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The politics of assessing risk for biological invasions: the USA as a case study

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The current regulation of biological invasions rests on an unwarranted presumption (that the invader will cause no harm) and on risk assessment procedures that are narrowly focused, subjective, often arbitrary and unquantified, and subject to political interference. Although this current approach dominates international treaties and most national policies, it has not stemmed the rising tide of biological invasions, as evidenced by several examples from the USA. Technical advances in measuring and predicting impacts of introduced species will improve risk assessments. Additionally, focusing squarely on the risks associated not only with a proposed species introduction, but also on the goals of the introduction and on alternative ways of achieving them, would lead to more-informed decisions permitting the introduction of a species and fewer problematic invaders. In assessing the alternatives to introductions, the precautionary principle should be given heavy weight, as should the distribution of possible costs and benefits.

Introduction

If any environmental threat can be viewed as irrevocable, it is biological invasions. Unlike chemicals, biological entities reproduce and spread autonomously, often over great distances, and even evolve to adapt to changing conditions [1]. Successes in eradicating invasive species [2] concern a tiny fraction of all harmful invasions and have often been won at great cost; for the most part, successful invasion is forever. The main political struggles over biological invasions occur because the increasing recognition of the harm that they cause coincides with the touting of free trade as the solution to social and economic ills.

Species introductions have fallen under the rubric of risk assessment worldwide (Box 1). Here, I argue that current risk assessment methods have not done a good job of guiding policy on, and management of, introduced species. Risk assessment became the governing paradigm for permitting introductions partly because the Sanitary and Phytosanitary (SPS) Agreement, part of 1994 accords establishing the World Trade Organization (WTO), includes a presumption of safety and requires proof that an introduction of a species is risky*. SPS enshrined risk assessment as the basis for limiting the movement of goods, including species. Multilateral treaties have followed this lead; for example, as part of the North American Free Trade Agreement, limiting movement of goods for SPS reasons must be based on risk assessment (Article 754.3c). Risk assessment, as interpreted in the treaties, must be quantitative. The US Government has also adopted this stance; for instance, Executive Order 13112 on invasive species mandates such assessment for the introduction of new species and spread of existing populations.

However, the international context is not the only reason why quantitative risk assessment dominates biological invasion policies. The US Government has increasingly moved towards risk assessment in all regulatory matters. This trend was highlighted by the appointment by President Bush in 2001 of John D. Graham as Administrator of the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget. Graham, founding director of the Harvard Center for Risk Analysis (http://www.hcra.harvard.edu), serves as a regulatory czar to ensure that regulations are based on quantification, cost–benefit analysis and risk assessment. Because the American Government is so committed to risk assessment for introduced species and has long conducted them on plant and animal species, consideration of the process in the USA provides insights into the strengths and weaknesses of such risk assessments.

How are risk assessments used to regulate introductions?

In the USA, among federal agencies, the US Department of Agriculture (USDA), the US Fish and Wildlife Service (FWS) and the US Environmental Protection Agency (EPA) have led in applying risk assessment to introduced species. The USDA conducts risk assessments for introduced species under a generic process (Box 2), whereas the FWS and EPA use no comparable document. In 1993, the US Congress Office of Technology Assessment (OTA) identified the key problems with using such generic risk assessments [3], problems that still persist.

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* Nico, L.G. and Williams, J.D. (1996) Risk assessment on black carp (Pisces: Cyprinidae). Report to the Aquatic Nuisance Species Task Force.

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Box 1. What is risk assessment?

Risk assessment was first defined by the US Government in a NRC report [31] wholly devoted to risks to human health. Although introduced species do cause health risks, most concern has been about risks to the environment, and the EPA adapted the NRC approach to ecological risk in 1992 [32].

