

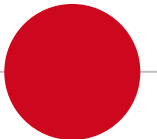
Efficacy and Safety of DNA vaccine against Viral Hemorrhagic Septicemia and Infectious Hematopoietic Necrosis in rainbow trout: preliminary results from the field trial

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2019 VHS and IHN epidemiology in Italy

With 37,000 metric tonnes produced in 2019, Rainbow trout is the main finfish species aquacultured in Italy

- 538 sites farming susceptible species to VHS or IHN
- 195 VHS free farms (+ 7 under surveillance) and 16 infected
- 190 IHN free farms (+ 7 under surveillance) and 14 infected
- 1 outbreak of VHS and 1 of IHN in 2019
- 1 new outbreak of VHS in 2020

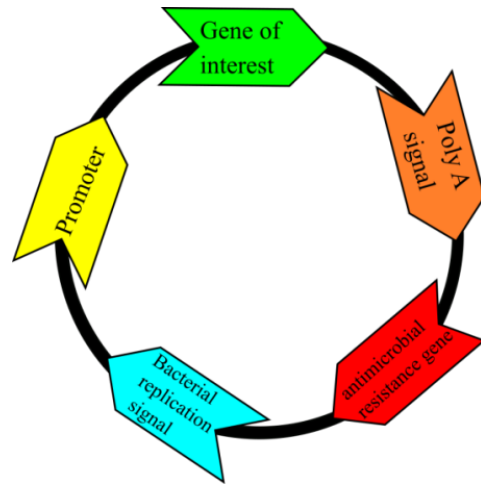


● Vaccination against VHS and IHN: EU regulation

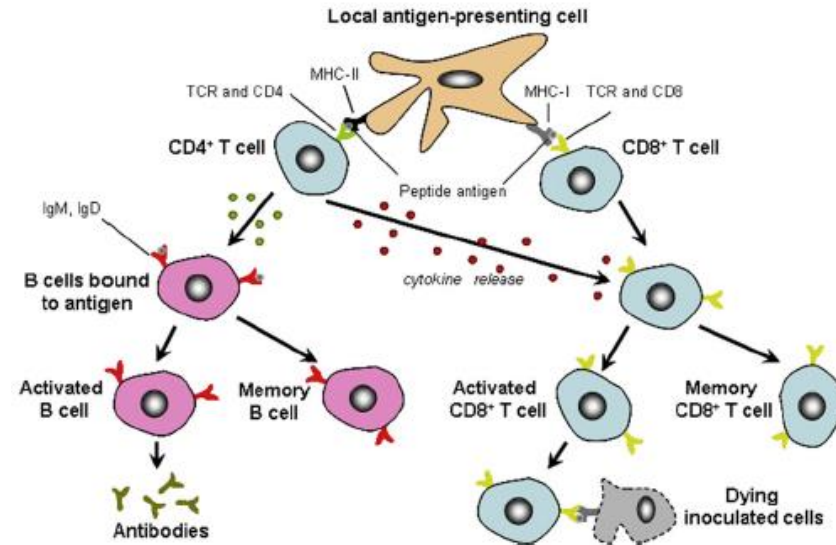
- **Council Directive 2006/88/EC of 24 October 2006**
- Art 48.2 vaccination against the non-exotic diseases listed in Part II of Annex IV **is prohibited** in any parts of their territory declared free of the diseases in question in accordance with Article 49 or 50, or covered by a surveillance programme, approved in accordance with Article 44(1) **Member States may allow such vaccination in parts of their territory not declared free from the diseases in question**, or where vaccination is a part of an eradication programme approved in accordance with Article 44(2).
- Art 48.4 **Paragraphs 1 and 2 shall not apply to scientific studies** for the purpose of developing and testing vaccines under controlled conditions. During such studies, Member States shall ensure that the appropriate measures are taken to protect other aquatic animals from any adverse effect of the vaccination carried out within the framework of the studies.

