Hazard analysis and critical control point systems applied to public health risks: the example of seafood

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Summary
The authors describe the way in which the two components of risk analysis – risk assessment and risk management – can be used in conjunction with the hazard analysis and critical control points concept to determine the allocation of resources at potential critical control points. This approach is examined in the context of risks to human health associated with seafood, and in particular with regard to ciguatera poisoning.

Keywords

Introduction
There has been much recent discussion on how risk analysis ought to be included in hazard analysis and critical control point (HACCP) systems (8). The early development of HACCP principles did not include risk analysis; rather, the initial concept was to employ HACCPs to achieve a product with minimal, and preferably zero, defects. The use of HACCPs as a means of enhancing food safety was developed to ensure the safety of food intended for space travel. Prior to using an HACCP system, nearly half of the food produced for this purpose was destroyed in the course of testing, whether or not the food met the demanding specifications. Since that time, food firms have voluntarily adopted and integrated HACCP principles into their quality control systems as part of a profit maximising decision. The HACCP concept can take numerous forms: those developed as part of a profit maximising strategy will necessarily be different from those mandated by the Federal Government.

The application of one form of HACCP which has been made compulsory by the Food and Drug Administration (FDA) for over twenty years covers the manufacture of low acid canned foods (LACF) (2, 3). The FDA also established the first Government-mandated programme specifically to require HACCP for fish and fishery products. Just as the seafood HACCP rule 'evolved' from the LACF and current good manufacturing practice (CGMP) rules, so HACCP rules will evolve and future improvements, particularly for government-mandated regulations, are likely to be inspired by two particular aspects of risk analysis: risk assessment and risk management, and in particular benefit-cost analysis. These tools help to focus on the most serious hazards, which can then be managed in a cost-effective way.

The two Federally mandated HACCP regulations (excluding LACF), are the seafood rule implemented by the FDA (7) and the meat and poultry rule implemented by the United States Department of Agriculture (USDA) (11). These rules have only made use of the two types of analyses indirectly. Both rules, for example, required benefit-cost analysis to satisfy Presidential Executive Order 12866 (1) and both made some adjustments to regulations to ensure that benefits exceeded costs. However, as discussed below, both risk assessment and benefit-cost analysis (or some variant thereof) may ultimately be useful in determining some of the specific parameters of HACCP systems. The FDA and the USDA rules also used risk assessment indirectly for some of the hazards covered, such as pesticides. Following the release of results of a risk assessment, pesticides are now considered hazards. However, identification of hazard as such does not necessarily mean that the hazard becomes a candidate for HACCP. The combination of severity and probability may not be significant enough to warrant intensive monitoring and corrective action. This paper focuses on how risk assessment and benefit-cost analysis can be integrated into HACCP systems. Seafood is used as an example.
Federally mandated hazard analysis and critical control point regulations

As with any Federally mandated health and safety rule, regulations based on HACCP principles attempt to correct for health and safety externalities (costs to consumers which are not internalised in the production process by producers). In the case of seafood HACCPs, these externalities arise in the processing of food. Hazards in food are difficult to trace back to the producer. Therefore, in the mind of consumers, these hazards are not associated with producers and ultimately do not alter the willingness of consumers to pay for the product based on the risk incurred. Consequently, producers are not always sufficiently concerned about controlling the hazards to the same standard as a Government-mandated programme. If there was a zero possibility of tracing a case of illness back to a particular firm, there would be zero private benefit to the firm from including that hazard in an HACCP plan, as there would be no possibility of either liability or loss of reputation of the brand name. Even when firms invest in the use of HACCPs at some point in the production process, the resultant increase in quality is difficult to convey to consumers, which means that the costs cannot be carried over to the product, which in turn makes competition more difficult. Given the alternative, the firm does not expend resources to reduce the probability of illness or death and no business costs incurred by the control of those hazards need to be relayed to consumers.

The question of what incentives exist to encourage a firm to adopt HACCP-based food safety programmes must be raised. The possible answers include those given below.

Firstly, while it is impossible to trace all foodborne disease to manufacturers, the costs of recalls – in terms of both the recall and the disrepute – can be considerable. However, the situation has changed with the advent of gene probes which can determine whether or not a pathogen in a food originated in a particular production plant. The use of gene probes is becoming increasingly popular in commerce. In addition, if a manager has made a mistake which leads to a recall, his career may be ruined.

Secondly, early users of HACCP systems used the production process as a way of distinguishing their product for both the retail and further processing markets. This has probably been the strongest incentive for firms which have implemented HACCP systems voluntarily.

