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PANDA

Permanent network to strengthen expertise on infectious diseases of aquaculture species and scientific advice to EU policy

Coordination Action

Scientific support to policies

Deliverable 7 - Reccomendations for prevention, vigilance and contingency plans for the identified disease hazards

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Contents Page

1. Executive summary 3
2. Introduction 3
2.1 Regulatory aspects in the EU 4
3. Terminology 5
4. Surveillance - general aspects 6
5. Wild aquatic animals (fisheries)- passive surveillance 7
5.1 Reporting barriers 8
5.1.1 Education 8
5.1.2 Technology 8
5.1.3 Feedback 8
6. Commercial aquaculture farms - passive surveillance 9
6.1 Reporting barriers 9
6.1.1 Education – responsible partnership 9
6.1.2 Incentives 10
6.1.3 Auditing 10
6.1.4 Feedback 10
7. Commercial aquaculture farms - active surveillance 10
7.1 Risk based surveillance 11
7.2 Risk profiling 12
8. Surveillance barriers 13
8.1 Organization 13
8.2 Complexity 13
8.3 Laboratory competence 13
9. Discussion and recommendations 13
9.1 Risk-based surveillance 13
9.2 Syndrome surveillance 14
9.3 Integrated information systems 14
9.4 Outbreak investigation teams 14
10. References 15
11. Appendix 1 - PANDA WP2 Disease Hazard List 16
12. Appendix 2 - Potential routes of introduction 18

1. Executive summary

The Directive 2006/88/EC focuses on risk based surveillance as both cost-effective and cost-efficient method to reveal the status of specific diseases in aquatic animal production. This implies the use of methods such as risk assessment and mathematical disease modelling which are generally well established in animal disease science. Risk profiling the specific disease threats should be a part of the different members/regions basic awareness.

As much as these methods focus on defined diseases there is also a need for a continuous flow of basic information to establish a general awareness of the unexpected as well as baseline knowledge of diseases both in aquaculture and in the wild. We suggest such information to be gathered by making use of the people in the closest contact with the animals. These are field operators in the industry, fishermen etc. Possible psychological and social barriers for reporting should be identified and overcome. By encouragement and a systematic flow of information to inform the public of diseases in aquatic animals (campaigns) also emphasising the society's need for this information, interest and necessary competence may then be established to fulfil data collection to an adequate level of accuracy.

A technological platform facilitating data collection needs to be made easily available for reporting. Adequate scientific competence should then analyse the input data and through a communications system within EU linking competent authorities and laboratories, an alert could be flagged with the appearance of diverging results from base line in time and space. Such a system at EU level could facilitate a rapid coherent response involving specialized (outbreak) investigating teams for evaluation of the situation.

2. Introduction

The growing global aquaculture industry of today is partly based on global trading in living and currently unknown pathogens across the world. This possibility is strongly focused through the various surveillance systems implemented to prevent and control the spread of infectious diseases, to reduce the cost associated with losses due to infectious diseases and sub-optimal health, and to document good quality and a sustainable production.

To advice in the risk posed by serious pathogenic agents, WP3 was establish in order to make recommendations for prevention, vigilance and contingency plans for the main disease hazards identified in WP2 (Appendix 1).

Since the start of this project EU has adopted Directive 2006/88/EC and the OIE has an on-going ad-hoc group working on revising their guidelines for surveillance.

The members of WP3 were;

- Edgar Brun, Section of Epidemiology, National Veterinary Institute, Norway (WP3 leader)
- Marios Georgiadis, Faculty of veterinary medicine, Aristotle University of Thessaloniki, Greece
- Vlasta Jencic, Veterinary faculty, University of Ljubljana, Slovenia
- Nacho de Blas, Laboratory of Fish Pathology, University of Zaragoza
- Chris Rodgers, IRTA, Spain

- Kenton Morgan, Department of Veterinary Clinical Science, University of Liverpool

The task force met six times during 2004-2006: San Carlos, Barcelona, Ljubljana, Lelystadt, Cairns and Weymouth. In addition, an amputated task force had a final technical meeting in Thessaloniki.

2.1 Regulatory aspects in the EU

The EU has adopted specific legislation in order to control and reduce the impact of diseases in farmed and wild aquatic animal populations. In the legislation, requirements are set for detection of diseases and establishing the status and distribution of diseases and pathogens. These requirements are expressed in the different surveillance programmes. The European legislation on surveillance for animal diseases is based on two principal acts;

- Council Directive 82/894/EEC on the notification of animal diseases within the community and
- Council Decision 90/67/EEC on eradication and monitoring of certain animal diseases.

