

Gaps in the Fish sector

Hearing of 08/06/26



Impact on ATM use incl.
absence or limited
alternatives

minor

Anesthesia for vaccination / eggs collection / weighing and sorting
=> rinsing after treatment with :
- tricaine (trouts) => import of spanish VMP
- benzocaine (see bass) => import MV esp.
- eugenol & isoeugenol (extemporaneous preparation)

=> Import (MR?) of spanish VMPs
(wish for a VMP with a 0 day WP for eggs)

Nearly solved :

Formaldehyde:
Import of the spanish VMP
according to the NMV protocol
(logistical constraints ++)

Existing solution :

PYCEZE:
end of shortage since oct 2022

MAJOR

n° 1

External parasitism (cutaneous-branchial)
Balneotherapy:
Import of the spanish VMP according to the protocol defined by ANMV



n° 2

Most common bacteriosis :
yersiniosis, furunculosis, vibriosis, lactococcosis

Only 2 available remaining antibiotics with MA for fish
=> cascade use, import of premixes, dosage to be revised

Vaccines: few MA in FR or frequent shortages
=> import or use of autogenous vaccines
=> wish for a bi(tri)valent vaccine (large trout)
and vaccine for furunculosis (char & brown trout)

Less common bacteriosis or on « minor » species
- Streptococcosis (sturgeon) => research on vaccine
- Flavobacteriosis (rainbow trout juveniles)
=> wish for a vaccine (work at Inrae & on biosecurity)

n° 3

Virosis
IPN (Infectious Pancreatic Necrosis - Togavirus)
=> biosecurity, import of vaccines, vaccination of reproducers
Emerging Virosis (reovirosis)
=> eradication policy: vaccines not required

+ n° 4

Hormons for reproducers:
No GnRH analogs with MA

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Participants: Matthieu Jamin (SNGTV aquaculture representative, veterinary practitioner exclusively in aquaculture in Morlaix); Xavier Sauzéa (CSMV representative, SELAS du Gouessant veterinarian); Antoine Rostang (Associate Professor in Pharmacology/Toxicology, Oniris); Claire Chauvin (veterinary epidemiologist, Anses Ploufragan)

Excused: Sophie Lebouquin-Leneveu (Deputy Head of Epidemiology, Health and Well-being Unit at Anses Ploufragan), Ségolène Calvez (Lecturer in Livestock, Nutrition and Health of Domestic Animals, Oniris)

for ANMV: Laure Baduel⁽¹⁾, Benoît Courty⁽²⁾, Mariette Salery⁽²⁾, Sandrine Rougier⁽³⁾, Laurent Fabry⁽³⁾ **Excused:** Béatrice Leroux⁽²⁾, Caroline Guittre⁽²⁾, Jacques Bietrix⁽³⁾

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Reminder of the responsibility of the remarks made during the hearing and reported in this report:

- The identification of therapeutic gaps (and the details of the situations expressed and the alternatives envisaged) is the responsibility of the representatives of the veterinary profession
- The ANMV provides supplements or answers to the technical and regulatory questions addressed. These supplements are systematically preceded by "Info ANMV: ... to distinguish the origin of the words expressed.

Prioritisation and evolution of gaps since the last hearing on 31/05/2024: see pages 9 & 10

Table summarizing the comments of the representatives of the veterinary profession *(new elements since the last hearing – in blue):*

0 VMP (Absence of appropriate VMP) is highlighted in yellow when requesting a medicinal product with a veterinary MA for the species and indication concerned