Thirdly, international requirements for HACCP-based regulations have forced some firms into adopting HACCP: in this instance, the only voluntary decision is whether or not to continue to market internationally. Firms which have adopted HACCP programmes for this purpose may now favour mandatory HACCP-based regulations so that similar costs are imposed on domestic rivals.

Finally, when a food safety scare does occur, firms marketing similar products may be affected by reduced sales as all are 'guilty by association'. For this reason, firms which have already implemented HACCP-based programmes may favour government-mandated HACCP regulations to eliminate 'free riders'. However, the more product differentiation there is in the market, the less this will be a factor.

Consumers who are fully informed of all the risks and the costs of mitigation would be unlikely to insist on 'zero risks'. Rather, a reduction of risks to a level beyond which further risk reduction would incur unjustifiable costs would probably suffice. Government intervention in the market attempts to prevent that externality by forcing producers to take the kind of care with the product that fully informed consumers would display through purchase behaviour.

However, just as private manufacturers may not cater sufficiently for food safety externalities and may prefer to under-invest, the reverse is true for government managers. Most governments are 'conservative' on matters relating to public health and tend to over-invest in this field. Even if no real incentives exist, governments always prefer to invest more in public health when there are public health externalities which imply costs that firms do not, by definition, internalise.

This divided outlook over how to manage public health hazards is acutely demonstrated when uncertainty prevails, which is all of the time. Management of uncertainty is the task of the risk manager and, in the case of food safety, the responsibility is shared between government and industry. In the HACCP rules mentioned above, the FDA and the USDA stated that manufacturers must exercise some control over a hazard if there is a 'reasonable probability' of the hazard being present in the finished product. However, considerable uncertainty about when a particular hazard will be identified in a food means that there will inevitably be disagreement over what constitutes a reasonable probability (9).

Furthermore, even if a specified, acceptable level of risk could be agreed on, such as reducing the probability of a pathogen being present at greater than 100 colony-forming units (CFUs) per gram of food to less than one in one million, there will always be uncertainty as to whether or not that level has been achieved. Moreover, uncertainty will always remain regarding the magnitude of effects such probability presents, both to the general population and to sensitive or highly exposed individuals. Even if the distributions of risk were fully known, there would still be disagreement over how to manage the distribution of benefits to the high-risk sub-populations (i.e., the variability).

Thus, where public and private costs diverge, firms (which only internalise private costs) will prefer to invest relatively little in managing the hazard. Government, entrusted with
accounting for all costs of illness, will prefer that investments cover all public health externalities. In addition, where there is uncertainty, firms may favour less investment (to meet the needs of stockholders) and government managers may prefer greater investment because of the structure of bureaucratic incentives.

There is no simple answer to how risk and uncertainty should be managed, but risk assessment and benefit-cost analysis can help to frame the debate between government and industry. Risk assessment, if performed properly, can quantify what is known and illuminate the areas in which more data – obtained through greater investment – can reduce the uncertainty and can ultimately contribute to more responsible management of risks. Benefit-cost analysis assists in clarifying the advantages and disadvantages of choosing between various policy options by identifying the benefits and costs of each. In addition, benefit-cost analysis may go further and reveal who benefits from a particular way of managing uncertainty and who pays the cost. Although this is not a perfect solution, addressing the debate by using common terms of risks, costs and benefits can serve to reduce the level of dispute.

Risk analysis

Risk analysis is a field of analysis which includes risk assessment, risk management and risk communication. As such, the discipline contains multiple tools to identify, quantify and suggest ways of managing human and ecological risks.

Risk assessment

The purpose of risk assessment is to answer specific questions concerning risk which are posed by the risk manager. The answers to such questions generally involve estimating the probability and severity of a particular risk. Some typical risk assessment questions include:

- What is the risk per unit of time of exposure to a particular hazard?
- What is the upper bound risk, either to the 90th percentile of exposure or to the most sensitive sub-group?
- What are the largest sources of risk (relative risks) in a process?

Risk assessment questions are posed to help a risk manager to establish either mitigation controls or targets for risk reduction (for example, tolerance levels).

Risk management/benefit-cost analysis

Risk management involves decisions on how to manage the risk identified in risk assessment. Economic analysis, particularly benefit-cost analysis, is a powerful tool designed to support risk management decisions. The purpose of benefit-cost analysis is to determine, from a set of policy options, the option which maximises net benefits (i.e., benefits minus costs). The analysis of benefits takes the outcome of one type of risk assessment – an estimate of the baseline risk – as a starting point. From this point, a benefits analysis will calculate the reduction in the baseline risk which might result from various policy options and will estimate the value of such reductions to society. Most often, this is conducted by examining market choices in which people pay more for safer goods or in which workers demand a higher wage for performing more hazardous jobs. Costs are equally difficult to measure, as the economic concept of ‘cost’ is defined as an unselected choice. In an ideal world, where competition drives the price of goods down to equal their marginal value, this is measured by the costs of compliance with regulations, which uses funds which could be employed for another purpose. Both benefits and costs are generally measured as ‘expected value’: that is, neither a best nor worst case.

