Therapeutic gaps in the Fish sector

Hearing on 31/05/24

Participants: Matthieu Jamin (aquaculture representative for SNGTV, veterinary practitioner in Morlaix); Xavier Sauzéa (representative of CSMV, veterinarian in SELAS Gouessant); Ségolène Calvez (Lecturer in Breeding, Nutrition and Pet Health department, Oniris vet school); Antoine Rostang (Lecturer in Pharmacology/Toxicology, Oniris vet school); Claire CHAUVIN (veterinarian, Anses Ploufragan) - **Excused:** Sophie Lebouquin-Leneveu (Deputy Head of Anses Unit for Epidemiology, Health and wellfare in Ploufragan)
for ANMV: Laure Baduel; Sophie Barreteau; Béatrice Leroux, Benoît Courty; Jacques Bietrix; Laurent Fabry **- Excused:** Caroline Guittré, Céline Lorteau

Reminder of the responsibility for the comments expressed during the hearing and reported in this report:
- The identification of therapeutic gaps (and details of the situations expressed and the alternatives envisaged) is the responsibility of the representatives of the veterinary profession
- The ANMV provides additional information or answers to the technical-regulatory questions addressed. These supplements are systematically preceded by "ANMV Info: …", to distinguish the origin of the words expressed.

Conclusion and evolution of gaps since the last hearing in December 2021: see p10

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

Disease	Problem encountered: **PhV:** Pharmacovigilance (efficacy or safety perceived as unsatisfactory) **Disp:** Availability, shortage **Reg:** Regulatory (cascade application, withdrawal period, restricted access) **0 VMP:** Absence of appropriate veterinary medicinal products (VMPs) **0 TS:** Lack of therapeutic solution	Problem type: PhV, Disp, Reg 0 VMP 0 TS	Alternatives identified	PRIORITIES Major: M minor: m (see p 9)
External parasitism Balneation treatment of cutaneous branchial parasitism mainly due to protozoa and monogenic worms	• **Therapeutic use of various products with biocidal activity, without marketing approval (MA) of veterinary medicinal products** (VMPs). Use of hydrogen peroxide, chloramine T (Halamid ®), mixtures of hydrogen peroxides and peracetic acid (INCIMAXX AQUATIC ®) or formalin that act on parasites in the water. Use of endoparasiticides (APIs), such as SLICE as systemic parasiticides on salmon in Norway, which act directly on the parasite. Bronopol (PYCEZE) has a MA • Product marketed under the biocidal TP3 status: HALAMID (chloramine T) and mixtures of hydrogen peroxide and peracetic acid (INCIMAXX AQUATIC ®).	**Reg**	**ANMV Info:** A "protocol to facilitate the process of import authorisation request for the MV Aquacen Formaldehydo 380 mg/mL" has just been finalised **The sector's representatives** welcome these advances and all the work carried out in recent years by the ANMV, which has helped to raise awareness among all stakeholders and to get out of the "regulatory wandering' to ensure greater safety for all. A meeting will be held with the GDS to inform them and estimate the forecast needs in order to assess the quantities to be imported for the next 4 months.	**M n°1**

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	Post-meeting MA note: even if these substances have an approved biocidal status (TP3), there is no biocidal MA for their parasiticidal medicinal use in fish (e.g. Halamid). Biocidal/VMP regulatory status not currently in question.		The veterinarian's commitment will be formalised with a transposition (written document) provided for the breeders and staff.	
	• **Regulatory problem depending on the interpretation of the action, prescription issues, diversity of livestock types**		➢ Maintain the current level of understanding of authorities, pragmatism and agility. **ANMV Info:** Environmental requirements still under consideration/drafting at European level[(1)] (to date, no exposure model for risk assessment because of absence of MA applications).	
<u>Bacteriosis therapy</u> **Most common:** yersiniosis, furonculosis, vibriosis, lactococcosis etc. Metaphylactic oral treatment of septicemic bacteriosis after coating the premix on the feed. -	**Almost no antibiotics VMPs for fish:** Only the following remain: - **FLUMIQUIL 3%** powder for oral solution: very diluted but better than nothing => to preserve. FLUMIX 16% was out of stock and then stopped. The concentration of FLUMIQUIL 3% is not really appropriate and sometimes, the use of FLUMISOL 36% or Flumiquil 10% (without MA for fish) is required despite the detrimental fixed withdrawal period (WP), or the need for medicated feed from a premix of flumequine with a MA in Spain. High clearance enabling short WP. Question about the dosage regimen, especially with such a diluted formulation. 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 around Good Practices (GPs) and dosing (normally defined for a wild population).	**Disp**	Reduction of the use of antibiotics thanks to vaccines and increase of the **use of autogenous vaccines**. 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)]. 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. There has been a preliminary work on the determination of the MIC of 8 ATBs against *Aeromonas salmonicida subsp salmoniciada* (ASS) (furonculosis agent) collected on farms, in order to further determine dosing regimens or exclude certain uses. A publication is planned for end 2024. Work on Good Practices (antibiogram) is also planned on this bacteria for a better use of ATBs. Regarding the re-evaluation of the dosing regimen, work was done in 2021 for enrofloxacin (former project): the correlation between the aforementioned MIC data of this study seems to	**M n°2**