Disease	Problem encountered: PhV: Pharmacovigilance (efficacy or safety perceived as unsatisfactory) Disp : Availability, shortage Reg: Regulatory ("cascade" use, withdrawal period, restricted access) 0 VMP: Lack of appropriate veterinary medicinal products (VMPs) 0 TS: Lack of a therapeutic solution	Problem Type : PhV, Disp, Reg 0 VMP 0 TS	Alternatives identified	PRIORITIES Major: M minor: m (see p 9)
<u>External parasitism</u> Balneation treatment of cutaneous branchial parasitism mainly due to protozoa and monogenic worms	• Therapeutic use of various products with biocidal activity, without a veterinary medicinal product (VMP) marketing authorization (MA). Use of Hydrogen Peroxide, Chloramine T (Halamid ®), mixtures of hydrogen peroxides and peracetic acid (INCIMAXX AQUATIC ®) which act on the parasites of the water body. Bronopol (PYCEZE)® has an MA. Emamectin (SLICE®), used as an antiparasitic on salmon lice, is available as a medicated premix in Iceland and Norway and also has a MA in several	Reg 1 VMP	Applications for the import of AQUACEN FORMALDEHYDO (VMP with MA in Spain), according to the protocol established by the ANMV. This is a positive step forward that meets a primary need and ensures good traceability (cessation of use of "industrial" formaldehyde in farming). However, the profession remains extremely dependent on the constraints inherent in imports, the availability of stocks, the storage of large volumes and handling methods. The situation was very tense with fish mortality in late summer 2025 due to	M N° 1

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	European countries. Product marketed under the biocidal status TP3: HALAMID (chloramine T) and mixtures of hydrogen peroxide and peracetic acid (INCIMAXX AQUATIC®). Post-meeting ANMV note: even if these substances have an approved biocidal status (TP3), there is no biocidal MA for their antiparasitic use in fish (e.g. Halamid). Biocidal/VMP regulatory status not currently in question. ANMV info: PRAZIVETIN, premix for gilthead bream is authorised for tapeworms (centralised MA of 24/04/25). Sea bream farms mainly located in Greece, Spain and Croatia. The production of sea bream in France is "confidential". Demand for a single farm in France. ANMV post-meeting info: As the MA is centralized and the manufacturing plant is located in Spain, it is possible to import the product into France with a label in French. Issues related to bitterness and compliance difficulties have supposedly been reported in Greece.		supplies issues from the laboratory. According to Mr Jamin's contacts with the Spanish MA holder, France does not represent a sufficient or strategic market to justify mutual recognition (MR) for France. The carcinogenic status of formaldehyde and the current lack of ecotoxicological evaluation for the use of this drug in France also seem to be one of the major obstacles to the submission of an MA application via MR, especially since the Spanish drug is only authorized for use in turbot and sea bream. Research, through technical monitoring and regular field tests, has not yet led to the development of alternative solutions to formaldehyde for certain parasitosis.	
	Regulatory problems depending on the interpretation of the action, prescription issues, diversity of types of farming...		Maintain the current level of understanding of the authorities, pragmatism, agility, trust and transparency. ANMV info: Environmental requirements still under consideration/drafting at European level⁽¹⁾. A guideline is still being drafted at ERAWP. This should be finalised at the end of 2026 and will then be submitted to public consultation. This will ensure that the requirements are harmonized.	
Bacteriosis therapy Most common: yersiniosis, furunculosis, vibriosis, lactococcosis, etc. Metaphylactic oral treatment of septicemic	Only 3 remaining antibiotic VMPs with MA for fish, which are: 1. FLUMIQUIL 3% powder for oral solution: very diluted but better than nothing = > to preserve, even if it is an emergency product with occasional and irregular needs FLUMIX 16% was out of stock and then withdrawn. The concentration of FLUMIQUIL 3% is not really appropriate and sometimes the use of FLUMISOL 36% or FLUMIQUIL 10%	3 VMP Disp	Reduction of the use of antibiotics thanks to vaccines and increase of the use of autogenous vaccines. As a reminder: The 3-year Medic'Eau project was initiated at Oniris vet school (FEAMP funding) to work on the dosage of ATBs in fish farming, taking into account the influence on commensal flora and the risks associated with the selection and diffusion of antibiotic resistance genes. The ecotox assessment is not currently foreseen in the project⁽¹⁾.	M N° 2