A new Council Directive was adopted October 2006 (Council Directive 2006/88/EC) on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animas. It includes all farmed aquatic animals; salmonids, freshwater fish, marine fish, oysters, crustaceans, mussels, clams, and abalones. The new directive updates and replaces the three existing directives;

- Council Directive 91/67/EEC concerning the animal health conditions governing the marketing of aquaculture animals and products
- Council Directive 93/53/EEC introducing minimum Community measures for the control of certain fish diseases.
- Council Directive 95/70/EEC introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs.

The new Directive introduces the idea of risk-based surveillance in EU legislation, considering also the impact of wild populations on risk of disease introduction and spread. Furthermore, it requires that all aquaculture establishments and aquatic animal farming areas are registered and animal and product movements are traced. Further, the listing of relevant diseases into three categories (I-III) has been reduced to two; non-exotic and exotic diseases.

Specific decisions have been published in order to lay down diagnostic methods and sampling strategies (Decisions 2001/183, 2002/878 and 2004/453), to establish disease free areas and non-approved zones (Decision 2002/308 and 2002/300) and to approve programmes for obtaining disease free status (Decisions 2003/634). In this context there is a requirement for all farms rearing or keeping of fish and molluscs susceptible to the listed diseases, to register and keep records of mortality and movement of animals into or out of the facility. In case of an outbreak epidemiological investigations have to be performed.

The inclusion of wild aquatic animal species is an acknowledgment that aquaculture to great extent, is performed in an open water environment where the understanding of the biological and ecological interaction between wild and farmed animals becomes important. Regulatory mechanisms and surveillance of wild populations are therefore needed in order to protect both wild and farmed populations.

The Directive 2006/88/EC emphasises the necessity to increase awareness and preparedness of the *competent authorities and aquaculture production business operators* with respect to prevention, control and eradication of infectious disease. This is necessary in order to ensure early detection (and notification) of new diseases by those in contact with aquatic animals and secure the operators are familiar with and apply rules for disease control and bio-security laid down in the Directive.

In March 2007, Directive 2007/2/EC (INSPIRE) was adopted. The directive lays down general rules in order to establish an infrastructure for spatial information in the European Community for the purposes of Community environmental policies and policies or activities which may have an impact on the environment. Aquaculture and its interaction with wild aquatic life has an impact on the environment, and the spatial requirements laid down in INSPIRE together with the requirements in Directive 2006/88 are important tools for a sustainable, environmental friendly aquaculture industry.

In June 2007, Regulation No 708/2007 was adopted. This regulation establishes a framework governing aquaculture practices in relation to alien and locally absent species to assess and minimise the possible impact of these and any associated non-target species on aquatic habitats.

3. Terminology

The terms exotic, emerging and re-emerging diseases were adapted for WP 2 and standardised as:

Exotic to the entire EU

A disease that is currently absent or unknown within the EU but could be introduced from another (third) country. This definition implies regional and zonal freedom.

Exotic to EU regions

A disease that is currently absent or unknown outside a limited distribution zone within the EU but could be introduced or transferred to another, currently uninfected, area. This may be the case for a disease which is confined to one particular region because of containment (i.e. movement) restrictions, where stamping out procedures are not possible, but that has potential for further spread if controls are removed. This definition embodies the potential for spread.

Emerging disease

is a disease that has already appeared but is increasing in incidence and becoming more geographically widespread (i.e. reported in new areas or populations). This could be due to a new strain of an organism and increased recognition or changes related to husbandry practices or environmental conditions. This definition considers a time factor and possible transfer to a new host.

Re-emerging disease

is present or has declined in incidence but has begun to reassert itself or reappear possibly with a more widespread distribution. This could be due to the genetic variation of an existing pathogen (e.g. drug resistant strains) or changes related to husbandry practices or environmental conditions or trade patterns. This definition implies increasing incidence of an already known and characterized disease.

4. Surveillance - general aspects

The major objectives for surveillance are to:

- generate a good epidemiological picture of the occurrence of the pathogen/disease in animal subpopulations (description by time, space, species) in order to prioritize the implementation of control and prevention programmes
- describe the prevalence of a pathogen or disease in specific population at a given time
- rapidly detect new diseases to prevent their establishment in the native population
- support claims of freedom from infection or disease for a country, zone or a compartment
- evaluate the impact of control programmes

These different objectives illustrate the fact that surveillance is a complex activity and that each individual surveillance programme has to be designed specifically for a given purpose and disease or disease agent in question.

Outcomes to be measured, level of confidence in the results, and sampling protocols need to be defined in detail during the design phase of the surveillance system. Subsequently, samples and descriptive data have to be collected, analysed and collated in a cost effective way. Resources need to be allocated for various training, establishing appropriate analytical methods as well as securing reliable logistics of the collected samples and epidemiological data flow.