The EPA defined ecological risk assessment as a process that evaluates the likelihood of adverse ecological effects from exposure to a 'stressor' (which can be a chemical, an introduced species, or any other entity that affects the environment). There are two main elements: (i) characterization of exposure; and (ii) characterization of ecological effects. Exposure simply means the co-occurrence of the stressor and a component of an ecosystem. For introduced species, exposure can be difficult to characterize, because they can move or be carried unpredictably. Characterization of ecological effects can range from straightforward (e.g. can a species that might be introduced eat a native species?) to complicated, as species can affect one another in many ways, even indirectly. Characterization of effects for chemicals is often experimentally tractable through toxicology tests, and some effects of introduced species can be tested similarly (e.g. tests of host plant acceptance for insects proposed for introduction for biological weed control). However, characterizing population- and community-level effects of introduced species is much less amenable to experimentation, and expert judgment is usually substituted [33], often resting on analogy.

Risk assessment can be qualitative or quantitative, but quantification is usually the goal. A risk assessment has a specific endpoint, which is a characteristic of an ecological component (e.g. increased mortality in fish) that can be affected by exposure and that is relevant to decisions about protecting the environment [32]. The characteristic measured as an endpoint is chosen because it is believed to indicate the actual environmental value that is to be protected. For instance, mayfly mortality can be a concern in its own right, but it is often viewed as an indicator of the impact of a stressor, such as pollution, on an entire ecosystem.

Aside from well-known concerns about what ecological indicators actually indicate (e.g. [34]), introduced species pose problems in defining endpoints because there are often lag-times, sometimes decades long, during which a new arrival remains restricted in range and population size and has limited impact on the invaded ecosystem, after which it spreads, often dramatically, and generates a major environmental problem [35]. Some of these abrupt changes can be related to an evolutionary change, such as adaptation to a new environment or acquisition of a new host [33]. Thus, an endpoint of 'no major changes in dominant tree species in regional ecosystems,' to be indicated by relatively short-term censuses of one or two particular dominants, could fail utterly ten or even 50 years after the assessment when the entire nature of the invasion changes.

First, the OTA lamented that non-agricultural risks, such as damage to natural areas, receive little attention (hence the USDA has been more active in this arena than has the FWS or EPA). Second, except for a few species on two federal blacklists, all federal agencies presume that species proposed for introduction, or products (e.g. wood) that might carry such a species, are harmless, and risk is only assessed when previous information suggests that one exists. Although technical innovations and much research progress promise to improve predictions [4], impacts of introduced species are idiosyncratic and currently difficult to foresee [5], so this presumption is unwarranted. Although not stressed by US Government agencies that have fine-tuned versions of the USDA generic process (e.g. FWS), a third problem is that the quantification of risk achieved by this process is largely illusory [4]. We have insufficient knowledge of most species to enable little more than an educated guess as to whether a species will establish and the impacts that it might cause. A process analogous to the USDA generic procedure was adapted for aquatic species in a report commissioned by the US Aquatic Nuisance Species Task Force [6].

Box 2. The USDA generic process

In the generic risk assessment process [32], experts estimate probabilities (as low, medium, or high) that a species disperses, survives, establishes initially, and spreads, respectively, as well as economic, environmental, and perceptual consequences of establishment and spread [33]. Total risk of establishment is then the product of the independent probabilities of dispersal, survival, initial establishment, and spread; this product scored as the lowest component probability (thus, for example, the product of three highs and one medium is medium). Total consequence of establishment is defined as the product of economic, environmental, and perceptual consequences, arbitrarily but consistently scored according to a table; for instance, the product of high economic, low environmental, and low perceptual consequences is scored as high total consequence [33]. Total organism risk potential is then defined as the product of establishment probability and total consequence of establishment, again consistently tallied according to a table. Associated with the estimated component probabilities are categories of certainty of the estimates: very, reasonably, or moderately certain, or reasonably or very uncertain. These estimates do not enter the calculation for total organism risk potential but can guide decision makers in determining what weight to place on an assessment.

In spite of their limitations, risk assessments are increasingly used to allow (or disallow) the import of species or goods that can carry them. In the USA, >24 assessments have been conducted [6] that have targeted primarily individual species as potential pests in their own right or as potential vectors of other pests.

