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Ms Maria Carrascosa, Red de Semillas

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**Ms Isabel López, PALT-Plataforma Andalucía
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Ms Hellen Wallace, GeneWatch UK

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Dear Ms Carrascosa, Dear Ms López, Dear Mr Then, Dear Ms Wallace,

Thank you for your letter dated 15 July 2016 on the authorisation of 3 genetically modified soybeans and teosintes.

Pesticides residues in food and feed are subject to a legal regime distinct from that of GM food and feed authorisations, and the assessment of the effects on health of pesticide residues is not a condition for the authorisation of GM food and feed under Regulation (EC) No 1829/2003.

The three GM soybeans applications have been positively assessed by EFSA, and no safety concerns as regards potential effects on human and animal health and the environment have been identified. Therefore, in line with Regulation (EC) No 1829/2003 and following the no opinion vote in the Standing and Appeal committees, on 22 July 2016 the Commission adopted the authorisation decisions for soybeans FG 72, MON 88708 x MON89788 and MON 87705 x MON 89788¹.

¹ OJ L 199, 26.07.2016

Food and feed to be placed on the market in the EU have to comply with all MRLs set under Regulation (EC) No 396/2005, not only for glyphosate, but also for isoxaflutole, dicamba and any other substance in the scope of that Regulation. Residue levels up to the MRL are safe for consumers.

Regarding glyphosate, on 11th July 2016, a qualified majority of Member States in the Standing Committee on Plants, Animals, Food and Feed voted in favour of a proposal by the Commission to amend the approval conditions of glyphosate. These conditions include a ban of the co-formulant POE-tallowamine from glyphosate-based products. In more general terms, the Commission, together with Member States experts and EFSA, has begun work on the identification of unacceptable co-formulants used in plant protection products, in order to further increase the protection of public health.

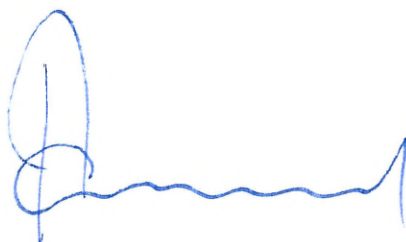
EFSA has recently published its Conclusion on the pesticides peer review of the active substance isoxaflutole². The Commission is currently analysing the outcome of that assessment and will in due course present a proposal to the Member States concerning the renewal of the approval of this active substance. If appropriate, the Commission may also propose an amendment of the MRLs in place for isoxaflutole. I seek your kind understanding that I cannot comment further at this point in time, as the Commission is in the process of establishing its position.

It is true that the legislation requires cumulative and synergistic effects of pesticide residues to be considered in the MRL setting, but only when the methods for assessment will be available. This is not yet the case and the legislation recognises that further work in this respect is needed. The Commission is working with the Member States, EFSA and other scientists to develop such a methodology for cumulative risk assessment. This is a very complex area of work which requires more time. I would like to emphasize that this issue is not specific to GM crops but pertains to all uses of PPPs, as it may also be necessary in conventional agriculture to treat a crop with PPPs containing different active substances, either as a result of pest pressure from different organisms or to manage possible resistance.

² EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance isoxaflutole. EFSA Journal 2016;14(3):4416, 115 pp. doi:10.2903/j.efsa.2016.4416

Regarding the occurrence of teosintes in Spain, as you mention in your letter, the Commission has mandated EFSA to assess whether, on the basis of the elements provided by the Spanish authorities, the existing scientific literature and any other relevant information, new evidence emerges which would affect the conclusions and recommendations of the EFSA opinions on cultivation of genetically modified maize. The Commission will assess the need for a possible follow-up in the light of the EFSA opinion, which is expected by the end September 2016, and in line with the EU legislation.

Yours sincerely,

A handwritten signature in blue ink, consisting of a large, stylized initial 'A' followed by a long, wavy horizontal line that ends in a small upward stroke.