Committee Report

Guidelines for development and application of aquatic animal health regulations and control programs

The creation of sound health regulations or disease control programs for any animal species is a complex endeavor. When the diverse stakeholder interests related to aquaculture are considered, this endeavor becomes daunting.

The AVMA Aquaculture and Seafood Advisory Committee designed the following guidelines as a tool to assist aquatic animal health professionals who discuss potential regulations or control programs with government and industry entities. The guide focuses on determining whether a regulation or program is appropriate and, if so, developing a suitable and effective aquatic animal health plan.

The Aquaculture and Seafood Advisory Committee was established in 1992 as an ad hoc committee of the AVMA Executive Board. The committee is composed of 9 veterinarians with diverse interests in aquaculture and seafood, and one non-veterinarian who represents the aquaculture industry. Participants from the USDA/APHIS and FDA serve as consultants to the Committee.

Knowledge of the involvement of specific infectious and noninfectious agents in disease pathogenesis has been valuable in the control of many diseases and the protection of the public health, but it has led to extreme reliance on antimicrobials, vaccines, and pathogen avoidance as the primary means of disease control. Today, we realize that it is normal to live in a community where pathogens exist, and it is reasonable to consider pathogens as natural parts of ecosystems. This has led contemporary epidemiologists to reinterpret the familiar concept of a triad interaction among host, environmental, and pathogen ("agent") factors in the genesis of disease, to a diad, where pathogen factors are considered a subset of environmental/ecological factors. This emphasizes the important role environmental quality plays in disease outbreaks. When present, infectious agents are only one of the environmental determinants that can be involved in the genesis of disease. As has been learned in terrestrial agriculture, economically beneficial mitigation of a disease may be possible through manipulation of one or more key determinants (causal factors), which may or may not include the pathogen.

It is economically important to select approaches to a disease (prevention, control, or eradication)on the basis of carefully collected and analyzed epidemiologic and pathogenesis data. The costs and benefits of all options should be evaluated along with the ability to measure the effects of implementation of each strategy. Relatively simple concepts have provided striking outcomes when implemented appropriately. It is important to avoid the misconception that a pathogen can be equated with a disease. This error can lead to disproportionate emphasis on the pathogen when other determinants offer easier, less costly, effective disease management. Avoiding and eradicating pathogens is a complex and expensive task that may not be an appropriate goal in many situations.

This document is intended to provide a systematic overview of the elements and approach necessary to develop and implement aquatic animal health regulations and programs.

Deciding Whether a Regulatory Effort or Health Management Program Is Appropriate

An important early decision in the process of promulgating a regulation or initiating a health program is to consider specifically whether a disease is appropriate for regulation/control effort or not. Widespread distribution of the disease, political boundaries, lack of host or environmental specificities that lend themselves to effective control, lack of good diagnostic or detection methods, or a low economic impact relative to regulatory or management program costs can be excellent reasons to make an early decision that a particular disease should not be regulated.

Input and general consensus from all involved parties and experts—The decision on whether a regulatory effort of health management program is appropriate must actively involve all interested parties and representatives of all regulatory authorities. This group must include knowledgeable members of the aquatic health professions from the onset. These potentially diverse participants must generate the will to move forward by examining the feasibility and weighing the benefits and risks of any action. They must establish consensus on an achievable goal and the criteria for evaluating progress toward that goal if any regulatory effort or program is to succeed.

The diversity of expertise needed to adequately consider the decision to proceed can be daunting. Nevertheless, the combined knowledge of biologists,

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Glossary

Aquatic animal—any vertebrate or invertebrate, wild or domestic, that is dependent on an aquatic environment, freshwater or saline, for part or all of its life cycle.

Certification/certified—meeting the agreed criteria for a program or regulatory standard.

Case definition—the sum characteristics (such as history, gross and/or laboratory findings) that define a particular disease for the purposes of a disease control program. It is important to note that these do not necessarily have to be the most sensitive or specific tests available as long as they are established to be adequate for a particular program to meet its goals.