The efficacy of a surveillance programme regarding prevention and vigilance depends on the ability to rapidly and correctly detect pathogen(s) or disease(s) when present. A surveillance system should therefore be considered and evaluated in a parallel way as for diagnostic tests and described and validated by its accuracy (sensitivity and specificity), precision and predictive values (Salman, 2004). An optimisation of the "test characteristics" of the programme is basically done by implementing risk assessments and other modelling or simulation methods to focus the most sensitive technical parts of the surveillance process (risk –based surveillance) to merit higher benefit/cost by focusing on the populations (and steps) most at risk for transmitting or acquiring the actual agent/disease.

There is an increasing awareness of the importance of understanding the interaction between wild animal-domestic animal-human in the evolution and spreading of pathogens in general as well as within the aquatic environment (as outlined in the EU-funded DIPNET-project). This ecological dimension creates a need for multidisciplinary networks in order to collate the variety of information needed for proper understanding the dynamic of diseases. A broad approach is therefore necessary to facilitate the development of generic surveillance systems and rapid responses to control infectious diseases in general and emerging pathogens in particular. With the present global movement of biological material it is a future challenge to get adequate and relevant information to establish such comprehensive surveillance systems.

Each survey conducted as part of the surveillance system at the farm level is strictly a point-in-time estimate, and the system has to be running for a period of time to give a fair picture of the stability of the situation. On the other hand if the system is running over time, the

sensitivity even for an imperfect system may increase dramatically.

A constraint to this stability is a possible change in the level of risk for disease agents to be introduced between samplings. Hence, the implementation and follow-up on bio-security measures is vital. Such measures are outlined in the new Council directive 2006/88 and include geo-registration, licences, record keeping (species, number, mortality), notification on trade and transport, and mandatory inspections by health services.

Surveillance is traditionally divided into active and passive surveillance. Active surveillance is based on a clear "case definition" – the knowledge of what we're actively looking for. Using this method, we focus specific disease or agent and the findings are described in relation to the characteristics of the population examined. Passive surveillance is testing samples by occasion – for whatever agent of interest to detect or exclude. This approach is well suited for discovering new pathogens or even exotic pathogens. One never knows when, where or how new diseases may appear and familiar exotic pathogens introduced to a native environment – even in a new species, may appear differently than anticipated. In sum, this emphasize that a fundamental aspect for a surveillance system for exotic diseases should include a system detecting and reporting "non-normal" observations – regardless of anticipations.

As the aquaculture industry expands, trade activity increases, new species are cultivated in new "non-native" areas; new diseases and new manifestations of known diseases will be more frequent. Also, due to numerous ways new disease causing agents may be introduced to the aquatic waterways in EU as indicated in Appendix 2 the total risk of incursion may be more concealed and higher than trade based risk assessment estimates suggest. This implies the need for an inclusive and flexible surveillance approach to support traditional surveillance as there is no clear awareness of where, what, how and to what extent a pathogen might enter, - a system not too constrained by limitation of experts and fiscal resources.

5. Wild aquatic animals (fisheries)- passive surveillance

Stated simply fish live in rivers, lakes and oceans and unless they float to the surface or are hauled out of the water in nets or on hooks they are largely invisible to human observation. Observations are sporadic and a dead fish or a fish with abnormal performance may be seen as a chance occurrence or may raise questions which may relate whether to disease or to water quality. However, these sporadic observations done by the general public are in fact efficient eyes of a surveillance system for wild fish populations and may constitute the basis for an early warning system. Similarly, natural beds of molluscs can only be visible at low tide (e.g. clams, cockles, mussels) or by diving (abalone) or through dredging (e.g. scallops, flat oysters). Mortality or gaping is the main visible symptom for mollusc diseases. Observations of dead or gaping molluscs will be sporadic and a posteriori (i.e. once the disease is already present if the mortality is due to a pathogen). In the case of wild molluscs, observations can be done by the general public, mollusc farmers (when molluscs are taken from natural beds to be ongrown) and also by shellfishermen.

A challenging question is thus; what level of mortality or morbidity would raise sufficient concern for a member of the public to report a finding?

An important aspect of such a system is feedback both at the individual and global level.

Everybody who reports should be given a feedback encouragement as a "thank you" Findings, when confirmed and collated should be presented informative and dynamic on an open web site together with explanatory scientific comments.

What to report? Obviously, such a system has to rely on broadly defined reporting parameters as death, signs/syndromes related to diseases such as deformation and abnormalities, abnormal behaviour, skin ulcers, and so on besides species. This will establish an inclusive first line of "surveillance eyes" that is not dependent on experts.

One of the first and basic achievements for such a system is to identify a background level of activity. Further, using a geographical information system and other techniques registering reporting intensity in time and space (trans-border) defined levels of intensity may initiate alerts to competent authorities to act.

5.1 Reporting barriers

Basically, there may be three potential barriers to disease reporting by the general public; the concept that it is not their business; it is an issue that concerns experts, or just the lack of an easily accessible reporting mechanism. The solution to these problems is empowerment and information technology.