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bacteriosis after coating the premix on the feed. -	(more appropriate but without MA for fish) is required despite the fixed withdrawal period - WP (=3 days as 2 days for other species), or the need for medicated feed from a premix of flumequine with a MA in Spain. For the record: <i>High clearance enables short WP. But questions raised about the dosage regimen, especially with such a diluted formulation.</i> <i>There seems to be a rapid development of resistance when used in the field. No data on fish through Resapath. It would be necessary to read up on the literature to be able to identify the clinical and bacteriological effect at the dosage used. In case of underdosing, there is certainly a risk pour A. salmonicida (MIC data being published – see opposite). There is no longer a wild population in France, and cross-resistance are observed with other quinolones. But the situation seems stable over the last 10 years. Questions arise about Good Practices (GPs) and dosing (normally defined for a wild population).</i> ANMV info: an EFSA report does indeed indicate resistance to fluoroquinolones, particularly in <i>Aeromonas</i>. 2. Oxoline acid (INOXYL OXOLINIC ACID 240 SALMONIDS premix): unusable in triploid trout (allergic) – sales until 2021. Never prescribed by Dr. Jamin and very little use because of very marked resistance with <i>Aeromonas</i>. 3. Oxytetracycline (medicated premix): inappropriate recommended dosage (55 mg/kg in the MA instead of 90-100 mg/kg). It is used at 90 mg/kg against vibriosis in sea bass or salmon. Oxytetracycline is essential in the treatment of allergic dermatitis in rainbow trout ("strawberry disease") and in marine aquaculture in case of vibriosis. For the record: <i>TRIBRISSEN POISSONS was abandoned in 22/10/20 (after 4 years of no sales). Flumequine: discontinuation of the medicated premix for salmon & trout.</i> Antibiotics are used mainly off label via the “cascade” with manufacturing of “medicated” feed on site (mainly) or in feed mills, either: - from medicated premixes registered (but no availability before 4-5 days in the best cases therefore not applicable in general because animals are at risk of dying in the meantime) or - from VMPs approved for other species.	Disp PhV (0 VMP)	<i>The objective is to identify the antibiotics of interest with an adapted and "agile" use and to find practical solutions or recommendations with a better "scientific framework" of the cascade use while taking into account the farming conditions. A preliminary work has been done on the determination of the MIC of Aeromonas salmonicida subsp salmonicida (ASS) (furunculosis agent) collected in aquaculture farms for 8 ATBs, in order to determine dosing regimens or exclude certain uses.</i> Part of the work on the sensitivity of Aeromonas has been published: for quinolones, virtual disappearance of the "wild" population (the most sensitive population) in France in trout farms (with cross-resistance between the different generations), very marked resistance to sulfonamides alone, but not when combined with trimethoprim, prevalence of resistance ± stable over the last 10 years except for tetracyclines (change from 50% to 60% non-wild strains in 10 years). Work on doxycycline has been published by a Turkish team: its 20% bioavailability in trout would be favourable to the development of an MA. The work on oxytetracycline in trout in a population-based approach with a PK study has been published and shows a bioavailability of 3%, which raises questions about the revision of the dosing regimen and safety for the environment. However, aquaculture vets report satisfactory effectiveness on some diseases (100% cure is obtained in 10 days in "strawberry disease" in rainbow trout), but not on all. For the record: Optimal dose re-evaluation requires a PK/PD study. Data were generated for the OTC on SSA in 2025/2026 (not yet published). The discrepancy between the measured PK data and the field feedback for certain infections needs to be better characterized (accumulation effect? elimination half-life of about 87 hours at 16°C vs. 120 hours at 10°C). Regarding the re-evaluation of the dosing regimen, work was done in 2021 for enrofloxacin (former project): the correlation between the above-mentioned MIC data and this study seems to discredit the use of this ATB for the management of SSA (its use does not meet the characteristics expected to combine both the fight against ABresistance and efficacy, including in 2nd intention use (critical ATB)).	
