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## ETHOXYQUIN as anti-oxidant in fish feeds - FACTSHEET

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### Introduction

Concerns have been expressed in different media on the presence in farmed fish of residues of the antioxidant ethoxyquin (E324), due to its use as a feed additive in animal feeds, and raising the possibility of detrimental effects on human health through consumption of such fish. This fact sheet aims to clarify the position of the use of ethoxyquin in animal nutrition and the effects of ethoxyquin in feeds.

### What is ethoxyquin?

Ethoxyquin is a quinoline-based antioxidant. Antioxidants are commonly used in the feed and food sectors to protect raw materials and final products against oxidation and rancidity. Examples of uses are for the protection of oil and fat products, as well as vitamins and carotenoids so as to avoid nutrient decay and their deficiencies in feeds.

### Why use ethoxyquin in feed?

The benefits of consistent nutrient quality in feed span the processing and handling of feedstuffs and all facets of animal production. Antioxidants prevent the losses of essential nutrients through oxidation in stored, mixed feeds that are also used in the farming of fish. Without the use of antioxidants, important nutrient resources become much less efficient in providing for animal dietary requirements. Fish meal and fish oil, used especially in fish feed manufacture, are very rich in highly unsaturated fatty acids including EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid), which are known to promote health in animals and humans. These materials are highly sensitive to oxidation and, thus, require protection. In addition, products of the oxidation of certain nutrients are known to present safety concerns.

It is a legal requirement of the International Maritime Organisation (IMO) to add an anti-oxidant to fishmeal - prior to shipping – to ensure safe transportation and storage of this raw material. The addition of an effective antioxidant to fishmeal, such as ethoxyquin, aims indeed to prevent the spontaneous combustion of fishmeal during shipping and storage.

The Food and Agriculture Organisation (FAO) of the United Nations published a list of “*commonly-used chemical preservatives generally recognized as safe*”<sup>1</sup>, including ethoxyquin, for use in compound feeds. According to the FAO, ethoxyquin has been demonstrated to be the most efficacious antioxidant, followed closely by BHT (E321) and BHA (E320)<sup>2</sup>.

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<sup>1</sup> <http://www.fao.org/docrep/x5738e/x5738e0b.htm>

<sup>2</sup> Butylated hydroxyanisole (BHA) and the related compound butylated hydroxytoluene (BHT) are phenolic compounds that are often added to foods to preserve fats.

## Are there alternatives to ethoxyquin?

The IMO and United Nations (UN) Model Regulations for the Transport of Dangerous Goods require that fishmeal shipped under Group B must be dosed with the following concentrations of antioxidant at the time of production:

- between 400 and 1,000 mg/kg (ppm) ethoxyquin, or
- between 1,000 and 4,000 mg/kg (ppm) butylated hydroxy toluene (BHT)

The fishmeal shipping rules are therefore restrictive towards the type of antioxidant as well as its dosage concentration. To allow for the use of alternative antioxidants or blends with other dosage levels, the UN needs to include these options into their Model Regulations which, in turn, will be adopted by the IMO. The Marine Ingredients Organisation (IFFO) is in the process of co-ordinating trials to investigate alternative antioxidant blends and reduced concentrations of ethoxyquin with the full support and encouragement by the United Nations Committee of Experts on the Transport of Dangerous Goods. It is imperative that alternative antioxidants are effective for safety reasons which will also have the benefit of low dosing levels of additive.

## EU legislative framework for ethoxyquin in feed

In the European Union (EU), ethoxyquin (E324) has been authorised as a feed additive (antioxidant) since 1970 under the former feed additive legislative regime (Directive 70/524/EEC<sup>3</sup>) for all animal species with a limitation on the quantity to be used in complete feed. The upper limit for ethoxyquin and other antioxidants (BHA and BHT) is 150mg per kg of complete feed for food producing animals.

As an authorised additive, ethoxyquin is subject to the re-authorisation procedure set in Regulation (EC) No 1831/2003<sup>4</sup>. The European Commission, assisted by representatives of EU Member States gathered in the Standing Committee on Plants, Animals, Food and Feed, will base their decision on whether to authorise ethoxyquin on an opinion from the European Food safety Authority. EFSA is the authority in charge of the risk assessment of any feed additive in the EU and is currently in the process of assessing ethoxyquin and its metabolites for their safety. The anticipated EFSA opinion will detail if any change is required for the continued safe use of ethoxyquin in the future. During the assessment, safety for target animals, humans (workers and consumers) and environment is examined.