5.1.1 Education

Empowerment in this instance means acknowledging that recognition of abnormalities does not need a specific training in diagnosis. It is simply about observation of e.g. death, behavioural abnormalities and alterations in shape colour of surface integrity. These may be observed by a wide range of individuals from the riverbank or beaches, fishing boat or kitchen. The casual canal stroller, the devoted recreational or professional fisherman or even the food handler in the kitchen are potentially the eyes of the system. Nation wide campaigns could be used to encourage and educate the public in reporting the basic needs.

5.1.2 Technology

The reporting system has to be flexible and easy accessible; a mobile phone (a call or through the short message system (*sms*)) using a free number (i.e. three digits similarly to common emergency-numbers) or direct registration on a dedicated web-based dynamic geographical information system. To avoid misuse, access to such a web site could be limited to e.g. licensed fishermen. In any method, location may be given easily by the reporting tool. Further information on findings may be retrieved through a few short questions basically focusing on syndrome descriptions.

5.1.3 Feedback

Any voluntarily (and mandatory) system needs mechanisms that encourage people to participate. These encouragements may be simple acknowledging their submission and participation or more specifically aimed to create and make available new information of interest. This living interaction between reporter and receiver is vital for a reporting system.

6. Commercial aquaculture farms - passive surveillance

Most operators (fish or shellfish farmers) and people working with control and diagnosis of aquatic animal diseases will not necessarily in their day-to-day work, think of new diseases appearing. However, as the aquaculture industry expands, trade activity increases, new species are cultivated in new "non-native" areas; new diseases and new manifestations of known diseases will be more frequent. Also, due to numerous ways new disease causing agents may be introduced to the aquatic system in EU, (Appendix 2) the total risk of incursion may be far higher than import risk estimates based on trade suggest. These routes are difficult to actively survey systematically as there is no clear awareness of where, what, how and to what extent a pathogen might enter. In the context of mollusc production, farmers do not handle their stocks every day but more likely when the tide allows access to certain farming areas or in the case of molluscs produced in deep water as infrequently as every month or two outside the critical period of maturation/spawning. This may result in a delay from the onset of mortality to reporting.

Surveillance of unknown or "non-existing" diseases, a proactive attitude regarding awareness, reporting and sampling strategies needs to be established. The "rare" events must be recognized as quickly as possible at the source. As the ones working in the field also are the ones first discovering irregularities, these people should be the detecting eyes of an unspecific passive surveillance system. The role of people who attend the animals at a day-to-day basis is critical to early recognition of the event and subsequent implementation of control measures.

However, the various production systems throughout EU may have different possibilities to comply with this formal system of requirements. This may be due to improper infrastructure, constraints on the operator's level or due to complexity in the production system. It is therefore, essential to focus on what barriers might limit reporting of diseases on the operators own account.

6.1 Reporting barriers

6.1.1 Education – responsible partnership

Field health workers and operators need to be made properly aware of the existence of exotic or emerging diseases. These are the people most likely to discover the first warning signs that may associate to clinical signs, mortality, reduced growth or to any unexpected, unexplained change in the normal pattern of the production cycle.

Such awareness may be triggered by adequate knowledge of the relevant diseases at field level. This is obtainable through the traditional educational system (seminars, qualification courses and son) but also more pro-active through campaigns, continuous flow of hand-outs, posters and internet postings of oral/written descriptions and pictures of the most relevant signs and diseases to be aware of. A mandatory network of health management advisers and/or compulsory updating should be encouraged.

Beside scientific knowledge, an essential part of this education is the ethical dimension emphasizing the importance of quickly and reliably informing the health care authorities as well as industrial neighbours and partners.

6.1.2 Incentives

It is often the experience that the consequences for the first one to report on a new and/or exotic disease may result in great economic problems. As shown in Appendix 2 there are several routes for introducing exotic agents and ignorance and carelessness are not necessary causes for disease incursion. It is therefore, essential that economic incentives for reporting "warning signs" are established. Such incentives need to be discussed and agreed upon by all stakeholders.

6.1.3 Auditing

Record keeping is not always of foremost priority both due to will or the availability of convenient systems and technology. In Directive 2006/88, criteria for identification of the farm, trade and movement of animals (tracing), and running production results (including mortality) are to be kept in registers on the farm. By adjusting such registers to fit the production line of the different aquaculture systems, they will potentially contain the epidemiological information needed for any outbreak investigation. By introducing an obligation to report at defined intervention thresholds (e.g. acceptable mortality rate pr month) these files may be especially efficient as early warning systems for unknown diseases. It is therefore, vital to keep such registers as updated as possible. The quality of the registers should be regularly audited by governmental appointed officers. As in account auditing, reports are sent to official authorities with the authorization to attend irregularities accordingly.