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	e.g. Sulfadiazine-TMP (oral or injectable solution used by on-site coating of feed), in more than 50% of cases (for aeromonas, furunculosis, yersiniosis, vibriosis), enrofloxacin (very rare use), florfenicol (for flavobacteria or aeromonas) ANMV Info: The monitoring of uses via CalypsoVet indicates in 2025: 2.5t of antibiotics for fish intended for consumption, of which 52% as medicated premixes, 43% oral (excluding premixes) and 5% injectable. The monitoring of sales in 2024 (similar results in 2025) indicates 8 drugs with sales attributed to fish (including off-label sales for flumequine, florfenicol, oxytetracycline and amoxicillin) with the Top 3 sales: - PS OXYTETRACYCLINE AQUACULTURE (the only premix sold) - FLUMISOL 36 % - Official declaration of abandonment for 26/08/25 - CALFLOR 300 MG/ML SOLUTION FOR INJECTION FOR CATTLE AND PIGS <i>The audited veterinarians underline the importance of FLUMISOL 36% for hatcheries but are surprised by its 2nd position in terms of sales because it is not used in trout and is much less used than sulfonamides and phenicolates. Its 2nd position in terms of sales is probably due to an overestimation by the MA holder of its proportion of use for fish.</i> Discussions are ongoing at CVMP and EC level regarding authorised substances via the “cascade” and conditions of use. There will also be the implementation, a priori in 2028, of an harmonised European survey of resistance in fish. • Yersiniosis: catastrophic situation in France on MAs that are too few in number and too often out of stock (another example with Alpha-Dip 2000, a dip vaccine against sea bass vibriosis _ MA of 1996 for Greece _ out of stock since 2025). For the record: vaccines and autovaccines work very well and this disease has declined sharply. MSD vaccine is often out of stock, which causes major problem for the sector. Consequences of shortages = orders for autovaccines, which are finally being preferred and used more and more, the only difference being the shorter expiry period (1 year instead of 2 years).	Disp	Concerning dosing regimens, there is also an ongoing European project (with a fish component) for TMP-sulfa (SuTAn project funded by JPIAMR - ENVT pilot and partnership with ANSES: results on equines and cattle. https://www.jpiamr.eu/projects/sultan/). ANMV info: PKPD population model in fish under analysis with A. Viel. Work on antibiotic susceptibility tests (Oniris & Laboceia & GDSEA) for <i>Aeromonas</i> has been carried out by comparison of solid and liquid media and their publication (with proposal of re-evaluated threshold values) is planned for 2027. Finally, with the exception of 1 and 2G quinolones (which are hardly used anymore) and florfenicol (a less old MA for the latter), all the ATBs conventionally used in aquaculture should be re-evaluated within 3 years. A project funded by EcoAntibio2 is being carried out in Oniris to enable the drafting of a guide of good practices for the production of ATB coatings on farms is almost finalized, with 3 protocols defined - a 4th to come (this in order to comply with IA (EU) 2024/1159). GP sheets are available to all (free download): https://bioepar.angers-nantes.hub.inrae.fr/recherche/projet-en-cours/enr-eau-bage The associated scientific data will be published in 2026-27. Involvement of all French aquaculture vets (via GTV aqua sector) in this project. The "antibiotic cascade" is well suited because it is reactive, the next day, the farm can be treated. At present, antibiotic prescriptions are for emergency treatment. The use of antibiotics is mainly focused on young fish (80% of fish never have antibiotic treatment). For enrofloxacin (very little used), there are no well-defined clinical breakpoints and the optimal dose is difficult to define. Need to facilitate the importation of medicated premixes if needed.
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	ANMV info: AQUAVAC ERM oral (oral emulsion) is now discontinued: only AQUAVAC Relera suspension (for dipping or injection) remains, with 2 different strains and for later vaccination, but in prolonged shortage until 30/06/2026. Possible use of autovaccines or importation of Yersi Fishvax (Fatro) vaccine for trout. Satisfactory vaccines for trout, but problem of specificity in other species. ANMV info: New MA (23/01/25) for ICTHIOVAC ERM for salmon yersiniosis. • Furunculosis: no vaccine approved in FR, therefore Alphaject 3000 (for furunculosis & vibriosis) is imported from Norway for high “added value” species, even if the vibriosis claim is not often necessary in FR. ANMV info: 5 applications in 2022, 3 in 2024, and since then also for ALPHAJECT 3000 (furunculosis) and ALPHA JECT MICRO 6 (MA in Norway) against: <i>Aeromonas Salmonicida</i> (furunculosis), <i>Vibrio Salmonicida</i> (coldwater vibriosis), <i>Listonella Anguillarum</i> serotype O1 and O2a (classical vibriosis), <i>Moritella Viscosa</i> (moritellosis) and INP for the small sector of salmon vaccination. Otherwise autovaccine more or less effective. • Vibriosis: occasionally autovaccine • Lactococci: emerging disease in Brittany and other regions of France: use of Biovac autovaccines. Various therapeutic strategies are currently being studied. Work and PhD thesis on the evaluation of Biovac autovaccines. ANMV info: 2 requests since 05/2024 and requests to import autovaccines manufactured by HIPRA or ACUIPHARMA	0 VMP 0 VMP 0 VMP	The number of Spanish medicated feed manufacturers has fallen from 4 to 1. ANMV info: 1 request for AQUAVET FLU 12 GR/KG in 2024. No others since. For the record: Switch to autogenous-vaccines (some auto-vaccines are authorised at registered manufacturers, while some others may be subject to derogation) The administrative process remains complex, with the need for a sample