No vaccine available in EU for use in Rainbow trout

● VHS/IHN and DNA vaccines: state of art



DNA vaccine structure



Tonheim et al., 2008. Adaptive immune response to DNA vaccine

- Low efficacy of inactivated vaccines against VHS and IHN
- Very good protection with DNA vaccines producing VHS/IHN G glicoprotein
- Previous field trial with promising results in Denmark

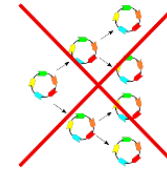
● VHS/IHN and DNA vaccines: state of art



Low Environmental risk

- ❖ Protein expressed is already present in the surrounding area
- ❖ Degraded in the environment
- ❖ Antimicrobial resistance gene is the only concern

Carthage Protocol on Biosafety Convention on Biological Diversity (2003)



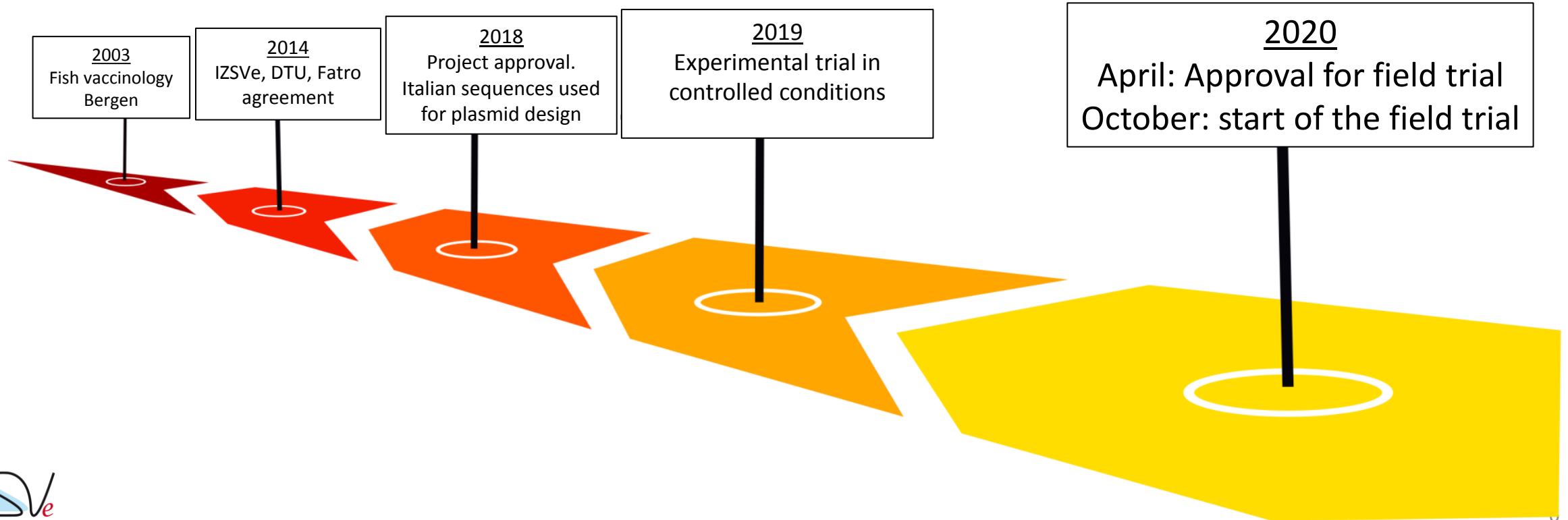
Plasmids don't replicate autonomously



Low probability of integration

● VHS/IHN DNA vaccines in Italy: a long time ago...


- ❖ In 2005 APEX-IHN® by Novartis approved in Canada for use in Atlantic salmon
- ❖ In 2017 Clynav® by Elanco approved in EU for use in Atlantic salmon