Assessing the risk posed by the Asian black carp

An example of assessment of risks associated with introducing a particular species to the wild in the USA is that of the Asian black carp *Mylopharyngodon piceus*[*]. This assessment mentioned that the carp might carry new diseases of fishes and mussels to North America, but it focused only on the potential direct impacts of the carp, such as eating native mollusks or competing with native fishes. The recommendations were to permit this species only as sterile triploids, only in contained facilities that were not near to open waters, and to study its biology more intensively. An update lamented that, although the carp had escaped just once into open water, both diploids and triploids were kept near open water and the species still had not been studied intensively even though it was increasingly widely used in ponds to control snails and pathogens[†]. Petitioned by a consortium of 28 state fisheries chiefs from the Mississippi Basin [7], the FWS solicited comments on listing the carp as 'injurious' under the Lacey Act, which would prevent its release to the wild, but, in 2003, the FWS reopened the comment period, and the fish remains unlisted. An upshot of the listing attempt is that FWS removed its fisheries biologist from the consortium, ordered him not to talk to the press, and removed funding from the consortium, apparently at the behest of

† Nico, L.G. *et al.* (2001) Black carp (*Mylopharyngodon piceus*): a biological synopsis and updated risk assessment. Report to the Aquatic Nuisance Species Task Force.

an Arkansas senator responding to catfish farmers who believe that the carp will control intermediate snail hosts of a trematode [8]. However, even if the black carp were listed, states would still determine whether it is legal to possess them and how they can be used. Only importation and interstate movement would be banned.

The carp risk assessment is an introduction planned to establish an ongoing population. Even the great challenge that such assessment poses pales in comparison with attempts to assess risks of unplanned introductions; that is, species carried inadvertently in cargo, ballast water, packing materials, or on other species.

Assessing risks of unplanned introductions

An early effort along the line of assessing unplanned introductions assessed the risk that a species will carry new pests to the USA, rather than constitute a new pest itself. For instance, the USDA [9] assessed risks of importing unprocessed logs of larch (several species of *Larix*; Figure 1) from the Soviet Far East. Because of time constraints, the Committee chose 36 species that could be carried on the logs for detailed analysis and concluded that each posed a great economic risk to commercial timber stands, ranging from US$25 million to US$58 billion. They did not attempt a cumulative estimate for all 36 species, much less for the 139 other species known from larch in this region, and there was no attempt to quantify non-timber impacts, such as on recreation, wildlife, or hydrology.

Subsequently, the process was expanded to assess whether unprocessed Douglas fir *Pseudotsuga menziesii* and Monterey pine *Pinus radiata* logs from New Zealand [10] or Monterey pine, coihüe *Nothofagus dombeyi*, and tepa *Laurelia philippiana* logs from Chile [11] might carry pests, in analyses exactly parallel to that of larch. Rather than a ban on the import logs of any species, the result of these risk assessments, as well as of a more recent one of importing logs of several Mexican tree species [12], was that they became the foundation, in 1995, of a 'Final Rule on Importation of Logs, Lumber, and Other Unmanufactured Wood Articles' that established treatment procedures (often heat) to lessen, but not eliminate, pest survival [13].

Pathways as routes of invasions

Invading species can frequently arrive by recurrent routes, so-called 'pathways'. These last four assessments were aimed at just one pathway: untreated logs. The larger goal is to identify all key pathways, determine risks associated with each, and sever or restrict the riskiest [14]. There is not yet a generic process for assessing pathway risk, beyond combining risks of introducing each particular species. Recent reviews of assessing pathway risk (e.g. [6,15]) propose no new approaches.

An example of a pathway introduction: the suminoe oyster

The introduction of the Asian suminoe oyster *Crassostrea ariakensis* (Figure 1) to Chesapeake Bay [16] exemplifies the absence of a process for assessing pathways, as well as the weaknesses of current risk assessment procedures. Faced with declining populations of the native eastern oyster *Crassostrea virginica*, the state of Virginia proposed introducing the suminoe oyster. This pathway had been tried previously with *Crassostrea gigas*, which failed to generate commercially adequate populations and also introduced pathogens of the eastern oyster [16]. During 2002, the state of Maryland opposed releases of *C. ariakensis* because they might cause ecological damage. However, the seafood industry advocated fast release of this species in spite of controversy over the risks and benefits; thus, in 2002, the National Research Council (NRC) was tasked with exploring the issue. The Council advocated a thorough risk assessment but determined that 'development of a quantitative risk assessment model for evaluating risks associated with…management options would require a great deal of additional research that could take many years to complete' [16]. For the report, the NRC simply enumerated risk categories (e.g. introducing new pathogens or competing with native species).

