

STATEMENT

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Assessment of the potential integration of the DNA plasmid vaccine CLYNAV into the salmon genome

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Abstract

The European Commission mandated EFSA to review a new data package provided by the company Elanco, for the possible integration/non-integration of the DNA plasmid vaccine CLYNAV into the genome of Atlantic salmon (*Salmo salar*) and to indicate whether EFSA agrees with the conclusions drawn by Elanco. The vaccine is injected into fish to confer protection against pancreas disease caused by the salmonid alphavirus. The majority of the experimental data provided by the company was for muscle tissue close to the injection site and for gonadal tissue. EFSA considers that the long persistence of DNA plasmid in muscle tissue close to the injection site and the potential heritability of an integration event in gonad cells support the focus of the assessment on both these tissues. The experimental data did not provide scientifically robust evidence for a true integration event. The company overall concluded that the likelihood of integration is negligible, based on considerations in the context of the company's environmental risk assessment, but did not provide a quantitative value for the rate of integration linked to the term 'negligible'. It is therefore not possible to evaluate this statement specifically with regard to integration rates. EFSA notes that knowledge about homologous and non-homologous integration predicts that integration could occur with certain frequency. Therefore, EFSA has constructed worst-case scenarios leading to upper estimates for possible integration rates of the DNA plasmid vaccine into the Atlantic salmon genome. EFSA concludes that, based on the worst-case scenarios described here and taking into account additional factors decreasing the likelihood of integration, the actual integration rate is likely to be orders of magnitude lower than the upper estimated integration rate calculated in the context of the worst-case scenarios. With the available evidence, the actual integration rate cannot be estimated with more precision.

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Keywords: CLYNAV, DNA plasmid vaccine, farmed Atlantic salmon, *Salmo salar*, plasmid integration, genomic DNA, genetically modified organism, salmonid alphavirus/pancreas disease

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