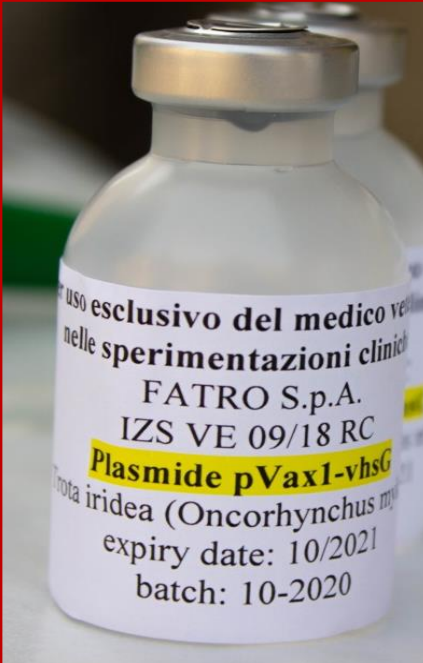
Field trial



-  Preore, Trento Province
-  08/10/2020
-  water temperature = 12°C



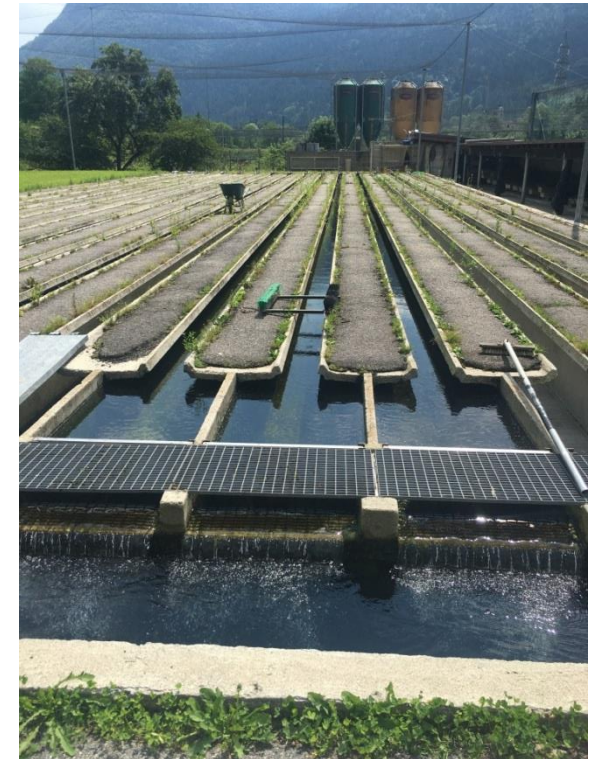
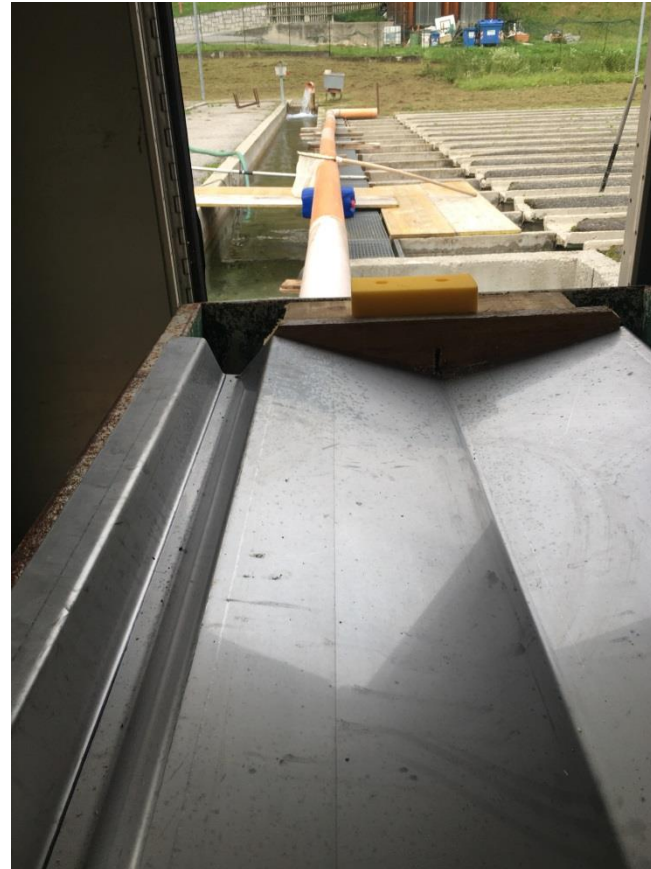
- ❖ Category I hatchery
- ❖ Rainbow trout juveniles weighting 8 grams approximately
- ❖ Tested negative for VHS/IHN/IPN/SAV, parasites and microbial growth. Testing for PRV-3 and BKD ongoing



uso esclusivo del medico veterinario
nelle sperimentazioni cliniche
FATRO S.p.A.
IZS VE 09/18 RC
Plasmide pVax1-vhsG
trout iridea (*Oncorhynchus mykiss*)
expiry date: 10/2021
batch: 10-2020

All bottles labeled with all the informations required by regulations

● Field trial



Field trial



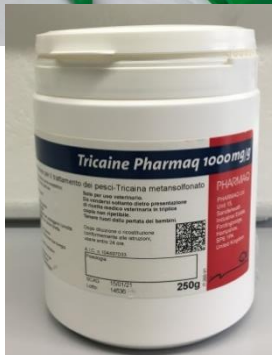
All procedures performed under the supervision of Veterinary authorities

| Experimental group | Treatment | N° of fish (8 gr) |
|--------------------|-------------------------------------|--------------------|
| Negative control | 0,05 ml PBS | 5000 |
| VHS vaccine | 0,05 ml vaccine 1 µg VHS | 5000 |
| VHS/IHN vaccine | 0,05 ml vaccine 1 µg VHS + 1 µg IHN | 5000 |

