EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Director

Brussels,
SANTE/E3/BMG/gm (2017)7035125

Dear Dr Then,

Subject: Reply to your open letters: market authorisation for genetically engineered soybeans with triple resistance to herbicides

I am writing to you with regard to your letters of 12 and 19 December 2017, with which you provided a final version of your background document related to the GM soybeans FG72 x A5547-127 and DAS-44406-6.

The document contains the same analysis of the data concerning the risk assessment of the GM soybeans FG72 x A5547-127 and DAS-44406-6 that you have submitted previously. The new elements are added references to the toxicity studies related to these soybeans.

As noted in our previous replies of 24 October and 8 December 2017[1], your analysis, based on documents retrieved from EFSA and on literature searches, concerns the risk assessment of these GM soybeans, which falls under the competence of EFSA.

Therefore, it appears to us that the final background document:

1. does not identify any data or evidence which would not have been considered by the EFSA GMO Panel during the respective assessments of the two soybeans applications;

2. refers to scientific publications and comments that were submitted as part of the public consultations on the respective EFSA scientific opinions; they have been assessed by EFSA who already concluded that they do not contain any new scientific elements that would lead the EFSA GMO Panel to reconsider its opinions[2];

---

1 Reference Ares(2017)5191856 and Ares(2017)6030603

2 Soybean DAS-44406-6: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00402 and soybean FG72 x A5547-127: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00439

Dr Christoph Then
Testbiotech
E-mail: christoph.then@testbiotech.org

3. refers also to publications which relate to plant protection products, falling outside the scope of the EU legislation on genetically modified food and feed.

On this basis, the analysis you have submitted does not justify your request not to proceed with the authorisation of these two GM soybeans.

Should you wish to further discuss on the risk assessment, I kindly suggest that you contact EFSA directly.

Yours sincerely,

Sabine Jülicher