Causal factors—a set of key determinants that are necessary to be present for disease to occur within a host population.

Control—disease management strategy whereby efforts are made to reduce the frequency of a disease to biologically or economically justifiable levels.

Cost-benefit analysis—an economic process for evaluating the costs and benefits of an event or an activity; calculating the estimated cost-benefit ratio estimate for a program or regulatory standard. Cost-benefit analysis should be applied to each risk mitigation measure to select the most efficient means of reducing the hazard.

Disease—functional and/or anatomic abnormalities in a population or the body of an individual caused by any environmental condition, infectious or noninfectious. Clinical disease is detectable by one or more of a person's senses. Subclinical disease is detectable only by selected laboratory tests or diagnostic aids. The detection of a potential pathogen does not constitute the detection of disease.

Epidemiology—the quantitative and/or descriptive study of the frequency, distribution, and determinants of health and disease in populations (contrast with "pathogenesis").

Eradication—disease management strategy whereby efforts are made to eliminate the pathogen from a defined population or geographic region.

Estimated cost-benefit ratio—the ratio of the dollar value of benefits that can be expected from a given cost investment.

Hazard—elements or events that pose potential harm; biological or chemical agents with the potential to cause an adverse health effect.

Incidence—a rate of disease describing the probability of a new disease case developing during a defined time interval. Crude true incidence (I) is calculated from the proportion of animals developing disease (D) during a defined time period (T) from the average population (N) at risk during that time period (I=D/N/T).

Pathogen—an infectious or noninfectious agent that is a potential contributing environmental factor to disease.

Pathogenesis—the mechanism and determinants of disease development in an individual or a population. These may or may not have an impact on the spread of disease within a population.

Prevalence—a proportion (P) indicating the number of cases of a disease (D) within a population (N) at a specific time (P=D/N).

Prevention—disease management strategy designed to exclude disease from a population or a defined geographic area.

Risk—the likelihood and magnitude of the outcome of the unwanted event; a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard exposure.

Risk analysis—the process that includes risk assessment, risk management, and risk communication.

Risk assessment—a scientifically based process for which answers to three questions are sought: (1) what can go wrong (hazard identification); (2) how likely is the hazard to occur; and (3) what is the severity of the effect if it does.

Risk-benefit analysis—a comparison of risks to the benefits inherent in the act being considered. A risk-benefit analysis is broader than a cost-benefit analysis.

Risk communication—the interactive exchange of information and opinions concerning risk among risk assessors, risk managers, customers, and other interested parties.

Risk characterization—a synthesis and summary of information about a potentially hazardous situation that addresses the needs of decision makers and interested and affected parties. It describes the larger context in which the hazard occurs. Are other hazards incurred by the mitigation proposed? What is the magnitude of the new hazards? Are there social or economic effects not reflected in the risk assessment or cost-benefit analysis? Who is affected by the hazard(s), by the mitigation(s)?

Risk management—the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

Risk mitigation—the alternatives developed from the risk assessment to reduce the effects of the hazard being evaluated.

Sensitivity (Test)—the probability that a diagnostic test for a particular disease or pathogen will detect a true positive when it is present. This is distinct from the general use of the term to indicate a threshold of detection.

Specificity (Test)—the probability that a diagnostic test for a particular disease or pathogen will detect a true negative (absence of disease or pathogen).

ecologists, veterinarians, epidemiologists, economists, husbandry men, regulators, and lawyers familiar with the species and disease being considered should provide the core information needed to establish a balanced, well defined, and achievable goal. These experts may need the additional input of toxicologists, microbiologists, parasitologists, virologists, or other specialized basic scientists to adequately establish the feasibility of goals or monitoring efforts.

