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Reykjavík October 19, 2018
Reference: ANR18100154/12.08

Subject: Comments of the Icelandic Government on the opinion of the EFSA CONTAM panel regarding risk for animal and human health related to the presence of dioxins and dioxin-like PCBs in feed and food, as adopted 14th June 2018.

The Icelandic Government welcomes the new EFSA CONTAM panel opinion on PCDD/Fs and DL-PCBs. However, there are several aspects regarding the established Tolerably Weekly Intake (TWI) for humans of 2 pg TEQ/kg bw/week that may require some further clarifications. Following are some general and more specific comments regarding the adopted opinion, its publication and possible use for regulatory purposes at a later stage.

The main concern is that the new TWI may have unfavourable consequences on seafood consumption. Consequently, the Icelandic Government raises the question on how this opinion will be communicated and/or later used for regulatory purposes for setting maximum limits for PCDD/Fs and DL-PCB in food. The industrially related exposure data may not reflect the exposure via food nor includes beneficial aspects of e.g. fish consumption.

The opinion lacks in-depth discussion on the pros and cons of seafood consumption, e.g. some intervention studies have shown beneficial effects of fish oil supplementation on semen quality, which highlights the need for a risk benefit approach (V. Esmacili et al., *Andrology*, 2015, 3 450-461).

In summary, although the scientific robustness of the opinion is acknowledged, it is important prior to communication and application of this opinion, e.g. as a basis for amendments in existing legislations or dietary recommendations, that a risk benefit study regarding seafood consumption is included and that the risk communication is harmonised.

For further clarification, some specific comments are listed below:

- According to the studies selected for critical effect, causable effect is seen between TCDD and impaired semen quality. It is difficult to evaluate these studies as no references are given in the short summary, but if the studies used for deriving the HBGV were by Mínguez-Alarcón et al. (2017), Mocarelli et al. (2008) and Mocarelli et al. (2011), the Mínguez-Alarcón study shows that effect appears to be primarily driven by TCDD only, slightly for PCDD (likely linked to TCDD), but not for PCDF. The same seems to be the case

for the two Mocarelli studies.

- The health-based guidance values (HBGV) calculated from these three studies for PCDD/Fs and DL-PCBs are based only on TCDD, where no association was found for other PCDD/Fs or DL-PCBs and exposure via food is not only TCDD, but a mixture of PCDD/Fs and DL-PCBs. As stated in the confidential summary, the main contributor to the current intake of PCDD/Fs and DL-PCBs is CB-126, which appears to be less potent in humans than suggested by the WHO₂₀₀₅-TEF. This highlights the need for reviewing the TEF-system. Therefore, care should be taken prior to revising existing maximum limits and recommendations for e.g. seafood consumption.

In line with our arguments the opinion acknowledges that:

- The TCDD levels seen in these studies, even in the lowest quartile, the serum levels of TCDD were high compared to present-day levels in humans in Europe.
- There is a need for risk-benefit evaluations of e.g. fish consumption related to PCDD/F exposure.

There is a need for prospective developmental epidemiological studies on PCDD/Fs and DL-PCBs at a low to moderate dose, representing general population and exposure via food.

For further information, please contact:

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On behalf of the Minister of Fisheries and Agriculture

[signed]

Stefán Ásmundsson
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[signed]

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