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	- **Oxolinic acid** (INOXYL OXOLINIC ACID 240 SALMONIDS premix): unusable in triploid trout (allergic) – sales until 2021 - **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 of bass or salmon. Oxytetracycline is essential in the treatment of rainbow trout allergic dermatitis ("strawberry disease") and in marine aquaculture in case of vibriosis. *pm: TRIBRISSEN POISSONS was abandoned in 22/10/20 (after 4 years of no sales). Flumequine: discontinuation of the medicated premix for salmon & trout.* 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**. E.g. **Sulfadiazine-TMP** (oral or injectable solution used by on-site coating of feed), in more than 50% of cases (for aeromonas, furonculosis, yersinosis, vibriosis), **enrofloxacin** (very rare use)**, florfenicol** (for flavobacteria or aeromonas) **ANMV Info:** oxytetracycline use are well reported to ANMV both in sales monitoring and in uses monitoring (Calypso). The use of TMP-Sulfa (without MA for fish), has not been declared in the sales monitoring, but these uses were well reported under Calypso for 2023. Off-label use of florfenicol has been reported in the monitoring of sales and also uses of fluoroquinolones since 2022 • **Yersiniosis:** vaccines and auto-vaccines work very well and this disease has declined sharply. The MSD vaccine is often out of stock, which causes major problems for the sector.	**Disp** **(0) VMP** **Disp**	discredit the use of this ATB for the management of AAS (its use does not meet the expected characteristics to combine both ATBresistance and efficacy purposes, including in case of 2nd intention use - as it is a critical ATB) A PK study will be published (Medic'EAU project) on oxytetracycline (OTC) and could serve as a basis for subsequent dosing estimate on certain specific bacteria (notably the "strawberry disease" agent): however, bioavailability is < 3%. **Dr Jamin** reports that 100% healing is achieved in 10 days for the "strawberry disease" (rainbow trout). The dose reassesment requires a PK/PD study which will be only carried out for ASS in 2025. The discrepancy between PK data and feedback from the field will be discussed in particular (accumulation effect? knowing that elimination half-life is about 87h at 16°C *vs* 120h at 10°C). With regard to dosing regimens, there is also an ongoing European project (with a fish section) for TMP-sulfa (SulTAn project funded by jpiamr and managed by the ENVT with Anses partnership: results are expected in 2 to 3 years - https://www.jpiamr.eu/projects/sultan/). Finally, with the exception of quinolones 1 and 2G (which are nearly no longer used) and florfenicol (with less old MA), all the ATBs classically used in aquaculture will be re-evaluated in the next 5 years. A **project funded by EcoAntibio2** is also planned at Oniris vet school to enable the drafting of a Good Practices guide for the coating process of ATBs in farms (planned for 2025). https://bioepar.angers-nantes.hub.inrae.fr/recherche/projet-en-cours/enr-eau-bage The "**antibiotic cascade"** is well adapted because it is reactive, the next day, the fish can be treated.	