and requests for exemption to include <i>Yersinia ruckerii</i> in multivalent autovaccines (to avoid a 2nd injection): would a simplification of the form be possible and also a derogation from the addition of <i>Yersinia</i>? ANMV post-meeting note: the principle of autogenous vaccine is that the strain is isolated to be reintroduced into the concerned farm. If the strain is authorised, no administrative steps are required. If the strain is not authorised, the manufacturer (EPAV) may request it. If the strain cannot be added to their authorisation (especially when a VMP with MA exists), then on a case-by-case basis, a derogation must actually be submitted, but this is only in this specific case. The form cannot be simplified, as it is used to assess the application and, in particular, the justification for it. Bivalent or multivalent autovaccines (AVs) work very well. Interest ++ because 2 or 3 bacteria are generally associated. Autovaccines account for about 50% of commercial vaccine prescriptions. However, AVs are difficult to substitute for vaccines in the primary vaccination series and are only available within 3 months, whereas it takes 2.5 months for producing 5-gram fish. ANMV info: applications for manufacturing under derogation: 8 in 2022 and 12 in 2023 and 7 since May 2024 The alternative of import requests is satisfactory if the ANMV retains a certain flexibility on the constitution of stocks. Desire for a bivalent injectable vaccine with yersiniosis and furunculosis valences for large trout and a furunculosis vaccine for Arctic char and brown trout. Wish (illusory?) for a trivalent vaccine yersiniosis, furunculosis + lactococcosis.	
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			ANMV info: New MA (23/01/25) for ICTHIOVAC ERM for yersiniosis in salmon recently marketed in France. Requests for vibriosis autovaccines: 2 in 2023 and 5 since 05/2024 with also requests for ACUIPHARMA or HIPRA autovaccines or VIBRI FISHVAC and ALPHA JECT MICRO 6.	
Control of non-common bacteriosis or in "minor" aquaculture species: - Siberian sturgeon (streptococcosis) - Control of flavobacteriosis: juveniles of rainbow trout	Sturgeon: search for a vaccination route on streptococcosis, but problem of research on immunity in sturgeons (ploidia, etc.). <i>The humoral response has been proven.</i> Ongoing research (<i>study of serotypic variations</i>) with Biovac to <i>increase the effectiveness of autovaccines</i>. Flavobacteriosis: No robust protocol in trout to control this disease. Antibiotherapy in case of acute crisis. Essentially florfenicol. No resistance to date, slight increase of MIC. <i>For the record: Gap efficacy in turbot and edwardsehellosis, an attenuated or recombinant foreign vaccine from Asia (Japan) could be interesting (to be further investigated), otherwise use of ATB (marbofloxacin).</i> Turbot is a marginal sector <i>that has finally disappeared from France</i>.	0 VMP	Antibiotic therapy. Current use of florfenicol. Wish for a flavobacteriosis rainbow trout vaccine. <i>Failures on Belgian experimental vaccines.</i> INRAe is continuing to work on a live attenuated vaccine. Difficulties related to the stage: animals too young to establish immunity. Work on biosecurity to delay the onset of the disease. ANMV info: no new MAs since last hearing <i>in 2024</i>	
Prevention of viral infections: - IPN (Infectious Pancreatic Necrosis - Togavirus) - Emerging virosis (reovirois).	- NPI affects all salmonids: salmon when transferred to sea and trout from 1st feeding (very small fry) at a time when vaccination is not feasible => salmon vaccines cannot be used on rainbow trout (juveniles less than 1.5 g). <i>The disease has decreased in the Salmo sector on juveniles following eradication work. Interest in vaccines remains relevant for Atlantic salmon in transfer.</i> - Some reovirois in salmonids. The 2 main virosis are not subject to vaccination under the FR regulations for eradication (IHN and VHS, health hazards of category 1). No vaccine solution. Difficulties in culture of reovirus. Work on identification and diagnosis test. Note: New MA dated 9/11/2022 for ICTHIOVAC VNN EMULSION INJECTABLE FOR BARS (with a longer duration of immunity than for the previous MA in 2019). <i>For the record: 2 MAs for injectable vaccines granted in 2019 & 2020 against the</i>	Reg 0 VMP	Immunization of breeding stock. In FR, there is little use of vaccines for viruses due to environmental problems because of the circulation of virus-carrying and asymptomatic fish. Biosafety, health management of transport and sites. See to develop imports if vaccines exist (since NO, but they remain very expensive, often heptavalent, etc.). ANMV Info: A single application for import in 2022 vaccine for NPI ALPHA JECT MICRO 6 (MA in NO) and 1 for ALPHA JECT MICRO 1 PD (MA in NO), same for 2024. <i>Too much dependence on foreign vaccines.</i> Vaccination of breeding stock to be considered (in Rainbow Trout). Customised viral vaccines (improperly called "viral autovaccines") could be authorised by ANMV on a case-by-case basis. The current DGAL PNES policy to eradicate virosis in the fish farming sector excludes the possible use of vaccines.	M n°3

