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# **Risk Assessment of the Use of XyRex® Formulations on Fish Used for Production of Fish Meal to Fish and Animal Feed: Effects on Animal Health, Human Health and the Environment**

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## **Authors' contributions**

*This work was carried out in collaboration among all authors. The opinion has been assessed and approved by the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of VKM. All authors read and approved the final manuscript.*

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## **ABSTRACT**

The XyRex® formulations are antimicrobial agents with sodium chlorite as the active substance. The Norwegian Food Safety Authority has received a request to authorise XyRex® formulations for use in refrigerated sea-water (RSW) tanks on board fishing vessels for pelagic fish caught for production of fish meal/fish oil for use in animal feed. The use of XyRex® formulations on fish for human consumption is not approved in Norway.

It is a premise that use of food processing aids should not pose a threat to health of humans or animals. The XyRex®-containing RSW will not be completely drained off before the production of fish meal/fish oil. The Norwegian Food Safety Authority has therefore requested The Norwegian Scientific Committee for Food Safety (VKM), Panel on Animal Feed, to assess the safety to humans and animals with regard to the use of XyRex® formulations with 12.5 ppm sodium chlorite, as recommended by the producer, in RSW on board fishing vessels for pelagic fish. The Norwegian Scientific Committee for Food Safety appointed an ad hoc group to answer the request from the Norwegian Food Safety Authority. The report from the ad hoc group has been discussed and approved by VKM's Scientific Panel on Animal Feed.

The use of the XyRex® formulations will mainly result in the release of sodium chlorite and sodium chlorate, which therefore are the components in the XyRex® formulations that may cause concerns for health risks. The amounts of these substances formed and transferred with the fish to the fish meal, fish meal-containing feed, and ultimately to the fish, meats, milk and eggs from animals eating the fish meal, are not known. Therefore, this evaluation is based on a worst-case scenario of transfer of the maximum amounts of these residues from the XyRex®-formulations, and the available information on theoretical transfer in each step from the RSW tanks on board fishing vessels into fish and animal feed and human foods.

The estimated exposures of farmed fish and domestic animals to sodium chlorite and sodium chlorate in their fish meal-containing feed are all below the tolerable daily intake (TDI) value of 30 µg/kg body weight (bw)/day, set for both sodium chlorite and sodium chlorate. Therefore, no adverse effects on fish or animal health would be expected by exposure to sodium chlorite and sodium chlorate from the use of XyRex® formulations in RSW on board the fishing vessels catching fish being used for fish meal being included in fish and animal feed.

The intakes of sodium chlorite and sodium chlorate for humans from consumption of farmed fish or domestic animals being fed on fish meal from XyRex®-treated fish were estimated assuming the worst-case scenario that all the sodium chlorite and sodium chlorate the fish and animals were exposed to were accumulating in their meats, or transferred to milk and eggs. These estimated average and high exposures to farmed salmon, pork, beef, chicken, turkey, milk and eggs are well below the TDI values for both sodium chlorite and sodium chlorate of 30 µg/kg bw/day. In reality, a significant amount of the sodium chlorite in the XyRex® formulations will be depleted during the disinfection process and not end up in the fish meal and thereafter in the feed, and both sodium chlorite and sodium chlorate will to a large extent be excreted rather than accumulated in the meats of fish and animals, or in milk and eggs. Therefore, the real exposure values are likely to be lower than the values estimated here.

The likelihood of by-product formation from the specified use of XyRex® formulations has also been addressed. Because the temperatures used for cooking and drying during fish meal production are well below the temperatures where dioxins and furans are formed, the formation of these substances during production is unlikely. Also, since the amounts of chlorine compounds present with the fish are low, we regard any significant health risks from chlorination by-products to be unlikely. However, further data might be needed to confirm that chlorinated compounds are not generated to a significant extent from the use of XyRex® formulations. Based on the available data on reactions of acidified sodium chlorite (ASC) and chlorine dioxide with proteins and lipids in poultry carcasses or fish, a significant formation of harmful, i.e. mutagenic, by-products from the use of the XyRex® formulations on fish is not expected. A negative effect on the quality of the fish oil, if substantial oxidation is taking place, can not be ruled out.

Release of RSW in harbour areas is forbidden by law in Norway. The concentrations of sodium chloride and sodium chlorate in RSW being released from the fishing vessels to open sea during transport will rapidly be diluted around the release point, and are therefore not likely to have any adverse effects. The specified use of XyRex® formulations in RSW tanks on board fishing vessels is therefore not expected to be of significant environmental concern.

The Panel on Animal feed has not evaluated the disinfecting activity claimed for the XyRex® products, nor any potential for development of bacterial resistance after use of the

XyRex® products, since these questions were not asked by the Norwegian Food Safety Authority.

*Keywords:* The Norwegian Scientific Committee for Food Safety; the VKM; XyRex.

Available:<https://vkm.no/download/18.645b840415d03a2fe8f11eff/1501078502180/47f018e0c2.pdf>

**NOTE:**

This work was carried out in collaboration between all authors. The opinion has been assessed and approved by the Opinion of the Panel on Animal Feed of the Norwegian Scientific Committee for Food Safety (VKM). All authors read and approved the final manuscript.

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**COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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