Limited by how the ownership to the information collected is defined and the access given to the different stakeholder, these records will over time generate information potentially for us in bench-marketing (especially useful for smaller companies) and identification of knowledge gaps to underpin and justify problems for future research and improvement beneficial for the industry.

6.1.4 Feedback

Based on the comprehensive legislation in EU, it is assumed that the EU as such and the individual member states or areas within a nation, will benefit from absence of exotic diseases and a reliable system for rapid detection of new diseases. This is partly due to less governmental money spent on control and/or eradication programmes, increased opportunities for trade and elevated perception by consumers for buying the products. The fulfilling of requirements and the participation of keeping a positive environmental health production should therefore, be economically noticeable to the individual producers.

7. Commercial aquaculture farms - active surveillance

The concept of a global trading in living aquatic organisms fundamentally implies the possibility of moving known pathogens across the world.

Acknowledging this, risk analysis has been used to assess the risk of disease introduction through trade (import risk assessment, IRA). IRA has been driven by the application of the SPS-agreement (Sanitary and Phytosanitary agreement) established by the WTO (1995). The agreement sought to make the setting of sanitary measures science-based and

recommended risk assessment as a suitable method. A scientific evaluation of the likelihood and consequences of the identified hazards should narrow the information gap between importers and exporters and enable common judgments about level of risk mitigating measures (Roberts et al., 1999).

However, freedom from exotic diseases assessed at the place of origin of the consignment can not be guaranteed. To minimize the probability of pathogen importation through trade, regulatory mechanisms are thus established according to acceptable level of protection for introducing exotic pathogenic agents (ALOP) into the EU. The ALOP as such, is a political issue and import risk assessment is commonly used to compare the actual risk of a commodity being traded (risk of incursion) to the ALOP, and to evaluate the steps regarded as most influential for the risk (sensitivity analysis). Import risk assessment is established as an important tool for risk based surveillance regarding introduction of new agents and diseases through legal trade (Peeler et al 2007).

7.1 Risk based surveillance

Risk based surveillance is a term commonly used without its theoretical bases fully been developed. The concept is discussed by Stärk et al (2006). The common understanding is anyway to design a system that will achieve an efficacy as high as in traditional surveillance but always a higher efficiency.

It is therefore essential in a risk based approach to identify the steps with a high probability to detect the agent or the disease if present, at the optimal cost-benefit ratio. Appreciating the need and efficiency of exciting restriction to import, we will argue that for all practical purposes, the first line in risk based surveillance for rapidly detecting new diseases (exotic, emerging) is done by a basically passive approach at the field level by the day-to-day observant. The need to develop this level is therefore commended.

Risk based surveillance is based on an active surveillance approach aiming to detect a specific disease or agent and quantify its presence, - active surveillance will as a rule, not detect any other disease agent present than it is designed for.

For active surveillance, there needs to be knowledge of where, when and how this aim most efficiently can be obtained. The design of an efficient scheme therefore, demands validated diagnostic methods ("test for purpose"), available knowledge on physico-biological properties of the pathogen, size and susceptibility of the populations, and the interaction of host and agent like carrier stages, time between infection and detection, stage of susceptibility, infectiousness, and organ tropism for the agent. For many of the exotic and emerging/re-emerging diseases this is not available knowledge at present (see Deliverable 6) and research needs to be done to fill the gaps.

For all practical purposes, active surveillance within the EU border (or within another geographical area) can only take place when the consignment at risk of carrying an exotic agent, has reached its final destination (the farm). This makes active surveillance dependent on an up-dated reporting system for trade and movement and available resources for field sampling and analyses.

A specific surveillance programme principally needs to be designed for each different disease in question and designed according to the population (unit of interest) and the biological properties of this agent/disease.

An active surveillance system should take into account ;

- consignments arriving to importing farms should strictly be sampled two - three times; first after a minimum incubation period for the actual hazard – days counting from the time of stocking the imported species as the probability of transport stress activating a dormant infection, secondly; at a median incubation period and thirdly at the maximum incubation period (or earlier if there have been increasing mortalities and slow adaptation to the new environment). The first two samplings could concentrate on mortalities and clinical signs while the third one should be obtained for laboratory confirmation of absence of the exotic pathogen in question. All samplings should be targeted and representative meaning the examination should be able to state the causation of mortalities as well as the state freedom from disease for the population. As freedom for disease is a concept not achievable without sampling the whole population, a detection level (maximum allowable prevalence) has to be politically defined.

- the exotic diseases or agent to look for will be determined by considering the species imported, the susceptible species present in the farm and in the neighbouring farms, water catchments area, and the disease status of the originating country. These considerations will be made by the relevant authorities that receive a notification from the farm prior to the arrival of the shipment.

- active surveillance has to be designed and coordinated by a competent scientific institution and the central authorities of each country. These institutions will be responsible for guidelines in performing proper sampling at the defined time and time intervals, while diagnostic laboratories are responsible for examination of the samples and reliable identification of the exotic disease agents using the right tests.