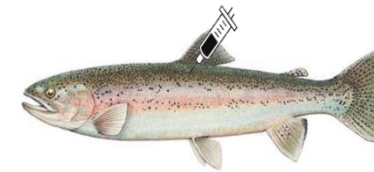
Based on results obtained in the controlled conditions trial, the dose of 1 µg/fish was selected for the field trial



Automatic feeding commercial syringes
0,5 x 3mm needles



Tricaine Pharmaq
100 ppm



All materials and working areas were sanitized with 1% HCl solution at the end of procedures

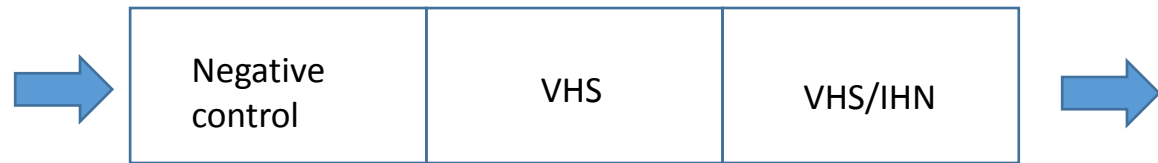
● RC09/18: Field trial



● Field Trial: what's next

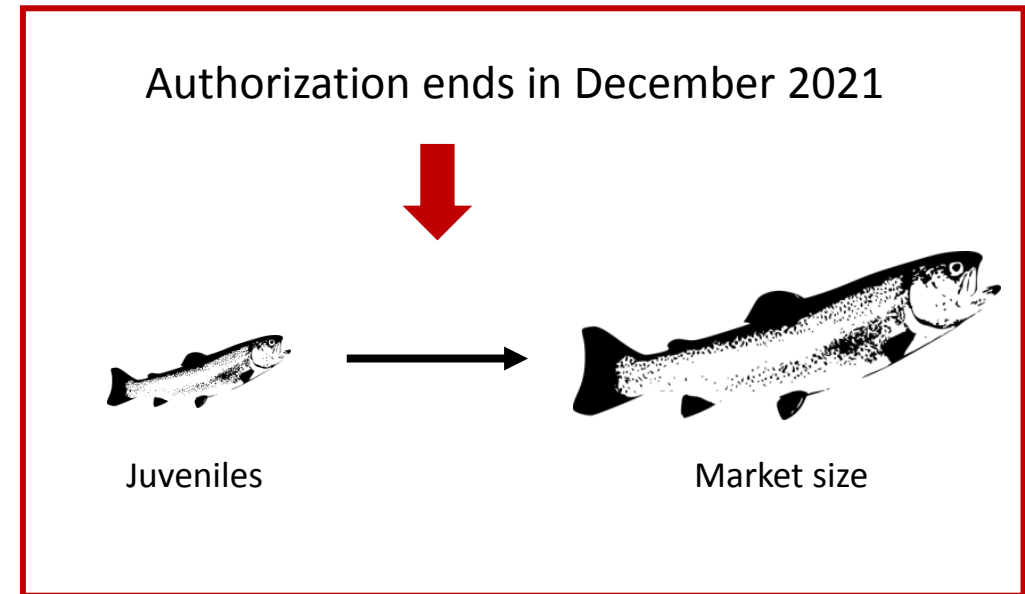
- ❖ <0,5% mortality after 3 weeks from vaccination (40 dead out of 15000)
- ❖ 60 gg before moving to Cat V grow out (co-infected with VHS and IHN)
- ❖ 1 raceway divided through grids

Experimental group order



- ❖ Same management (density, monitoring, feeding) as other fish in the farm

! At the onset of mortality, fish will be tested for determining cause of disease/death



Many thanks to:

- Dr. Bortolotti (Trento Provincial Veterinary Authorities)
- Dr. Dorigoni (Local Veterinary Authorities)
- Dr. Guana (Local Veterinary Authorities)
- Trocoltura F.lli Leonardi (Trout farming company)
- Fatro spa (vaccine producer)
- Dr Faccenda (Edmund Mach Foundation)
- Dr Povinelli (Edmund Mach Foundation)



Thank you for your attention
Questions?