Sustainable Performance

AQUAVAC® RELERA

FOR ACTIVE IMMUNIZATION AGAINST ENTERIC REDMOUTH DISEASE (ERM) TO REDUCE MORTALITY CAUSED BY HAGERMAN TYPE 1 AND EX5 BIOGROUP (BIOTYPE 2) STRAINS OF *YERSINIA RUCKERI.*

EX5, a strain of *Yersinia ruckeri*, the causative agent of Enteric Redmouth Disease (ERM) is spreading through trout stocks in Europe.

AQUAVAC RELERA protects against both the original Hagerman and EX5 strains - minimising the significant costs associated with this disease.

MSD Animal Health

AQUAVAC® RELERA

Enteric Redmouth (ERM) disease vaccine for use in Rainbow Trout *(Oncorhynchus mykiss)*

For active immunization against ERM to reduce mortality caused by Biotype 1 and Biotype 2 (EX5-like) strains of *Yersinia ruckeri*.

Proven Immersion Vaccine

- Provides up to 4 months protection against ERM
- Relative Percent Survival (RPS) of over 60% against a virulent biotype 2 challenge

Safe and Easy to Use

- Safety proven in fry as small as 5g

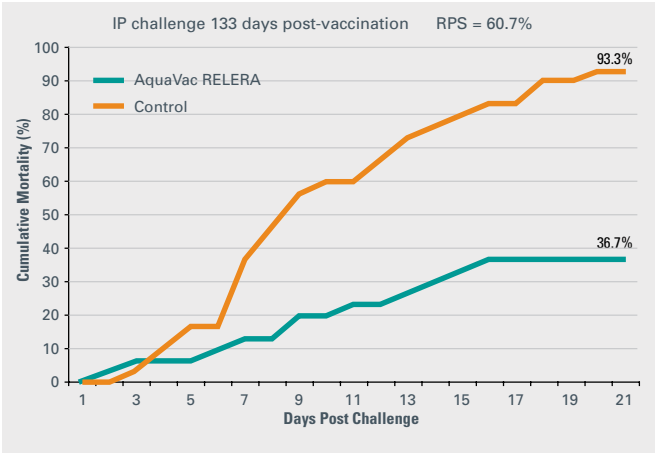
Contains biotypes 1 and 2 of *Yersinia ruckeri*

- First and only registered vaccine containing both biotypes
- Biotype 2 strains are causing increasing mortalities throughout Europe

Full EU DCP license

- Vaccine is available for trout farmers throughout Europe

Graph 1. AquaVac RELERA laboratory study to assess duration of immunity



Graph 1. Mortality results from an EX5 challenge study 4½ months after the fish were vaccinated with AquaVac RELERA. Vaccinated fish suffered 36.7% mortality and controls 93.3%, giving an RPS of 60.7% for the vaccinated fish. This demonstrates good protection against EX5 for at least 133 days after vaccination with AquaVac RELERA.

A strain sampling program was established by MSD Animal Health to examine the potential spread throughout Europe of EX5-like and other biotype 2 strains of *Yersinia ruckeri* and this program is ongoing today.

The results of this sampling program are illustrated in figure 1, showing the countries from which EX5-like or other biotype 2 problems have been identified so far.

Figure 1 shows a map of all the countries that have been demonstrated to have either EX5-like or other biotype 2 problems (MSD Animal Health. Data on file).