The Council noted that it would be impossible to control the spread of the oyster if it were introduced to Chesapeake, and they saw a great risk of illegal plantings, including of reproductively viable diploids. The heart of the chapter on risk listed management procedures that might lessen

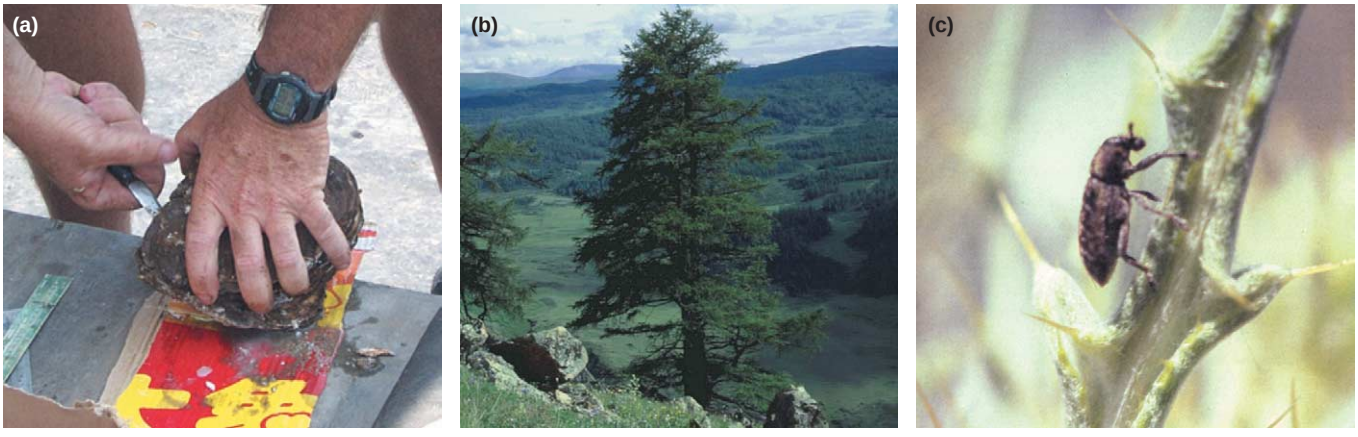

Figure 1. Examples of species that give cause for concern in the USA. **(a)** The Asian suminoe oyster *Crassostrea ariakensis* has already been introduced into Chesapeake Bay and is now the focus of a one-year environmental impact assessment. **(b)** The larch *Larix siberica* has been highlighted as a potential vector of invasive species. **(c)** The Eurasian weevil *Rhinocyllus conicus*, introduced originally to control populations of the musk thistle *Carduus nutans*, now threatens native thistle species. Reproduced with permission from (a) Loren Coen, (b) Oleg Kosterin, and (c) Svata Louda.

certain risks. In no instance was a quantification of risk or its reduction attempted.

Even this preliminary, qualitative risk assessment was quickly overtaken by events. When Robert Ehrlich became Governor in January 2003, the stance of Maryland changed dramatically, with the state now pursuing its own program of introduction of the suminoe oyster to Chesapeake Bay in advance of the NRC report [17]. Pressured by the Virginia Seafood Council to allow field trials, and with Maryland now unopposed, the NRC was asked for a preliminary report before completing its study. On 21 February 2003, the NRC listed risks of the proposed field trials, including the likelihood that fertile diploids would be released, and argued that there is insufficient scientific information to evaluate risks of the introduction, a statement repeated in the final report [16]. Nevertheless, on 25 February, the Virginia Marine Resources Commission voted to let the field test proceed, and oysters were distributed in the Bay and elsewhere. Thousands have been lost to the wild from ruptures of mesh bags, spillage during transfers, and because of equipment damage during Hurricane Isabel [18]. Now the US Army Corps of Engineers plus Virginia and Maryland agencies are conducting a one-year environmental impact assessment (rather than the five-year time frame advocated by the NRC) of risks associated with introducing fertile diploid *C. ariakensis* [19]. Should the suminoe oyster fail, there is no current reason why a version of this saga would not recur for another species; the general pathway of its introduction was never addressed.

