### EPA Region 10 NPDES Permitting Section Comments on Washington Department of Ecology's Upland Finfish Hatching and Rearing General Permit:

## 5/26/2021

EPA Region 10 NPDES Permitting Section recommends that Ecology amend the following permit and fact sheet provisions to clarify that to be authorized in discharge, Investigational New Animal Drugs (INADs) must be labeled correctly, used in accordance with U.S. FDA and U.S. FWS regulations and protocols, and be used in a consistent manner with Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulations. This NPDES general permit cannot be used to authorize use of pesticides in a manner inconsistent with FIFRA regulations. Broadly speaking, an NPDES permit cannot be used to authorize something that is otherwise illegal under other federal regulations. The permit and fact sheet should be revised accordingly. We recommend amending language as follows:

#### Permit Comments:

### P17 H.5. –

[...] and/or the EPA for hatchery use, or approved as an Investigational New Animal Drug (INAD) <u>that is</u> <u>labeled correctly, used in accordance with established protocols, and that does not violate FIFRA.</u> (see S6.B).

### S6.B. –

[...] Permittees may use USFDA approved Investigational New Animal Drugs (INADs) provided the facility <u>a) is signed up as an INAD study participant through USFWS; b)</u> meets the conditions detailed in the facility's INAD permit application; <u>c) uses INADs that are labeled correctly and do not violate FIFRA; c)</u> and reports the use on the Disease Control Chemical Use Form required in S5.C.1 (Disease Control and Chemical Use Annual Reporting).

### Appendix G -

[...] At production aquaculture facilities, it is illegal to use any drug that is not approved unless it is being used under the strict conditions of INAD protocols or an extra-label prescription issued by a licensed veterinarian. <u>Permittees may use USFDA approved Investigational New Animal Drugs (INADs) provided the facility a) is signed up as an INAD study participant through USFWS; b) meets the conditions detailed in the facility's INAD permit application; c) uses INADs that are labeled correctly and do not violate <u>FIFRA; c) and reports the use on the Disease Control Chemical Use Form required in S5.C.1 (Disease Control and Chemical Use Annual Reporting).</u></u>

### Appendix G -

The link to the INAD list is not active. This link may be what you intended: https://www.fws.gov/fisheries/aadap/inads.html

# Fact Sheet Comments:

P 11 – Pollutants of Concern –

[...] Permittees may use USFDA approved Investigational New Animal Drugs (INADs) provided the facility <u>a) is signed up as an INAD study participant through USFWS; b)</u> meets the conditions detailed in the facility's INAD permit application; <u>c) uses INADs that are labeled correctly and do not violate FIFRA; c)</u> and reports the use on the Disease Control Chemical Use Form.

## P 11 – Pollutants of Concern –

EPA recommends that Ecology clarify that 'Diquat' – listed under external controls – <u>must be labeled</u> <u>correctly and that the NPDES permit cannot be used to authorize use of pesticides in a manner</u> <u>inconsistent with FIFRA labeling.</u>

## P 17 – Technology based effluent limits

Disease control chemicals must be used in accordance with label instructions, and approved by USFDA or USEPA or under an INAD. <u>Permittees may use USFDA approved Investigational New Animal Drugs</u> (INADs) provided the facility a) is signed up as an INAD study participant through USFWS; b) meets the conditions detailed in the facility's INAD permit application; c) uses INADs that are labeled correctly and do not violate FIFRA; c) and reports the use on the Disease Control Chemical Use Form. WDFW has jurisdiction over fish pathogens, treatment, and aquaculture disease control.