From: [redacted] (EVIRA) <[redacted]@evira.fi>
Sent: 27 September 2018 11:47
To: [redacted] (SANTE); SANTE CONSULT-E3
Cc: [redacted] (EVIRA); [redacted]@mmm.fi'
Subject: Answers of Finland to the Commission's questions

Dear [redacted] and others,

Please find below the answers of Finland to the Commission's questions raised up at the last PAFF GMFF meeting on 11 September 2018.

GM field trials in Finland

Currently there is one field plant trial with hybrid aspen ongoing. The trees are conventional transgenic GMOs. All the currently ongoing clinical trials with GMMs have been considered as contained use, not deliberate release, and the organisms used in the clinical trials have all been conventional transgenic GMOs. The CA has made two decisions on field trials with organisms modified with new mutagenesis techniques, one considering oilseed rape and another one on Arabidopsis thaliana. In both cases the Board decided, on the basis of expert opinions that the field trials are out of scope of the Gene Technology Act. The field trial with Arabidopsis was never performed. According to the information received from the operator, the field trial with ALS herbicide tolerant spring oilseed rape was performed only with plant lines in which was the tolerance was conferred by mutations arising through spontaneous somaclonal variation and traditional chemical mutagenesis techniques. To our knowledge no transgenic or gene edited cultivars have been in DUS or VCU tests; however, information of the breeding technique is only required about the GMO status of the cultivar and not specifically which mutagenesis method was used.

Potential products produced by mutagenesis on the market

- *human and veterinary medicines (e.g. vaccines and gene therapy products) and diagnostic products*
- *plant, animal and human cell lines and tissue cultures for research, development and diagnostic purposes*
- *microbial and algal strains for research, development or production purposes*
- *human, animal and plant pathogens for research and diagnostics*
- *industrial strains for e.g. food, beverage, medicine, enzyme, vitamin or biofuel production*
- *food and ornamental plants and trees with*
    - *heat and insect tolerance*
    - *disease and herbicide resistance*
    - *reduced nitrogen use*
    - *flavor constituents*
    - *altered colour or oil composition*
    - *lignin or cellulose production*
    - *altered phenotype*
    - *reduced toxicity or allergenicity*
    - *altered reproductive traits (e.g. male or female sterility)*
    - *rapid growth*
- *animals*
    - *test animals (mice, rats, dogs, fish, amphibians, Drosophila, Caenorhabditis, etc.)*
    - *production animals: e.g. non-horned dairy cattle, pigs (tailless, disease resistance), poultry (selective female chickens, eggs for efficient vaccine production, disease resistance)*

- *fish for food or ornamental purposes (e.g. rapid growth, alte ed phenotype, disease resistance, reproduc ive traits)*
- *pet anim ls such as dogs, cats and birds with altered phenotype or disease resistance*

Controlling i nported pro lucts for new breeding techniques

The Customs supervises p oducts according to an annual plan. P oducts prod ced with mutagenesis will be included in t e annual G 1O supervision plan. At the moment methods for th detection of GMOs produced with new breedin techniques are not available. We are waiting for the commissi n to publish suitable methods.

Could the si nplified appr val procedure according to the directive (Article 1) be used to the mutagenesis techniques?

Article 16 co ld be useful if it can be used to for a broad range o products, b t it would not solve the technical problems wi h the detection and supervision of certain mutagen zed product . In the long run, when the number of gene edit d products i creases globally, Article 16 may not serve as an efficient solution for all the legal problems.

Other comments

Reliable met hodology for the detection of products modified with novel mutagenesis methods is absolutely required to ensure legal certainty. This is especially crucial for organisms wit point and deletion mutations, which may be challenging to tell apart from any natural counterparts. Also, a constantly updated listing of products on he market o tside EU is essential to focus the supe vision on relevant products. Estimates are needed about the amoun of additional supervision resources needed annual y to ensure sufficient supervision capacity within EU. A certificate describing which breeding method was used in the development of a particular animal, plan or microbia strain could help supervision, but it w uld also constitute a substantial administrative burden in th various production chains.

Best regards,

[redacted]

Please note that this e-mail address is not functional after this day. My new e-mail address from 1 October ongoing is [redacted] mmm.fi.

[redacted]

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RUOKAVIRASTO
Livsmedelsverket • Finnish Food Authority

Elintarviketurvallisuusvirasto, Maaseutuvirasto ja osa Maanmittauslaitoksen tietotekniikan palvelukeskusta ovat **1.1.2019 Ruokavirasto**.

Livsmedelssäkerhetsverket, Landsbygdsverket och en del av Lantmäteriverkets central för ICT-tjänster går samman till **Livsmedelsverket 1.1.2019**.

The Finnish Food Safety Authority Evira, the Finnish Agency for Rural Affairs and a part of the National Land Survey of Finland's Centre for ICT Services become **the Finnish Food Authority on 1 January 2019.**