### **Status of assessment by EFSA**

After a technical hearing with the EFSA and the European Commission in November 2014, the applicant (FEFANA-ANTOXIAC) proposed a roadmap to the authorities, including a calendar, to generate the data necessary for a complete assessment of the product. In January 2015, the applicant received a request for additional information from EFSA where the most urgent items were identified. The generated data were submitted by the applicant to the EFSA and to the European Commission at the end of June 2015. In the meantime, the applicant is performing one further study that will be submitted during the second half of 2015. Based on the available data provided, it is anticipated that EFSA will issue a first scientific opinion on ethoxyquin before the end of October 2015. After the publication of the EFSA opinion, it is expected that the European Commission and the Member States will start discussion on ethoxyquin without delay and, if necessary, decide on any management measures to be taken regarding its authorisation. This discussion will most probably take into account the timeline to generate, during the coming years, the information necessary to perform a complete assessment, as indicated in the full roadmap.

<sup>3</sup> Council Directive of 23 November 1970 concerning additives in feeding-stuffs (70/524/EEC).

<sup>4</sup> Regulation (EC) N° 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.

## Ethoxyquin in food products

Feeding trials on animals have shown that, in some instances, minimal levels of ethoxyquin and its metabolites are transferred from the feed to animal products.

For example, in a scientific study made by the NIFES<sup>5</sup> (the National Institute of Nutrition and Seafood Research, Norway), the highest concentration of ethoxyquin in salmon fillets was found to be 0.2 mg/kg while the average values in any individual year between 2005-2009 ranged between 0.02-0.04 mg/kg.

In the EU, there are no Maximum Residue Limits (MRLs) for ethoxyquin in respect of fish and fishery products or for other food of animal origin. However, based on the results of the re-evaluation of ethoxyquin as a feed additive by the EFSA, MRLs might be established in animal products for the EU. Some countries outside the EU have introduced MRLs for ethoxyquin, which vary with the type of food and the country concerned. For example, the USA has adopted 0.5 mg/kg for meat and eggs, 3 mg/kg for chicken liver and 5 mg/kg for fat. In Japan, a MRL of 1.0 mg/kg is set for fish. The values found by NIFES are lower than the MRLs set for food products in the USA and Japan.

CODEX FAO/WHO has set Acceptable Daily Intake (ADI) levels for ethoxyquin and its metabolites at 0.005 mg/kg body weight and an Acute Reference Dose (ARfD) at 0.5 mg/kg body weight. Analysis of ethoxyquin levels in farmed fish species (including cod, salmon, halibut and trout) has shown that consuming fish with these levels of ethoxyquin contributes as little as 4% and up to 15% of the ADI of ethoxyquin on the daily consumption of a 300 g portion of fish.

## Conclusions

The EU authorities regularly monitor the use and safety of all feed additives to ensure safety of the feed chain. Ethoxyquin has been authorised as a feed additive at the EU level since 1970. It is undergoing a re-evaluation by EFSA, where a first opinion is expected by the end of October 2015.

There is no Maximum Residue Level set for residues of ethoxyquin in animal products that could result from a transfer from feed to animals. Such a MRL might be set in the light of the EFSA re-evaluation.

The amounts of ethoxyquin & metabolites that are consumed by eating farmed fish are at least 6 times lower compared to the international standard for the safety of food products, i.e. the Acceptable Daily Intake set by CODEX.

EU authorities will decide, once the EFSA opinion is available, what level of safety is appropriate for EU consumers and, in this respect, whether or not to maintain the authorisation of ethoxyquin as a feed additive and under what conditions.

Operators of the feed supply chain support all efforts to ascertain further information on the permitted level of ethoxyquin in complete feed. The feed industry ensures that at all times ethoxyquin is used responsibly and that the levels of the antioxidant do not exceed the legal limits currently set in the EU.

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<sup>5</sup> <http://nifes.no/en/ethoxyquin-in-fish-feed/>