- surveillance programmes that are in place in EU member states for different pathogens should adjust to each other in order in such a way that number of visits by the local officials for clinical inspections and sampling, become efficient.

7.2 Risk profiling

The list of disease regarded by WP2 as serious diseases to the EU is given in Appendix 1. For the exotic diseases no surveillance is on-going in EU and according to WP 2, most of these diseases are not likely to be picked up by existing surveillance for other diseases. Also, for many of them there is no established method suitable for surveillance.

The animals cultured, the susceptibility to different diseases, and the production systems vary throughout EU. Accordingly, each member states or region should increase awareness through establishing a country/region disease risk profile based on the individual diseases and the potential risk for each disease to be introduced and established.

8. Surveillance barriers

8.1 Organization

As water is not restricted to administrative boarders, it is necessary to relate any surveillance system dealing with aquatic animals to the water catchments areas of interest including all stakeholders in this/these area/(s).

8.2 Complexity

Exotic diseases or new diseases in general, may in a naive environment as well as in new species, present themselves in a different manner than expected. A surveillance system for detecting these diseases therefore needs to be on alert for a broad spectre of signs. However, for many of the aquatic organisms – wild and some cultured species as well, especially molluscs – the probabilities for an early detection of diseased or dead animals may be low. For fulfilling all scientific needs for coping with this variety of challenges, a reliable surveillance system may easily become very complex and costly to launch.

8.3 Laboratory competence

Diagnostic laboratories have a key role in the surveillance and each country should have access to at least one laboratory technically equipped and with necessary trained personnel to perform tests for exotic diseases. The capability of molecular characterisation should also exist, at least in one reference laboratory in the EU for each one of the exotic agents. All laboratory findings should be recorded in detail. Often laboratories report that no significant pathology or disease organism is found, after checking for known and established pathogens.

The laboratories should be urged to pursue further testing (for exotic diseases) in situations where no known organisms are found in samples from populations that exhibited increased mortalities,"unusual" clinical signs, etc. As a future research goal**,** all NRL's and other laboratories implicated in this surveillance system, should be linked as the ability to exchange information on exotic agents identified by different laboratory can be instrumental in epidemiological linking outbreaks that may occur in different geographical regions.

9. Discussion and recommendations

9.1 Risk-based surveillance

Risk-based requirements are already included as a general surveillance approach in directive 2006/88 as well as in relation to trade through the import risk assessments laid down in the SPS agreement. The analytical/modelling tools dealing with these requirements are well established and applied.

A risk based approach is designated towards specific agents identified as hazards in specific consignments. The approach will however, not be "water proof ". Inadequacies in the diagnostic tools and representative sample, and the lack of essential information regarding the disease, susceptible species and vectors that might carry the agent, will all reduce the sensitivity of the models.

9.2 Syndrome surveillance

Introduction of exotic diseases and development of new diseases may happen independently of trade in aquatic animals. Normal migration routes or migration due to changes in the biotope will together with the exchange of commodities world wide using water as part of the cargo (e.g. ballast water) increase the probability for moving disease agents from one place to another. Agents may be transported as such in diseased animals or carried as part of the normal or occasional flora in a new species introduced. This implies that an exotic disease may first be detected in the wild and not necessarily in an (importing) farm. This is a challenging situation for a surveillance system that needs the participation of all stakeholders, including the general public.

To increase the probability of rapid detection, we therefore argue that in addition to existing system, a passive surveillance system should strongly be encouraged through technically and educational means where non-experts are made aware of the significance, and competent of reporting their occasional findings. Communicating the importance of exotic diseases should be a task for the authorities as well as encouraging the establishing of a feasible reporting system accessible for the public as well as the operators in the field.

Passive and active approaches are complementary in a complete surveillance system for exotic diseases and together will broaden the surveillance area and increase the sensitivity of the surveillance.

9.3 Integrated information systems

The results from the investigations should at the most simple level, be shared throughout a network of designated laboratories. Aggregated or conclusive diagnostic information may easily conceal details that might show importance at a later stage. Similarly, we emphasize the need to share the epidemiological (including spatial) information collected from disease outbreaks, trade in aquatic animals in general and environmental water parameters including the potential presence of phytoplankton species. Spatial epidemiology including the use of geographical information systems should assist the findings.

The spatial and time distribution can easily be mapped to show the real-time occurrence of diseases and associated risk factors together with relevant environmental data by nation and zones throughout EU. An integrating system for such metadata should be made available trans-boundary as part of a contingency plan for rapid access and intervention when needed.