Disease must be definable and diagnosable—The feasibility of achieving the goal is of tantamount importance to the decision to proceed with a program or regulation. Although it is important to maintain a willingness to make decisions in the absence of complete knowledge of a disease, it must be possible to accurately diagnose a disease to have any hope of long-term control, much less eradication. A well constructed case definition may be the best diagnostic approach for a specific program.

Without reliable diagnostic capability, there is less potential to achieve net benefit through regulation, regardless of the potential risk posed by the disease. However, diagnostic testing should serve the purposes of the proposed program and not vice versa. The level of sophistication used in diagnostic testing should be appropriate to the goal and the economic realities of the program.

Test sensitivity and specificity should be evaluated for each disease under consideration. Diagnostic test sensitivity and specificity are usually inversely related. The choice of a given diagnostic test for a stated goal of a regulation will be made on the basis of these properties.

Favorable cost-benefit or risk-benefit ratio—It is common for initial reactions to a disease problem to generate an "eliminate all risk" attitude, particularly in parties experiencing the impact of an outbreak. For many diseases, the real costs of implementing regulations to achieve the most desirable goal would far outstrip even the most generous estimates of the economic, social, and biologic benefits of complete control. Factors to consider when defining acceptable risk should include, but are not necessarily limited to, any public health, economic, or potential biodiversity impact of the health problem. It is also important to consider whether these impacts are expected to be long or short term.

A real challenge in developing any disease regulation or control program is assessing the actual "threat." For various reasons, interests will try and portray the threat of the disease more or less than what it actually is. One of the biggest challenges is attempting to sort out "fact from fiction" in the risk analysis. Therefore, it is fundamental to try to accurately and objectively determine the effect of disease in the absence of the control measures, including the savings in disease-associated production resources.

Means of measuring progress—Measuring the success or progress toward the goal is a critical requirement for the future refinement or perhaps abandonment of a regulation or program. This is particularly important when the knowledge base on which the reg-

ulation or program is established is incomplete, a common situation in fish health matters. The group should establish the time interval that the program will be reviewed to determine whether it should be eliminated or modified. The group must also come to agreement on which data will be used to evaluate the program and make sure that the appropriate data infrastructure for making those decisions is or will be in place by the time of the first sunset evaluation.

Adequate funding available?—The monetary implications of the goals must be established. Adequate resources must be found and secured BEFORE the program is implemented. Working through a structured process, such as what is presented in this document, can often greatly enhance the receptiveness of potential contributors, as it illustrates a clearly and carefully thought-out plan. One should not try and go forward with an under-funded program even though there often is immense pressure to do so as a sign of action. If available resources are not deemed adequate to accomplish a stated goal, then a more modest goal should be considered. The cost-benefit analysis should be redone to ensure that this new goal is worth the effort. If it is not, then the difficult decision should be made that a coordinated disease control program is not an option.

Steps to Developing Appropriate and Effective Aquatic Animal Health Regulations

Bring together all potentially affected parties and expertise and determine the will to proceed—It is essential that all relevant public and private interests are represented in the preliminary decision-making process. Not only is this fair but it aids in the "buy-in" process and helps to prevent the program from being impeded in later stages by groups or agencies that did not feel they participated. In addition, there should be a good cross-section of expertise to contribute to the decision-making process, including: diagnosticians, aquaculture managers, pathologists, veterinarians, epidemiologists, and economists. The latter two are especially critical because the decisions to be made involve complex quantitative assessments on a population/herd level. Involvement of an outside person able to facilitate the group deliberations can be very beneficial. Current regulatory authority should be defined and representatives of those agencies should have the authority to "sign-off" on group consensus.

The number of diseases dealt with at a time should be limited, because additional or concomitant programs can greatly decrease the feasibility of each and tax the resources available.

Establish collective goal—For a particular disease, there should be considerable time and effort devoted to establishing a defined goal that is quantifiable. The range of appropriate goals includes: maintain disease incidence, reduce disease incidence, eliminate the disease, and/or eliminate a pathogen. The goal should define a time period, geographic region, and host population. The goal should be agreed to by everyone.