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	<i>viral nervous necrosis virus of sea bass (ICHTIOVAC VNN and ALPHAJECT MICRO 1 NODA) – Mediterranean market.</i>		Genetic selection programs also exist for IPN in trout. Significant progress in the PNES program. Clear progress in the sector: Normandy and the North have eradicated VHS and IHN.	
Hormones (GnRH analogues) for 'broodstock' in farms of sea bass, sea bream, sturgeon (and trout)	Absence of VMPs with GnRH analogues for "parental" broodstock (not intended for consumption) in sea bass, sea bream and sturgeon farms. ANMV info: The withdrawal of the European MA for GONAZON (azagly-nafarelin) granted on 20/07/2003 for female salmonids (induction and synchronization of ovulation) and female dogs (prevention of gonadal functions) was requested by Intervet and notified on 19/03/2012.	0 VMP	There is a product in the US, restricted to ornamental fish, OVAPRIM (sGnRHα, analog of salmon gonadotropin releasing hormone + dopamine inhibitor) which is marketed by Syndel. ANMV post-meeting info: No exceptions are provided for in the EU regulations allowing a "fish not intended for human consumption" status. The use of such a product containing substances for which no MRL has been established is contrary to the provisions of Articles 114 and 115 of Regulation (EU) 2019/6 on the off-label use of VMPs.	M n°4
Anaesthesia for: -vaccination by injection; - eggs collection for consumption; - eggs collection for fertilisation; - weighing and sorting (in particular in marine or freshwater perciform farms)	Current use of: 1. Tricaine imported from PharmaQ, rather on trout 2. Benzocaine imported from AQUACEN (ES), rather for sea bass in temperate water. 5L bottle not very practical (use of extemporaneous preparation for smaller volumes). 3. Eugenol and isogenol (extemporaneous preparations) <u>Uses rarer than tricaine and benzocaine</u> Imports are an answer to the problem, but they are cumbersome. Recurring needs => wish to simplify applications to improve responsiveness. Spanish MA holders are not interested in extending their MAs to France, as this would require additional work and would not generate any additional sales compared to import applications. Withdrawal period (WP) issue. The WP for tricaine is 70°days $\approx$ 1 week: OK for vaccination but not applicable for eggs harvesting. Anaesthesia for egg harvesting (trout caviar) is done for animal welfare considerations but the WP is not applicable and substances are not metabolised. A complete rinsing of the fish is therefore carried out before the eggs are harvested.	0 VMP Reg	A fairly French practice of collecting eggs from live fish. The fish are completely rinsed before egg harvesting (anesthesia then soaking then rinsing). <u>Current practices work well, but perhaps they should be made more secure.</u> An anesthetic containing zero-day egg WP would be needed. <u>Dr. Jamin's research did not detect any residues.</u> ANMV info: since the last hearing on 05/2024, import applications for TRICAINE PHARMAQ (AMM in ES). No applications for Eugenol/iso Eugenol (MAs exist in Norway and Iceland for Atlantic salmon and rainbow trout: AQUI-S 540 mg/mL concentrate for treatment solution for Atlantic salmon and rainbow trout) ANMV post-meeting Note: AQUACEN® Benzocaine 200 mg/mL has been approved in France through mutual recognition (MR) on July 29, 2026. It is the only anesthetic authorized in France for use with salmon and trout (by dipping).	m