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	As a result of the shortages, orders are being placed for auto-vaccines, which are being preferred and used more and more, the only difference being the shorter expiry date (1 year instead of 2 years). **ANMV Info:** AQUAVAC ERM oral (oral emulsion) is still out of stock until end of 2023 and AQUAVAC Relera suspension (for dipping or injection) is out of stock until 08/2024 with import of Fatro vaccine (from IT), Yersi Fishvax Vaccines are satisfactory for trout, but there are specificity issues for other species. • **Furonculosis: no vaccine approved in FR,** therefore Alphaject 3000 (for furonculosis & vibriosis) is imported from NO 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 Otherwise, autogenous vaccines are **more or less effective.** • **Vibriosis:** occasional use of auto-vaccines • **Lactococcosis:** emerging disease in Brittany and other regions of France: use of Biovac autogenous vaccines	**0 VMP**	At present antibiotics prescriptions are for emergency treatment. The use of antibiotics is mainly concentrated on young fish (80% of fish are never treated with antibiotics). For enrofloxacin (very limited use), there are no well-defined clinical breakpoints and the optimal dose is difficult to define. Need to facilitate **the import of medicated premixes if needed.** **ANMV Info:** 1 request for AQUAVET FLU 12 GR/KG in 2024 **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 *Yersinia ruckerii* in multivalent autovaccines (to avoid a 2nd injection): would a simplification of the form be possible and also a derogation from the addition of *Yersinia*? **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 work very well**. This alternative is of great interest because 2 or 3 bacteria are usually associated. Autovaccines account for about 50% of commercial vaccine prescriptions. **ANMV Info:** The number of manufacturing requests under derogations recorded at ANMV were 8 in 2022, 12 in 2023 and already 12 in 2024.	

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			Wish for a bivalent injectable vaccine with yersiniosis and furonculosis components for large trout and a furonculosis vaccine for arctic char and brown trout. Wish (illusory?) for a trivalent yersiniosis, furonculosis + lactococcosis vaccine. **ANMV Info:** no new MAs since last hearing **ANMV Info:** 2 applications for vibriosis autovaccines in 2022, 2 in 2023 and already 2 in 2024.	
Control of non-common bacteriosis or in "minor" aquaculture species: • Turbot (edwardsiellosis) • Siberian sturgeon (streptococcosis) • Control of flavobacteriosis: juvenile rainbow trout	• **Efficacy gap in turbot and edwardsiellosis, a foreign attenuated or recombinant vaccine from Asia (Japan)** could be interesting (to be explored), **otherwise use of ATB (marbofloxacin, etc.).** Turbot remains a marginal sector. • **Sturgeon:** search for a route of vaccination on streptococcosis, but **problem of research on immunity in sturgeon** (ploidy). Research in progress with Biovac. • **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.	**0 VMP**	=> See vaccine import from Japan? **ANMV info:** no import request recorded => Antibiotherapy in other species **Wish for a flavobacteriosis rainbow trout vaccine: research in progress?** Current use of florfenicol. Inrae continues to work on a live attenuated vaccine. Difficulties related to the stage: animals too young for the establishment of immunity => **current work on biosafety** to delay the disease onset. **ANMV Info:** no new MA since the last hearing in 2021	
<u>Prevention of viral infections:</u> • IPN (Infectious Pancreatic Necrosis - Togavirus) • Emerging virosis (reovirosis).	• 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). • Some reovirosis 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).	**Reg**	**Immunisation of breeding flocks.** In FR there is little use of vaccines for viruses due to environmental concerns because of the risk of 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 Customised viral vaccines (improperly called "viral autovaccines") could be authorised by ANMV **on a case-by-case basis**.	**M n°3**

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	pm: 2 MAs for injectable vaccines granted in 2019 & 2020 against the Bar viral nerve necrosis virus (ICHTIOVAC VNN and ALPHAJECT MICRO 1 NODA) – Mediterranean market.		DGAL PNES policy to eradicate virosis in the fish sector, so no recourse to vaccines. Genetic selection programs also exist for IPN in trout. Significant progress of the PNES program. Clear progress in the sector: Normandy and the North have eradicated SHV and IPN.	
Anaesthesia for: -vaccination by injection; - eggs collection for consumption; - eggs collection for fertilisation; - weighing and sorting (in particular in marine or freshwater perciform farms)	In the FR aquaculture sector (marine or fresh water farms, various species, etc.) **phenoxyethanol was discontinued** because of lack of legal status. 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) Imports are an answer to the problem, but they are cumbersome. Recurring needs => wish to simplify applications to improve responsiveness. Spanish marketing authorisation (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 ≈ 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. **ANMV Info:** since the last hearing of 12/2021, 8 import applications were recorded for AQUACEN BENZOCAINE 200 mg/mL (MA in ES) and 23 for TRICAINE PHARMAQ (MA in ES), no applications for Eugenol/isoeugenol	**0 VMP** **Reg**	Fish are completely rinsed before the eggs are harvested. The assays did not reveal residues or at values below the MRL. An anaesthetic with a zero day egg WP would be required. ⇨ Risk of residues to be further evaluated ? Harvesting eggs from live fish is mainly a french practice.	**m**