Why the current system does not work

The oyster case exemplifies the domination of decisions by politics and the inadequacy of the current regulatory framework, including risk assessment procedures. In this instance, there is no legal requirement for states to wait for a risk assessment, even an abbreviated one, and no federal approval is needed for a state to introduce an animal that is not listed as 'injurious' under the Lacey Act. In any event, as noted for the carp, even if a species is 'injurious', a state need not limit its possession, and of course it could escape and reach another state (or be deliberately introduced). Similar cases have shown that objections by other states (or indeed nations) do not trump state rights [3].

The recent discovery of two parasitic protists (*Bonamia* spp.) in suminoe oysters grown off North Carolina [20] is also instructive. One or both parasites are suspected to have caused massive die-offs of the experimental *C. ariakensis*. Their origin is unknown, but native mollusk hosts are suspected. The concern now is that the infected *C. ariakensis* in North Carolina could spread the parasite to *C. ariakensis* (or other species) in Chesapeake Bay and beyond. Notably, the NRC tabulation of risks did not include such infection.

The above cases point to a reconsideration of risk assessment for introduced species. The presumption of innocence, although it accords with US jurisprudence, puts a heavy burden on stakeholders wishing to stop an introduction. Impacts of introduced species are idiosyncratic and often unpredictable [5,21], and our ecological knowledge of most species is insufficient to allow a well-informed opinion without substantial study. For most planned introductions, the NRC estimate of several years for a credible assessment of presumed innocence [16] is probably not far off the mark.

With respect to pathways that bring inadvertent introductions, assessing the presumption of innocence is even more onerous. First there is the question of which species are likely to move, with what probabilities, via a particular pathway. Gathering such information is possible but requires substantial effort. For example, a survey of floors of 3001 empty sea cargo containers to estimate the risk of bringing insects into Australia by this pathway found 7426 insects, either live or dead [22]. However, assessing the likelihood that any species will establish and become problematic is much harder (and was not attempted); in many cases, it might require an effort similar to that required for a credible risk assessment for the carp or oyster.

The problem imposed by the presumption of innocence is exacerbated by adoption of quantitative risk assessment as the means to determine levels of risk from an introduction. Not only is it difficult, if not impossible, to imagine all risks, but there is also a limit to how quantifiable certain risks are and difficulty in specifying the time frame over which impacts might be expected (Box 1). This is why current procedures rely heavily on qualitative estimates by experts: low, medium, high and the like, and on arbitrary algorithms to combine risks of various sorts and estimates of different experts; often, they can do no better. This is also partly why it is difficult for a nation to defend exclusion of a proposed introduced species, or product that might carry one, against a charge of economic protectionism; such a defense must be based on a quantitative risk assessment, and a valid assessment is probably impossible for most potential introduced species and pathways that might carry them. The move to exclude frozen Canadian salmon from Australia [23] is telling. Australians argued that such salmon had a substantial probability of introducing pathogens, a reasonable concern, as witness the devastating impact of whirling disease on rainbow trout in the USA, which reached North America in frozen trout from Scandinavia [24]. The Australians listed various possible risks, but they could not quantify them, and the appeal by Canada was sustained, partly on the grounds of absence of a quantitative risk assessment proving the danger, and partly because Australia does not subject other imports to the same high safety standards that it wished to impose on the salmon.

Risk assessments, essentially judgment calls, are subject to political influence, even if the judgments are expert judgments. It is always possible to find experts to support a position of little risk, even if they belong to a minority. As is seen in the carp and oyster cases, commercial stakeholders wishing to proceed with an introduction, and politicians who support them, can wield great power in transforming a judgment about risk into policy.

Is there an alternative?