⁽¹⁾Concept paper for the development of guidelines on the environmental risk assessment of aquaculture veterinary medicinal products was put out for public consultation in 2021: https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-development-guideline-environmental-risk-assessment-veterinary-medicinal-products_en.pdf lines. The European ERAWP sub-group of the CVMP aims to finalise the guidelines by the end of 2026.

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Therapeutic gap: in the process of being resolved	Initial problem	Problem type	Solution / Alternatives Reason for: Resolution in progress / Removal of the therapeutic gap	GAP initially Major: M minor: m
with existing solution				
External parasitism Treatment by balneation of cutaneous-gill parasitosis • Use of formaldehyde without veterinary MA in France	➤ Therapeutic use of various products with biocidal activity, without MA for a veterinary medicinal product (VMP) but some of the substances used are approved as biocidal (TP3). Use of peracetic acid or formaldehyde that act on parasites in the water mass.	0 VMP	ANMV info: Numerous import authorization requests for AQUACEN FORMALDEHYDO since the beginning of 2026, with significant quantities. As a reminder: A "protocol to facilitate the import authorization process for MV Aquacen Formaldehydo 380 mg/mL" was finalized following discussions between the ANMV and the DGAL and the fish farming sector and signed in 2024 by aquaculture veterinarians to commit to respecting it. Representatives of the sector welcome these advances and all the work carried out in recent years by the ANMV, which has made it possible to raise awareness among all stakeholders and to get out of the "regulatory wandering" for better security for all. A commitment from the veterinarian is formalised with a transposition (written document) provided for farmers and staff. The ANSES opinion signed in July 2021 stated "that the alternatives identified may not be sufficient or suitable in certain situations (physiological stage, category of fish or parasites)". As the WG did not wish to work on the use of formaldehyde in certain situations, the ANMV undertook work on the risks associated with such use and the conditions that could make it possible to consider an authorisation to import the Spanish VMP containing formaldehyde. In Spain, the context is different: use in a closed environment = > easier control of effluents. In the context of classified installations, there is a reporting obligation to be specified above a certain release threshold for formaldehyde.	
• Availability of PYCEZE	➤ Only one "aquaculture" drug with MA: PYCEZE, with a single indication (saprolegniosis) and only two target species. For the record: Sale by Elanco to the aquaculture branch of MSD, the market leader.	Disp	➤ ANMV info: PYCEZE is back on the market since 10/2022. The situation is stabilised.	➤

