Background

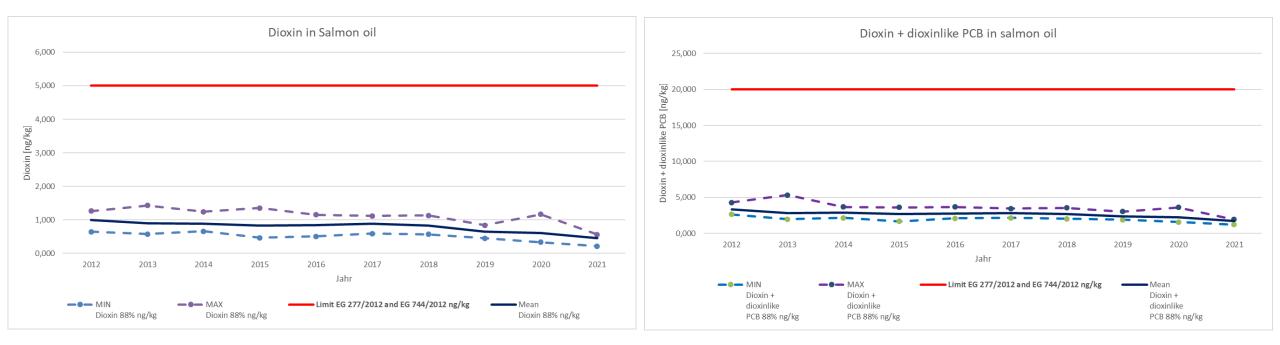
- Bioceval GmbH is an EC approved fishmeal factory located at Cuxhaven (Northern Germany), which uses by-products from farmed salmon (Salmo salar) sampled at EC approved fish processors in order to produce a crude salmon oil (and salmon fishmeal) in feed grade quality.





Feed Safety

- Beside other analyses on feed quality and potential risks (pesticides, heavy metals etc.), the crude salmon oil is regularly analysed on dioxin and the sum of dioxins and dioxin-like PCB.



- In the 356 analyses carried out since 2012, all analyses have been well below the limits set in European regulations.

- The causal explanation for the much lower concentration in farmed fish (like Atlantic Salmon) compared to the often high contamination in fish from capture fishery is, that wild fish take up dioxins and dioxin-like PCB via the natural food chain. Farmed fish, in contrast, is fed with regulated and controlled aquafeed, which has very low concentrations of dioxin and dioxin-like PCB.

Current legislation in the European Community concerning crude fish oil used as feedstuff

- Limits are set in regulations (EC) 277/2012 and 744/2012 concerning maximum contents of dioxins, dioxin-like PCB and indicator PCB.

- Frequency and scale of fish oil analyses on dioxins are defined in regulation (EC) 183/2005 (incl. updates in EC 2015/1905).

According to annex II, section "DIOXIN MONITORING FOR OILS, FATS AND DERIVED PRODUCTS", point 2c an analysis on dioxin has to be done:

(c) Feed business operators producing fish oil:

(i) 100 % of the batches of fish oil if it is produced from:

- products derived from fish oil other than refined fish oil;
- fisheries with no monitoring history, of unspecified origin or from the Baltic Sea;
- fish by-products from establishments manufacturing fish for human consumption that are not EU approved;

- blue whiting or menhaden;

(ii) 100 % of the outgoing batches of products derived from fish oil other than refined fish oil;

(iii) one representative analysis per 2 000 tons as regards fish oil not referred to in (i);

(iv) fish oil decontaminated by an officially approved treatment as referred to in Annex VIII of Regulation (EC) No 767/2009 and in Commission Regulation (EU) 2015/786 (***)

shall be analysed and documented as part of the HACCP system.

Interpretation of Bioceval regarding salmon oil: (c) (iii) with one representative analysis per 2000 tons

Interpretation of Veterinarian Authorities and private certifiers (e.g. GMP-plus): (c) (ii) with analysis for each batch produced

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- blue whiting or menhaden;

(ii) 100 % of the outgoing batches of products derived from fish oil other than refined fish oil;

(iii) one representative analysis per 2 000 tons as regards fish oil not referred to in (i) or fish oil exclusively produced from aquaculture fish;

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Conclusion

- Because of the demands of authorities and because salmon oil batches produced from by-products are comparatively small (90-150 t), more than 350 analyses had to be done since 2012 at external, certified labs – with 300 € costs per analysis this sums up to >100.000 € and requires additional storage capacities due to the time delay caused by transportation and analysis of the oil samples.

- Our risk assessment suggests that the present sequence of each batch being analysed is not justified but can considerably be reduced without increasing any risk for feed safety.

- In September 2019 a letter was sent to the European Commission asking for clarification in regulation (EC) 183/2005 concerning the frequency of dioxin analyses for fish oil and to exclude fish oil exclusively produced from farmed fish from the 100% analysis obligation.

Up to now (March 2021) no information is available about any activity by EC authorities in reaction to our letter. This is regrettable not only for Bioceval, but also for the various companies which produce feed materials from by-products of the more than one million tons products from aquafarming in Europe. Obviously some reminder and support is needed in order to ..

modify the relevant EC regulation 183/2005 in a way that it becomes clear that fish oil derived from farmed fish does not fall into the group of fish oil for which a 100% analysis on dioxin / dioxin-like PCB is needed.

This would allow to invest the resources (time and money) into other project to optimize feed safety and to reduce risks from other unwarranted substances.