[(1)]Post-meeting info 2021: a concept paper for the development of guidelines on environmental risk assessment of veterinary aquaculture medicinal products was submitted to 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. The CVMP European ERAWP subgroup has worked on the comments received.The aim is to propose guidelines for Oct 2024.

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Resolution in progress	Existing solution		Reason for ongoing resolution / disappearance of the therapeutic gap
External parasitism Balneation treatment of cutaneous branchial parasitism • **Use of formaldehyde without MA**	➢ **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.		**ANMV Info:** A "protocol to facilitate the import authorisation process for the MV Aquacen Formaldehydo 380 mg/mL" has just been finalised, following discussions with the DGAL and the fish sector. This protocol was recently signed by the vets specialists in aquaculture who have committed to respecting it. ***For the record:*** *The Anses opinion was signed in July 2021.The latter stated that "the identified alternatives may not be sufficient or appropriate in certain situations (physiological stage, fish or parasite category)."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 envisage an authorisation for the import of the Spanish VMP containing formaldehyde.* *In Spain, the context is different: use in closed environments => easier treatment of effluents.* *For classified installations, there is a reporting obligation to be specified above a certain discharge threshold for formaldhehyde.*
• **Availability of PYCEZE** (only antiparasitic agent with MA)	➢ **Only one "aquaculture" medicinal product with MA:** PYCEZE, single indication (saprolegnose) and only two target species. Sale by Elanco to the aquaculture division of MSD, the market leader. **Build-up of large rolling stock**, due to previous shortages => foreseeable impact on short-term sales.	**Disp**	➢ **ANMV Info:** PYCEZE has returned to the market since 10/2022. **Participants' comments:** its availability has to be monitored, particularly in the context of the sale of Elanco's activity to MSD ➢ ***For the record:*** *Cessation of marketing initially planned in France by Elanco, but following the 2019 post-meeting actions, implementation of actions for a return to the market. Import of the Chilean VMP CRESS authorised by the ANMV following the 2019 hearing: only one application in 2021, 4 in 2020. CRESS was used in hatcheries to prevent saprolegnosis on eggs and fry.Transport time had to be taken into account (boat), hence the need to build up buffer stocks.*

Responses to other Questions/requests from the 2021 hearing:

- **Update pharmacovigilance, increase reporting, reporting on vaccines.** It would be interesting to determine a threshold (number of dead fish) for post-marketing reports.
  ANMV Info: Meeting in October 2022 with the SNGTV aquaculture committee (Dr. JAMIN and Dr. LEBRETON) to discuss this point again. Overall, it was not considered relevant to continue this work for the following reasons:
  - At pharmacovigilance level, the concept of serious cases is no longer taken into account in the reporting obligations for veterinarians since the EU Reg 2019/6 (all cases must now be reported).
  - For the committee, it is very difficult to determine general thresholds of severity of an adverse event (e.g. mortality rate) because these criteria vary greatly depending on the type of production and the type of breeding.

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- The detection of an adverse event does not, in principle, raise any problems for practitioners of the sector (who are quite few in number), even though it is often difficult to determine the role of the drug *vs* that of other external factors.

- Opening of a pharmaceutical establishment specialising in vaccines, autovaccine in FR
  ANMV: For the manufacture of fish autovaccines, it is currently CEVA-Biovac that is mainly concerned.
  Autogenous vaccines applications: 8 in 2022 for trout and 1 derogation for sea brass, 12 in 2023 for trout; 8 in 2024 for trout

