Commission will approach EFSA to identify the reasons for the alleged increased delays to carry out the completeness checks and where appropriate reflect on possible improvements.

- The increase of EFSA resources should contribute to speed up the risk assessment process. Six opinions are expected by the end of August 2007.

- Zero tolerance for non-approved GMOs is a firm principle [redacted] (7)

- The Commission has drafted measures to address the issue of discontinued products that have been approved under the old EU regulatory system. Commission has consulted stakeholders on the measures (biotech providers, seed association-and traders i.e. COCERAL and FEFAC).

- The Commission is proceeding with applications for authorisations. One application was presented to the regulatory committee in December 2006. New authorisations are expected but there is no projected date.

The US will report on this "positive" list back home and see whether it is worthwhile pursuing the discussion. [redacted] added that it would be useful to have a note from the appropriate level (e.g. concerned Commissioners) confirming in general terms EC's information in order to convince the sceptics in DC.

Overall conclusions and follow-up:

From Commission side, the meeting has been useful to identify [redacted] that the US would possibly use [redacted]. On US side, there seems to be interest in pursuing the dialogue while reserving their right to pursue arbitration on a RPT of the WTO panel report. However, we will need to deliver. The following steps should be considered:

- The US asks for a letter sent at the appropriate level (Commissioners or DGs) confirming the EC's engagement following this first technical meeting.

- The Commission should move forward the two pending hybrids maize for which the risk assessment has been completed last year; the two draft decisions are currently in ISC; they should be presented to a regulatory committee at the earliest opportunity (SANCO indicated that the authorisation could be adopted by [redacted]).

- Although of no interest for the US, the approval of the pending oilseed rape (Ms8xRf3) would be a signal that the orientation debate did not establish a new moratorium.

- On the issue of discontinued products, the Commission should share with the US information on the nature of the measures after the discussion with the MS (on 2nd March).

- Inform the US on the follow-up to the issue of antibiotic resistance marker gene. The Commission (DG SANCO) should consider providing a copy of EMEA opinion to the US for transparency.

[redacted]

Copy: [redacted],
Messrs [redacted] (TRADE),
[redacted] (DC delegation) [redacted] (CAB)