At this point it is reasonable to establish a sunset mechanism that will evaluate progress toward the goal in a realistic time frame and establish whether sufficient progress is being made toward the goal to justify continuing. The time frame should take into account any time factors in the agreed on goal and allow for completion of the steps outlined in this document.

Evaluate the knowledge base (what is known?)—A report should be generated on what is already known about the disease to summarize the current knowledge base. This should include: etiology, detection methods and their sensitivity and specificity, geographic and host ranges, pathogenesis, incidence and/or prevalence, economic, public health, and biodiversity impacts, etc. This body of knowledge should be reviewed and discussed to gain perspective about the intended goal, and the commitment that will be required to accomplish the goal.

Define what is not known and what needs to be known to proceed—The knowledge base on a particular disease will never be complete and decisions will have to be made despite insufficiencies and gaps in knowledge. What is not known about the disease should be clearly delineated. The consequences of acting without the information should be listed. The impact on the goal should be evaluated and time and resources should be estimated to procure any information/studies needed.

It is folly to proceed when the assessment of the knowledge base of the disease in question indicates much uncertainty in the program, especially when the risk-benefit ratio is high (*see* Perform a risk-benefit analysis of potential courses of action).

List and evaluate the possible courses of action—Include the option of no action. Other possible actions to consider include passive surveillance, active surveillance, management through therapeutic means, modification of physical and/or social environmental conditions, alteration of production schemes (ie, isolating life stages), vector control, carrier elimination, quarantine, mass vaccination of target species, mass vaccination of wild reservoirs, development of resistant stocks, facilities certification, test and slaughter, and depopulation without testing).

Whatever courses of action are deliberated, including no action, it will be crucial to determine and establish appropriate efforts to educate those who will be affected by the program and the general public at large about the goals and reasoning behind the actions being implemented.

Evaluate feasibility of achieving the goal using the course of action under consideration—Knowing the specificity and sensitivity of the diagnostic methods, the prevalence or incidence of the disease, and the geographic and jurisdictional distribution of the disease, can the agreed on goal be accomplished through perfect implementation of the course of action being considered? If so, how much variation from perfect implementation will derail success? How likely is the implementation to achieve the goal?

Perform a risk-benefit analysis of potential courses of action—Does the course of action chosen result in a net benefit to society? A risk-benefit analysis involves transforming estimated risks and benefits of a program to a common unit allowing comparison through the calculation of a ratio. Having achieved this, it is clear that the lower the risk-to-benefit ratio, the more favorable the strategy. Achieving a good estimation of the ratio, however, is a complex and challenging process made more difficult by the lack of any accepted standard approach. Nevertheless, a careful risk-benefit analysis should be evaluated before any course of action is implemented.

The common unit chosen for standardization usually is money. This blurs the concept of risk-benefit analysis with that of cost-benefit analysis, which usually considers a much more limited range of inputs. For good decision making in aquatic animal health issues, it is valuable to include models of impacts on environmental quality, biodiversity, and public health into the analysis along with more traditional production and market projections. It is problematic that the generation of a risk-benefit analysis requires the combination of inputs from a large number of models, most of which are not well validated, and all of which will have wide confidence intervals. Here the collaboration of expert quantitative epidemiologists and quantitative biologists familiar with the industry, the disease, and their respective issues is critical. Even the most gifted epidemiologist will not be able to achieve a useful analysis without the data outlined in section on knowledge base.

Summary

Disease management is a complex and multifaceted process. Decisions on how to proceed are often difficult to make on a purely clinical basis. This, when coupled with conflicting interests from industry, natural resources agencies, regulatory authorities, and other users of the resource, makes development and application of aquatic animal health regulations and control programs extremely daunting. The systematic approach presented in this document can facilitate the success of any disease regulatory or management endeavor. This document can be used as a checklist to help guide industry groups, regulatory agencies, and fish health professionals through the process of developing effective health program strategies.