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PRIORITIZATION

Prioritisation of participants (excluding ANMV) Identified gaps	Mathieu JAMIN	Xavier SAUZEA	Claire CHAUVIN	Antoine ROSTANG	PRIORITIES in 2021 Major:M minor: m
External parasitism Balneation treatment of cutaneous branchial parasitism mainly due to protozoa and monogenic worms	**M n°1** Big challenge. Requests to be consolidated Availability of PYCEZE® to watch.		**M n°1** Important Anses work. Implementation awaited. Uses have been greatly reduced and import of AQUACEN® will now be possible	**M n°1**	**M n°1**
Bacteriosis therapy **Most common:** yersiniosis, furonculosis, vibriosis, lactococcosis etc. Metaphylactic oral treatment of septicemic bacteriosis after coating the premix on the feed. **Control of non-common bacteriosis or in "minor" aquaculture species:** • Turbot (edwardsiellosis) • Siberian sturgeon (streptococcosis) • Control of flavobacteriosis: juvenile rainbow trout	**M n°2** Use of antibiotics with MA for other species *via* the "cascade". Issue of availability/import of premixes and medicated feed. Orientation towards on-farm manufacturing. Use of autovaccines ± satisfactory.		**M n°2** For animal welfare considerations, it is important to have options such as autovaccines.	**M n°2** Due to the shutdown of medicated feed plants, it is important to maintain flexibility with regard to uses *via* the "cascade".	**M n°2**
Prevention of viral infections: • IPN (Infectious Pancreatic Necrosis - Togavirus) • Emerging virosis (reovirosis).	**M n°3**		**M n°3**	**M n°3**	**M n°3**
Anaesthesia for: -vaccination by injection; - eggs collection for consumption; - eggs collection for fertilisation; - weighing and sorting (in particular in marine or freshwater perciform farms)	**m** Restriction of use of tricaine not well understood		**m**	**m**	**m**

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Conclusion and changes in gaps since the last hearing in December 2021:

Positive development for:

- **External parasitism:** the supervised use of formaldehyde is now possible thanks to the finalisation by the ANMV and the signature by the sector of a "facilitation protocol" of the process of import authorisation for Aquacen Formaldehydo 380 mg/mL, a Spanish VMP containing formaldehyde, following discussions with the DGAL and the fish sector.
  The protocol is valid for 12 months from its signature, pending further steps regarding environmental risk and users'safety.
  Return to the market of PYCEZE, the only parasiticide with MA for fish, since October 2022.

No notable improvement for:

- **Bacteriosis therapy:** only 2 remaining antibiotics with MA for fish still marketed in France, and with inappropriate concentrations or dosages
  => "cascade use" of antibiotics with MA for other species, imports of Spanish VMPs or use of autovaccines
- **Prevention of virosis:** a new MA, work on biosecurity measures
- **Anaesthetics:** use of imported VMPs

	Hearing of 13/12/21	Hearing of 31/05/24
Major GAPS	**1. External parasitism** Balneation treatment of cutaneous branchial parasitism • Therapeutic use of various products with biocidal activity (including formaldehyde), without MA for VMP. • Only one antiparasitic agent with MA: PYCEZE, with concerns about availability **2. Bacteriosis therapy** • **Most common:** yersiniosis, furonculosis, vibriosis, lactococcosis etc. • **Non-common or in "minor" aquaculture species:** - Turbot (edwardsiellosis) - Siberian sturgeon (streptococcosis) - Control of flavobacteriosis: juvenile rainbow trout **3. Prevention of viral infections:** • IPN (Infectious Pancreatic Necrosis - Togavirus) • Emerging virosis (reovirosis).	**1. External parasitism** Balneation treatment of cutaneous branchial parasitism • Therapeutic use of various products with biocidal activity, without MA for VMP **2. Bacteriosis therapy** • **Most common:** yersiniosis, furonculosis, vibriosis, lactococcosis etc. • **Non-common or in "minor" aquaculture species:** - Turbot (edwardsiellosis) - Siberian sturgeon (streptococcosis) - Control of flavobacteriosis: juvenile rainbow trout **3. Prevention of viral infections:** • IPN (Infectious Pancreatic Necrosis - Togavirus) • Emerging virosis (reovirosis).
Minor gaps	**Anaesthesia**	**Anaesthesia**
Under resolution		**External parasitism** • **Use of formaldehyde: finalisation by the ANMV of a "facilitation protocol" of the process for import authorisation of the Spanish VMP AQUACEN® Formaldehydo 380 mg/mL,** following discussions with the DGAL and the fish sector. Signature by the sector. • **Availability of PYCEZE®** (single VMP with MA): **return to the market since Oct 2022**