NORTH ATLANTIC SALMON CONSERVATION ORGANIZATION

ORGANISATION POUR LA CONSERVATION DU SAUMON DE L'ATLANTIQUE NORD

Council

CNL(02)49

Update on Transgenic Salmon
(tabled by the USA)

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Update on Transgenic Salmon (tabled by the USA)

The US Food and Drug Administration (US FDA) and Aqua Bounty Farms have approached the National Marine Fisheries Service, U.S. Fish and Wildlife Service and Canadian regulatory agencies to share information preparatory to designing an environmental risk assessment of transgenic salmon. Topics of relevance include the regulatory context, risk management in the regulation of transgenic plants, risks presented by salmon cultivation, changes induced by genetic modification, and risk mitigation and management.

The US FDA has determined that it will regulate transgenic fish as a new animal drug. A drug is defined as any articles intended to affect the structure and function of an animal. The approval process for a new animal drug is rigorous and includes a review of the environmental safety of the drug, its mechanisms of use and its disposal. The US FDA has further determined that an Environmental Assessment (EA) under the National Environmental Policy Act (NEPA) is required. The EA will include an assessment of the potential risks to wild populations of Atlantic salmon, related species, other non-target animals and the habitat and resources on which the species depend. The EA process is currently at the problem formulation stage where all of the issues and concerns that need to be addressed within the EA are identified. Conducting the risk analysis for the EA is expected to take at least one year.

The National Marine Fisheries Service and US Fish and Wildlife Service will remain involved in this process with the US FDA and the applicant to ensure that concerns for wild populations are adequately identified and addressed, including conducting the appropriate section 7 consultation under the ESA. The US has made the FDA aware of the action NASCO has taken on transgenic salmon and the US FDA was also notified separately by the NASCO Secretariat.