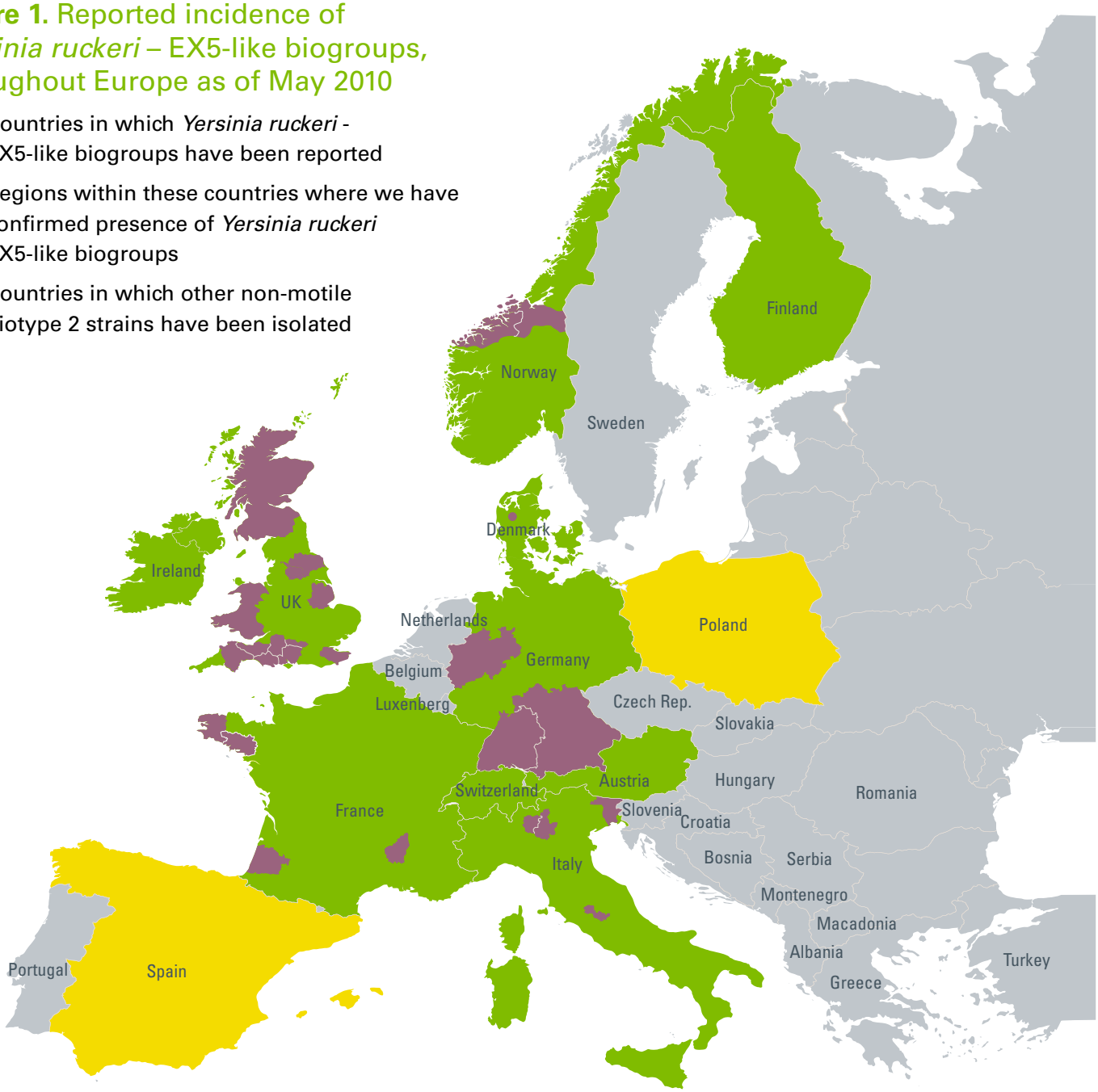
- UK
- Ireland
- France
- Norway
- Finland
- Austria
- Switzerland
- Italy
- Germany
- Denmark

In addition, other non-motile biotype 2 strains have also been reported by other groups in:

- Spain (Wheeler R. et al, 2009)
- Poland (Alicja Kozinska & Agnieszka Pekala, Department of Fish Diseases of the National Veterinary Institute of the National Research Institute)
- USA (North Carolina) (Arias C.R. et al 2007)

Figure 1. Reported incidence of *Yersinia ruckeri* – EX5-like biogroups, throughout Europe as of May 2010

- Countries in which *Yersinia ruckeri* - EX5-like biogroups have been reported
- Regions within these countries where we have confirmed presence of *Yersinia ruckeri* EX5-like biogroups
- Countries in which other non-motile biotype 2 strains have been isolated



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Target species: Rainbow Trout (*Oncorhynchus mykiss*)