Responses to other 2021 Meeting Questions/Requests

- Opening of a pharmaceutical establishment specialising in vaccines, autovaccine in France
ANMV: For the manufacture of fish autovaccines, it is currently CEVA-Biovac that is mainly concerned.
 Requests for auto-vaccines: 8 in 2022 for trout and 1 derogation for sea bass, 12 in 2023, 8 in 2024 and 12 in 2025 for trout

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PRIORITIZATION

Prioritization by participants (excl. ANMV)	Mathieu JAMIN	Xavier SAUZE	Claire CHAUVIN	Antoine ROSTANG	PRIORITIES for 2024 Major: M minor: m
Gaps identified					
<u>External parasitism</u> Treatment by balneation of cutaneous branchial parasitosis mainly due to protozoa and monogeneous worms	M n°1 File to be consolidated for more robustness and sustainability: situation still precarious for crucial needs and requiring large stockpiles. Major issues. Environmental study to be consolidated		M n°1 Important work by ANSES to ensure the import and use of AQUACEN under good conditions	M n°1	M n°1
<u>Bacteriosis therapy</u> The most common: yersiniosis, furunculosis, vibriosis, lactococcosis, etc. Metaphylactic treatment of septicemic bacteriosis by the oral route after coating the premix on the feed.	M n°2 Use <i>via</i> the cascade of antibiotics with MA for other species. Problem of availability/import of premixes and medicated feed. Move towards on-farm production. More or less satisfactory use of auto-vaccines. Continue to consider import requests with “understanding.”		M n°2 For animal welfare considerations, it is important to have the option of auto-vaccines. Dependence on antibiotics such as florfenicol and on imported vaccines.	M n°2 Given that the medicated feed factories have shut down, it is important to maintain flexibility with regard to the “cascade” use. Remaining issue of delays in obtaining the medicated food.	M n°2
Control of non-common bacteriosis or in "minor" aquaculture species: • Sturgeon (Siberian streptococcosis) • Control of flavobacteria: juveniles of rainbow trout					
<u>Prevention of viral infections:</u> • IPN (Infectious Pancreatic Necrosis - Togavirus) • Emerging virosis (reovirosis).	M n°3		M n°3	M n°3	M n°3
Hormons (GnRH analogs) for 'brooding' in farms of sea bass, sea bream, sturgeon (and trout)	M n°4		M n°4		
Anesthesia for: - vaccination by injection; - collection of eggs for consumption; - harvesting of eggs for fertilization; - Carrying out medium weights and sorting (especially in marine or freshwater perciform farms)	m		m	m	m

Therapeutic gaps in the fish sector

Hearing of 08/06/26

Conclusion and changes in gaps since the last hearing in May 2024:

Favourable trend for:

- **External parasitism: supervised and safe use of formaldehyde** now possible thanks to the "facilitation protocol" for the import of Aquacen Formaldehido 380 mg/mL, a Spanish VMP containing formaldehyde but which requires very large stockpiles. A situation to be consolidated and sustained. Environmental risk assessment and user' safety still need to be further studied. **Situation stabilized for PYCEZE**, an anti-parasitic drug with MA for fish, since its return to the market in October 2022.

Less favourable trend for:

- **Bacteriosis therapy: only 3 remaining antibiotics with MA for fish** are still marketed in France => "cascade use" of antibiotics with MA for other species, imports of Spanish VMPs or use of autovaccines. Important work well advanced on inappropriate concentrations/dosages of certain ATBs and on on-farm coating good practices.
- **Vaccines with MA in France: major availability problems** => use of autovaccines or import of foreign vaccines inducing major dependence and weakening of the sector.
- **Newly expressed need for a GnRH analog** for broodstock (bass, sea bream and sturgeon farms)

	Hearing of 31/05/24	Hearing of 08/06/26
MAJOR gaps	1. External parasitism Treatment (dipping) of cutaneous-branchial parasitosis • Therapeutic use of various products with biocidal activity, without MA as VMP. 2. Bacteriosis therapy • Most common ones: yersiniosis, furunculosis, vibriosis, lactococcosis, etc. • Non-common or in "minor" aquaculture species: - Turbot (edwardsiellase) - Siberian sturgeon (streptococcosis) - Control of flavobacteria: juveniles of rainbow trout 3. Prevention of viral infections: • IPN (Infectious Pancreatic Necrosis - Togavirus) • Emerging virosis (reovirosis).	1. External parasitism Treatment (dipping) of cutaneous-branchial parasitosis • Importation of the Spanish VMP according to the ANMV protocol 2. Bacteriosis therapy • Most common ones: yersiniosis, furunculosis, vibriosis, lactococcosis, etc. • Non-common or in "minor" aquaculture species: - Siberian sturgeon (streptococcosis) - Control of flavobacteria: juveniles of rainbow trout 3. Prevention of viral infections: • IPN (Infectious Pancreatic Necrosis - Togavirus) • Emerging virosis (reovirosis). 4. + Hormons (GnRH analogs) for broodstock in farms of sea bass, sea bream, sturgeon (and trout)
Minor gaps	• Anesthesia	• Anesthesia
Under resolution	External parasitism • Use of formaldehyde: finalization by the ANMV of a "facilitation protocol" for the import authorization process of the Spanish VMP Aquacen Formaldehido 380 mg/mL, following discussions with DGAL and the fish industry. Signature by the sector.	External parasitism • Use of formaldehyde: import authorizations for the Spanish VMP Aquacen Formaldehido 380 mg/mL according to the ANMV "facilitation protocol".
Existing solution	Availability of PYCEZE (single VMP with MA): back on the market since Oct 2022	Availability of PYCEZE (only VMP with MA): stabilized situation since the return to the market in October 2022