The Norwegian Scientific Committee for Food safety (VKM) GMO Panel requests that the applicant provides additional information on the stacked event Soybean MON 87705 x MON 89788.

4. Toxicological assessment

4.2.5. Repeated dose toxicity studies using laboratory animals

The applicant has performed acute toxicity testing separately for the CP4 EPSPS protein. This test was however not performed according to the OECD guideline 401. The exposure doses were 0, 49, 154 or 572 mg/kg which does not fulfill the OECD guideline 401 limit test application (2000 mg/kg bw). This acute toxicity test does not give any further information about possible toxic effects of the stacked event soybean MON 87705 x MON 89788.

The Norwegian GMO Panel requests that the applicant conducts/provides data from additional feeding studies, including a minimum 90 day study according to OECD guideline 408 using rats fed the stacked event Soybean MON 87705 x MON 89788 derived from crops both treated and untreated with Roundup during cultivation.

The Norwegian GMO Panel request that the applicant also performs feeding studies conducted on production animals other than broiler chickens, e.g. *Salmonidae,* to determine potential effects to the health and production quality of animals given feed where the main feed composition is derived from soybean MON 87705 x MON 89788. It is known that soybean products and mainly soybean concentrate (not soybean oil) is an important fish feed ingredient in feed to salmonids, and according to a recent report from one of the leading fish feed producers in Norway (Bærekraftrapporten, Skretting 2011), 150 000 ton soybean concentrate was used as a vegetable protein ingredient in 2011.

The Norwegian GMO Panel requests that the applicant provides data on levels of glyphosate residue in the harvested raw materials of the stacked event Soybean MON 87705 x MON 89788 as well as in the final processed products i.e. soybean meal, oil etc. to be used in food and feed.

3.3. Compositional analysis

The Norwegian GMO Panel strongly suggest that the applicant provides information on sterol levels in the different oil fractions as proposed in OECDs “Revised Consensus Document on Compositional Considerations for New Varieties of soybean[*Glycine max* (L.) Merr]: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens, Aug. 2012”.

Alterations in biochemical composition of cultivated plants may possibly occur in response to pesticide treatment. Thus, one may not exclude that Roundup e.g. may change the composition patterns of proteins, fatty acids or other substances in the plants. In the documentation provided by the applicant it is shown that Soybean MON 87705 x MON 89788 was treated with 0.92 – 1.26 Kg a.e/ha of

Roundup across the reported sites. These levels reside within the normal dosage range when treating soybean crops. The Norwegian GMO Panel suggests that the applicant also provides information on biochemical composition of soybean MON 87705 x MON 89788 plants when treated with the maximum allowed concentrations of Roundup to account for differences in Roundup application practices.

In the dossier it is stated that the levels of daidzein were determined to be “non-equivalent more likely than not”, and that the difference between the MON 87705 × MON 89788 (NT) and reference mean values was 384.88 µg/g dwt, whereas the difference between the control and reference mean values was 398.26 µg/g dwt. It is however not mentioned, neither in text or table(s) in which plants these differences are elevated for daidzein. The Norwegian GMO Panel requests that this is clarified by the applicant. ǁ

Part II, Table 8. Page 64 of the Dossier. Seed Fatty Acids (% Total FA)

The Norwegian GMO Panel requests that the values of Table 8, page 64 be clarified; in several of the columns the numbers do not add up to a 100%. In addition, the values for MON 89788 are given as percentage of dry weight, which makes it impossible to compare the single event against the stacked event. The results presented are difficult to interpret and needs to be clarified by the applicant.

Since large quantities of soybean concentrate is used as a vegetable protein ingredient in animal feed (e.g. fish feed) in Norway, The Norwegian GMO Panel requests that the applicant provides detailed information on the nutrient/anti-nutrient composition of soybean concentrate from the stacked event MON 87705 × MON 89788.