In light of the increasing number of problematic introductions [21] and in spite of heightened publicity about them [25], the entire framework of presumption of innocence

and risk assessment has rarely been questioned. Its hold is so firm that, at times, authors espouse it in apparent contradiction to the very evidence they present. For instance, a recent NRC overview of prediction of invasion impacts by plants and plant pests [26] recognized the subjectivity of such assessments, the problem of political influence, the frequently arbitrary quantification and how it 'imparts to some policymakers and a large part of the public a scientific aura and a sense of knowledge that might not be warranted' [26]. Nevertheless, the authors concluded that pest risk assessments are crucial because they furnish a framework for gathering and synthesizing information.

The authors are correct that thorough, unbiased risk assessments force attention on many (but never all) risks that might attach to an introduction, as well as to information gaps that must be filled if risks are to be better understood and perhaps quantified. However, the near-impossibility nowadays of quantification and prediction means that risk assessments are *pro forma* preliminary steps that rarely, if ever, exclude introductions or close pathways, although they can lead to procedures that lessen some of the risks associated with them. In addition, the fact that these assessments are focused exclusively on the proposed introduction or pathway, rather than on the desired benefit (often economic) from the introduction or pathway, greatly constrains perspectives on how much risk as acceptable.

Alternatives assessments: an expanded approach to environmental risk?

O'Brien [27] suggests an expanded approach to environmental risk (although she does not apply it to introduced species), termed 'alternatives assessment', which would more properly embed risk assessment in decision-making processes. There are three key elements. First is an overarching role for the venerable (but controversial) precautionary principle (Box 3). Second is to focus on the goal of an action rather than on the action itself, and to ask how we can avoid or minimize damage while achieving that goal. Third is to consider a full range of alternative ways to achieve that goal. In fact, as it might apply to introduced species, 'alternatives assessment' need not be an alternative to risk assessment. Rather, it places risk assessment as currently practiced in an expanded context, by, for example, focusing on the goal of the introduction beyond just establishing the new species.

An example O'Brien gives concerns giving bovine growth hormone to cows to enhance milk production. She contends that enhanced rotational grazing among well-maintained pastures could accomplish the same increase in milk production. It is easy to think of similar situations in which wider consideration of alternatives to species introduction could provide insight. For example, Louda has called for consideration of a range of alternative actions when decisions are made about whether to introduce a biological control agent to manage an invasive pest [28]. For instance, the Eurasian weevil *Rhinocyllus conicus* (Figure 1) has been widely introduced in North America to control introduced musk thistle *Carduus nutans* and threatens native thistle species [28]. Louda contends that musk thistle is a pest only of mismanaged overgrazed pastures, and that native plants outcompete it in well-managed pastures [28]. In the carp example, this approach would mandate consideration of other ways to control trematodes or their snail hosts. In the oyster example, it would necessitate assessing risks of attempting to restore eastern oyster populations, including the risk that such attempts will fail.

Box 3. The precautionary principle

The precautionary principle adopted by the Rio Convention on Biodiversity (1992) says simply that precautionary measures are warranted even if some causal relationships have not been fully established, so as not to foreclose on future options by irrevocable action in the face of uncertainty. It has been interpreted in so many ways that its very mention can be controversial if it is not strictly defined [36].

However, the precautionary principle is not universally admired. The day before the Rio Convention was signed, a group of scientists distributed the Heidelberg Appeal, lambasting the principle as unscientific and potentially harmful to science. A current bête noire of environmentalists, Bjørn Lomborg, sees it as preventing proper prioritization of potential actions by assuming that local environmental protection should always trump all other considerations [37]. In its extreme form, it has been taken to imply banning all activities that might harm the environment, no matter with what probability [38]. A more moderate interpretation is that we should act if a hypothesized effect is serious and there is good *prima facie* evidence of a causal nexus, even if the matter is not completely settled scientifically [39].