Contents per dose
Inactivated cells of *Yersinia ruckeri* ≥ 75% RPS*
(Hagerman type 1 strain)
Inactivated cells of *Yersinia ruckeri* ≥ 75% RPS*
(EX5 biotype strain)
*RPS : relative percentage of survival in Rainbow Trout

Excipient
Residual Formaldehyde ≤ 0.05% w/v

Indications
Active immunization against Enteric Redmouth disease (ERM) to reduce mortality caused by Hagerman type 1 and EX5 biotype strains of *Yersinia ruckeri.*

Immersion route
Onset of immunity:
336 degree days (28 days at 12°C) for Hagerman type 1 and for EX5 biotype.
Duration of immunity:
6 months (205 days at 12°C) for the Hagerman type 1.
4 months (133 days at 12°C) for the EX5 biotype.
Please note that the level of protection against the EX5 biotype wanes during the indicated period.

Injection route (only for booster vaccination):
Duration of immunity: Immunity has not been studied beyond 28 days (336 degree days).

Contra-indications: None

Adverse reactions
Injection administration can induce very slight adhesions (Speilberg score 1) at the site of injection, which may persist for 7 weeks but are normally no longer observed 3 months after injection. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Dosage and administration
Primary vaccination should be by the immersion route only. In the event that a booster vaccination is required to extend the duration of immunity for a further 28 days then the injection route should be used.
The development of protective immunity is dependant on the water temperature.
Shake the bottle before use.
Primary vaccination by immersion: (Fish of at least 5g) Place the fish into batches and immerse for 30 seconds in the diluted vaccine. A litre of vaccine (making 10 litres of diluted vaccine) allows the vaccination of a maximum of 100 kg of fish.
Booster vaccination by injection: (Fish of at least 12 g)
The product is administered by intra-peritoneal injection in the ventral area, just anterior to the pelvic fins. The dose is 0.1 ml per fish. The fish should be anaesthetised prior to vaccination.
Primary vaccination by immersion: Dilute the contents of the bottle (1 litre) in 9 litres of hatchery water, clean and suitably oxygenated. Dilute the contents immediately after opening the container, and use diluted vaccine immediately.
Booster vaccination by injection: The vaccine must be administered using a multi-dose injection applicator incorporating a mechanism to prevent flush-back. This applies equally to hand-held and automatic systems.
Careful injection technique is important to minimise adverse reactions.

Withdrawal period: Zero degree days

Storage precautions
Store and transport refrigerated (2°C to 8°C).
Do not freeze. Protect from light.
Keep out of the reach and sight of children.

Special warnings
Do not administer to broodstock or fish intended as broodstock.
Only vaccinate healthy fish.
Do not vaccinate if the water temperature is below 12°C.
Avoid stress at the time of the handling of fish, as well as temperature variations, in particular between the vaccine suspension and the water of the holding area.
The minimum weights for fish before vaccination must be respected. Protective equipment should be used to avoid self injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.
Do not mix with any other vaccine/immunological product.

Disposal advice
Any unused vaccine should be disposed of in accordance with national requirements.

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References

Arias C.R., Olivares-Fuster,O., Hayden Karl., Shoemaker C. A.,Grizzle J.M. and Klesius P.H. (2007) First report of *Yersinia ruckeri* Biotype 2 in the USA. Journal of Aquatic Animal Health 19:35-40.
Wheeler R., Davies R.L., Dalsgaard I., Garcia J., Welch T.J., Wagley S., Bateman K.S. & Verner Jeffries D. W. (2009) *Yersinia ruckeri* Biotype 2 isolates from mainland Europe and the UK likely represent different clonal groups. Diseases of Aquatic Organisms Vol 84, 25-33.

AQUAVAC® RELERA is only available via your animal prescriber or veterinary surgeon from whom advice should be sought.
AQUAVAC® RELERA contains inactivated cells of *Yersinia ruckeri* (Hagerman type 1 strain) and inactivated cells of *Yersinia ruckeri* (SP/07/04 strain). **POM-V.** AQUAVAC® RELERA is the property of Intervet International B.V. or affiliated companies or licensors and is protected by copyrights, trademark and other intellectual property laws. Further information including side effects, precautions, warnings and contraindications is available on the product SPC or datasheet or from MSD Animal Health UK Limited.

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