

From: [REDACTED] (SANTE)
Sent: 19 September 2016 18:14
To: [REDACTED] (SANTE)
Subject: FW: 3 ISC on approval of GM maize for cultivation- 2016/01312, 2016/01316, and 2016/01321 on the genetically modified maize Bt11, Mon 810 and 1507.

Follow Up Flag: Follow up
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From: [REDACTED] (SANTE)
Sent: Wednesday, June 15, 2016 3:35 PM
To: [REDACTED] (ENV); [REDACTED] (ENV)
Cc: [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE)
Subject: RE: 3 ISC on approval of GM maize for cultivation- 2016/01312, 2016/01316, and 2016/01321 on the genetically modified maize Bt11, Mon 810 and 1507.
Importance: High

Dear [REDACTED], many thanks for your detailed comments given in CIS.

As discussed over the 'phone, this is to reassure you that EFSA opinions take account of the more recent substantial evidence: EFSA opinions have been updated several times (most recently in 2015), in order to ensure that the environmental risk assessments are fully up to date, based on the most recent publications. These elements are inserted in the relevant recitals of the three Decisions.

Regarding in particular Teosinte, all available information was requested from all possible sources by DG SANTE as soon as we have been informed of the issue (ie this year) and we have already mandated EFSA to assess the impact of the presence of teosinte on the environmental risk assessment conclusions of MON810, Bt11, 1507 and GA21 in the EU by September 2016. This EFSA opinion will therefore be taken into account before the vote of the Committee, which should take place around October or November 2016.

As for the minimum distances with conventional cultivation, we agree with you that it is an important economic component of GMO cultivation, not linked to risk assessment. As explained over the 'phone coexistence has always been seen and accepted as such by all Member States as a subsidiarity issue (also confirmed in Directive 2001/18/EC, which states that Member States may adopt at national level coexistence measures).

The decision for a threshold for adventitious or unavoidable presence of GMO varieties in conventional seeds is by definition a horizontal issue which cannot be addressed in individual authorisation decisions of specific GMO

products. In fact, it can only be done via the regulatory procedure with scrutiny (or delegated act once the GMO legislation is aligned).

We hope the above alleviates your concerns and that you can agree there is no reason for the Commission not to act at this point in time on these pending applications. Thank you for confirming this.

Many thanks

[REDACTED]

PS [REDACTED] and his colleagues kindly contributed to reply recent correspondence on Teosinte and re confirmed the Commission's earlier statements, namely that Teosinte is unlikely to be included in the Union list of invasive alien species, particularly as DG ENV is not aware of any risk assessment in this regard. We suggest you inform us of any potential new development on your side in this regard.