9.4 Outbreak investigation teams

Conclusions drawn by the laboratories on behalf of the investigations and the data analysis performed either specifically or on reports from syndromes may initiate further investigation and follow-up action. As most regions or nations will not by themselves have proper competence to diagnose and handle exotic diseases, a certain number of specialized *outbreak investigations teams* should be established and made available throughout the EU. These teams should react at short notice and represent the available multidisciplinary knowledge necessary to properly investigate and advice the competent authorities. These teams should have easy access to production and transfer data which are necessary for such investigations.

Such teams should not take away the responsibilities for routine inspections by authorized officials to ensure bio-security routines are working and epidemiological information is made available.

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11. Appendix 1 - PANDA WP2 Disease Hazard List

Exotic Diseases		
	Disease agent	**Susceptible species**
Fish	**Epizootic haematopoietic necrosis virus**	***Perca fluviatilis* and *Oncorhynchus mykiss* (EHNV)**
	Red sea bream iridovirus	***Pagrus major*, *Seriola quinqueradiata*, *Seriola* spp., *Lateolabrax* sp., *Oplegnathus fasciatus*, *Epinephelus malabaricus*, *Epinephelus* spp., *Lates calcarifer* and *Thunnus thynnus*, as well as possibly Perciformes, Pleuronectiformes and Tetradontiformes**
	Streptococcus agalactiae	***Sparus aurata, Liza klunzingeri, Pampus argenteus, Oreochromis* spp.**
	Trypanoplasma salmositica	**Salmonids and other freshwater fish**
	Ceratomyxa shasta	**Salmonidae**
	Parvicapsula pseudobranchicola	***Salmo salar***
	Neoparamoeba pemaquidensis	***Salmo salar***
	Aphanomyces invadans	***Anguillidae* spp., *Caranx* spp., *Plecoglossus altivelis*, *Clarius* spp., *Channa striatus*, Cichlidae, Cyprinidae, *Lates calcarifer*, *Mugil cephalus,* Siluridae and many other different species (incl. possibly *Brevoortia tyrannus*)**
Mollusc	***Perkinsus marinus***	***Crassostrea virginica*, *C. gigas* and *C. ariakensis***
	***Marteilioides* spp. (*M. chungmuensis* : Marteilioidosis)**	***Crassostrea gigas and C. nippona***
Crustacean	**Yellowhead**	***Penaeus monodon*, *P. japonicus*, *P. vannamei*, *P. setiferus*, *P. aztecus*, *P. duorarum*, *P. stylirostris*, *Palaemon styliferus*, *Fenneropenaeus merguiensis*, *Metapenaeus ensis*, *Euphausia* spp. and *Acetes* spp.**
	Taura	***Penaeus vannamei*, *P. stylirostris*, *P. setiferus*, *P. schmitti*, *P. aztecus*, *P. duorarum*, *P. chinensis*, *P. monodon* and *P. japonicus***
	Infectious hypodermal and haematopoietic necrosis	***Penaeus vannamei*, *P. stylirostris*, *P. occidentalis*, *P. monodon*, *P. semisulcatus*, *P. californiensis*, *P. japonicus*, *P. setiferus*, *P. aztecus* and *P. duorarum***
	***Coxiella cheraxi* (crayfish systemic rickettsiosis)**	***Cherax quadricarinatus***
Amphibian	**Ranavirus[1]**	**Amphibians**

Non-Exotic Diseases		
	Disease agent	**Susceptible species**
Fish	**KHV**	***Cyprinus carpio***
	ISAV	***Oncorhynchus kisutch*, *Salmo salar*, *Salmo trutta, Oncorhynchus mykiss*, *Clupea harengus* and *Lepeophtheirus salmonis***

	Streptococcus iniae	***Oncorhynchus mykiss*, *Paralichthys olivaceous*, *Sardinops melanostictus*, *Brevoortia patronus*, *Morone saxatilis*, Cichlidae and *Lates calcarifer***
	Lactococcus garvieae	***Oncorhynchus mykiss, Seriola quinqueradiata* and *Coris aygula***
	Gyrodactylus salaris	***Salmo salar*, *Oncorhynchus mykiss*, *Salvelinus alpinus*, *S. fontinalis*, *Thymallus thymallus*, *Salvelinus namaycush* and *Salmo trutta***
Mollusc	***Candidatus Xenohaliotis californiensis***	***Haliotis* spp. (e.g. black abalone *H. cracherodii*, red abalone *H. rufescens*, pink abalone *H. corrugata*, green abalone *H. fulgens* and *H. tuberculata*, white abalone *H. sorenseni* and possibly *H discus hannai*)**
	***Nocardia* spp. (Pacific oyster nocardiosis)**	***Crassostrea gigas* and possibly *Ostrea edulis***
	Perkinsus olseni/atlanticus	***Haliotis ruber*, *H. cyclobates, H. scalaris*, *H. laevigata*, *Anadara trapezia*, *R. Philippinarum, Austrovenus stutchburyi* and Pitar rostrata**
Crustacean	**Whitespot**	***Penaeus japonicus*, *P. chinensis*, *P. indicus*, *P. merguiensis*, *P. monodon*, *P. setiferus*, *P. stylirostris*, *P. vannamei*, *P. aztecus* and *P. duodarum***
Amphibian	**Ranavirus**[1]	**Amphibians**
	***Batrachochytrium dendrobatidis* (amphibian chytridiomycosis)**	**Amphibians**