Costs and benefits and risk assessment

Because the current method asks only about risks associated with an introduction, it does not consider risks associated with other ways in which the goals of an introduction (e.g. increased income for horticulturists) might be achieved, or who bears the costs if risks are realized, and who benefits from an introduction that is permitted. Costs and benefits are explicitly considered in decisions following from risk assessment, and at least sometimes in assessments themselves (as in the Soviet larch example). Benefits and costs of species introductions, whether they proceed as planned or cause unexpected damage, are unequally shared by different segments of society [29]. The problem that seems inadequately treated currently is that a substantial benefit that might accrue to a few has more political weight than a substantial cost that might be borne forever by all. We must ask if potential benefits to catfish farmers in Arkansas or seafood-packing houses in Virginia and Maryland should weigh so heavily as to risk permanent change to the entire Mississippi Basin or Eastern Seaboard. Certainly, risk assessments in those cases do not adequately address alternatives to introductions, doubtless because this was not the assessors' assigned task. However, the ultimate goal in each case is primarily the economic well being of an industry. In some instances, thinking far outside the box is warranted. For example, are there ways that catfish farmers can earn a living other than by rearing catfish in high-density, enclosed populations?

'Alternatives assessment' also invokes the controversial precautionary principle (Box 3). However, perhaps

OIRA Administrator Graham, the most important person, from the standpoint of US regulatory policy, takes a more nuanced stance [30] than do detractors of the principle‡. Arguing against the frequent perception that the European Union has increasingly adopted the precautionary principle in regulatory matters whereas the USA rejects it, Graham sees a useful role for the principle so long as hypothesized risks are not drawn from thin air, so long as uncertainty is just one factor considered in making decisions, and so long as cost–benefit analyses and risk assessments are conducted for all alternatives. This view is completely compatible with alternatives assessment for introduced species. Much rests on the exact interpretation of the precautionary principle. A reasonable interpretation is that incomplete knowledge should not automatically halt a proposed action, but that it is important to provide a margin of error and be wary of potentially harmful activities, particularly if effects are irrevocable and poorly understood. Graham's recognition that risks that cannot yet be proven or quantified have weight and his apparent openness to a wider conception of future risks and benefits at least suggest the possibility of a reconsideration of the process for permitting introductions.

Of course, for the process to produce more rational decisions about introductions, decision-makers who use risk assessments will have to be unbiased and have a degree of expertise about a complicated issue. This is not necessarily the case today. For instance, the Animal and Plant Health Inspection Service of the USDA, the main US agency that decides about introduction permits, has competing priorities: 'to facilitate exports, imports, and interstate commerce…' but also to 'reduce to the extent practicable, *as determined by the Secretary [of Agriculture]*, the risk of dissemination of plant pests or noxious weeds' ([26], my italics). This is a profoundly schizophrenic mission; an entity tasked with facilitating commerce should not also determine risks of commerce. I also suggest that the Secretary of Agriculture should not have the final word on what is practicable or desirable in terms of risk of introduction. The Secretary is but one of many stakeholders, a political appointee, and tightly wed to the current risk assessment approach. It is unlikely such a person would question its underlying tenets and appropriateness.

Conclusions

Risk assessment for introduced species in the USA has not succeeded in regulating the movement of species into the country, but an expanded approach entailing assessing alternatives to introduction, plus consideration of the probabilities of various costs and benefits associated with an introduction, could lead to better policies and permitting decisions. For such a method to work, political considerations must be minimized and decision-makers using the process should not be closely associated with persons or entities advocating introduction.

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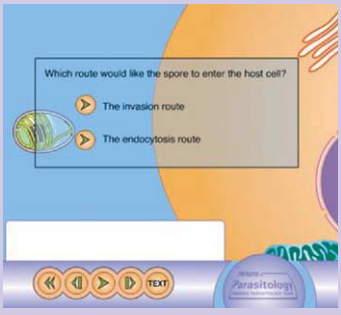

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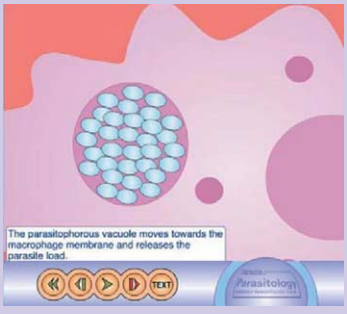

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