[1]It is thought that several amphibian Iridoviridae are exotic but others are already present in the EU and appear to be emerging

12. Appendix 2 - Potential routes of introduction

Potential routes for introducing exotic or new diseases to the EU or between regions within EU (not exhausted)

Live aquatic animal importation	Ornamental fish and shellfish Animals for aquaculture and (re-)stocking Animals for consumption Eggs - gamets Animals for feed production Animals for research Animals for sport (catch and release) Aquarium –zoo/display
Aquatic animal products	
Inactivated vaccines	
Transport (legal – illegal)	Ballast water Changing of transport water Accidents
Wild aquatic animal populations	Ordinary migration Migration due to climate change Flooding Escaping from fish farms Release of exotic fish (when they grow too big) into lakes/rivers Accidental introduction with shellfish stocks (e.g. *Rapana venosa* introduced to France through imports of *Ruditapes philippinarium*)
Fishing	Various equipment Boats

Some comments:

Import for aquaculture and (re-)stocking

Whenever quarantine is possible for example import of sturgeon brood fish from outside EU, this should be enforced for at least one maximum incubation period of the hypothesized exotic disease.

Ornamental fish

All importers should be licensed. Regardless of whether quarantine is possible to implement or not, there should be traceability of all movements of all ornamental fish and shellfish after their importation. This should be the responsibility of the importer. For example, if an outbreak of an exotic disease occurs in some fish from a batch of imported ornamental fish,

the importer should be able to declare, where all the remaining fish from the same importation are, so that veterinary authorities can visit and take the necessary measures. Also, a passive surveillance system will be very important for these fish, since it is most probable that if any exotic diseases will be introduced in ornamental fish, they will be found through passive surveillance. Again, the importance of this system must be emphasized with the importers, the pet-shop owners, the owners of aquaria and their associations, etc.

Human consumption

It is difficult to survey animals – animal products imported for consumption. Therefore, it is important that there is an efficient traceability system. There should be certification for every import and restaurants should to facilitate adequate border control, report to the local competent authorities about importing aquatic animals and products. The member-state should be responsible that the animals are not released in natural waters or in the case of bivalve molluscs relaid in waters disconnected from natural waters and that the transport water is adequately treated. Live fish and shellfish importation, keeping, handling and treatment of disposal should be included in the HACCP system of these restaurants.

Illegal transportation

The importance of this is related to the extent of this phenomenon and purpose of the transport. This might be especially serious when fish and shellfish are brought illegally in the EU for stocking of natural waters for fishing, ongrowing or other purposes. Vigilance for such activities must be increased, especially for species like oysters which can be kept alive outside water and which are therefore easy to import 'in the pocket' (e.g. the introduction of Bonamia ostreae into the EU ws via the import of flat oyster spat) and in areas where it is known that such occurrences have existed in the past. Furthermore, the fishermen should be educated to understand that such practices jeopardize the viability of fishing itself. If illegal transportation cannot be eliminated, at least we should increase awareness in people who may see the first signs of exotic diseases in natural populations in order for them to report immediately any suspicion.

Ballast water

Sea water as ballast has commonly been in use for the last 30-40 years (http://www.norden.org/nordfiskeri/sk/nordfiskeri-9-2000.pdf). An empty ship of 200 000 tonnes needs about 40 000 tonnes of ballast water for a safely manoeuvring to a new harbour. In 2000 it was estimated that about 35 000 ship were in need of using ballast water and it is estimated that the amount of water moved by cargo ships is about 3-4 billion tonnes annually (http://www.naturvern.no/data/f/0/66/09/0_2401_0/1Belastet_vann.pdf).

The ballast water will contains all kinds of living micro-organisms from the original geographical place which then is discharged in a remote catchments area (port). It is anticipated that about 5-10 % of the relocated species in the ballast water will establish in their new environment. In addition it is shown that species of fish, crustacean and shell fish may be part of the fauna included in the ballast water and may potentially act as vectors for pathogenic agents. A future reduction of this problem may be seen through the international ballast water convention adopted by the UN's International Maritime Organization 13. February 2004 (http://www.imo.org/) to be implemented during 2009-2016. This agreement states that all ships by 2016 shall be technical equipped to manage ballast water in order to

prevent, minimize and ultimately eliminate the transfer of harmful aquatic organisms and pathogens through ships' ballast water and sediments.