An important aspect of benefit-cost analysis is that the marginal value of an activity can be measured, not the average or total value. In other words, each additional level of risk reduction has some benefit attached and some cost to achieve that reduction. The comparison is made between those marginal benefits and costs. In fact, risk assessment and cost-benefit analysis, besides being interdependent, have much in common. Firstly, neither is science in the traditional sense of studying a refutable hypothesis: rather, both try to separate the known from the unknown. The ‘unknown’ is the uncertainty and both risk assessment and cost-benefit analysis often contain much uncertainty. Both seek to quantify answers to the questions posed by risk managers or, if the answers cannot be quantified, to answer qualitatively in a fashion which facilitates decision-making. As stated earlier, HACCP principles were not designed for either benefit-cost analysis or risk assessment. HACCPs provide a quality control tool designed to replace or supplement end-point sampling, particularly where such sampling is inefficient.

Risk analysis and hazard analysis and critical control points

The HACCP system is a seven-step process designed to manage risk, as follows:

a) hazard analysis
b) critical control point identification
c) establishment of critical limits
d) monitoring procedures
e) corrective actions
f) record-keeping
g) verification procedures.
The purpose of HACCP is to manage risk, which requires investments in capital and labour (costs), and to produce benefits in terms of reduced risk of foodborne disease or illness resulting from chemical, physical or biological hazards. However, how much money will be invested in managing a particular hazard will depend on how conservative or liberal the risk manager chooses to be. Figure 1 illustrates the contrasting attitudes towards managing risks which would emerge as disagreements over the stringency within HACCP control measures.

Fig. 1
Diagram of the uncertainty of the marginal costs of a potential regulation

The two curves labelled $MC_H$ and $MC_L$ represent the upper and lower bounds (the range of uncertainty), respectively, of the marginal costs of a potential regulation. Within each particular curve, marginal costs increase more rapidly as the regulation becomes more stringent, i.e., a movement to the right on the curve. The other two curves represent the upper ($MB_H$) and lower ($MB_L$) bounds of the marginal benefits which would accompany an increase in the stringency of a requirement. As shown, marginal benefits decline more rapidly as the stringency of the regulation increases. The point $S_L$ represents a case in which the regulation is moderately stringent, as might be chosen by a risk manager who believes that marginal benefits will be lowest and marginal costs will be highest. As discussed earlier, in the case of public health externalities which firms do not account for, the risk managers of these firms will prefer to establish a tolerance at or to the left of the point $S_L$. On the other hand, a government risk manager would prefer to believe that potential marginal benefits would be high ($MB_H$) and marginal costs low so that a position at or to the right of $S_H$ would be preferred.

Any position to the right of $S_H$ or to the left of $S_L$ is inferior to a position between these two points. At point $S_{LL}$, for example, the stringency of the regulation can be increased and the (lowest) marginal benefits will exceed the (highest) marginal costs, even when the uncertainty factor is taken into consideration. Conversely, at point $S_{HH}$, the marginal benefits of decreasing the stringency will exceed the marginal costs. By generating such information and agreeing that marginal benefits should equal marginal costs, the inferior stringencies to the left of $S_L$ and to the right of $S_H$ can be eliminated. Thus, while the problem of handling uncertainty is not completely resolved, benefit-cost analysis can provide a format for honest discussion.

The structure of the law is the mechanism which will ultimately decide how such disputes are to be resolved. Essentially, uncertainty is managed by assigning 'ownership' of the burden of proof to either the government or the regulated body: these two fundamentally different ways of managing uncertainty associated with risk are a result of the way in which Federal law has evolved. This burden of proof will ultimately determine the levels at which safety tolerances are established. For example, producers of new food and colour additives are obliged to prove that an additive is safe before it can be introduced to the food supply. As the burden (and thus the cost) of proof lies with the manufacturer, the government chooses to regulate conservatively. In Figure 1, this is represented by a position at or to the right of the point $S_H$. On the other hand, the government must establish that a compound is unsafe before taking action on a previously sanctioned compound which is already present in the food supply. In this case, the obligation to produce data to close the uncertainty gap falls on the government, and, where this is difficult, the legal tolerance level is likely to be higher (low stringency, $S_L$) than if industry were under the same obligation. Imports are a special case in that the importers have the burden of proof for all hazards. These asymmetric laws were probably established by Congress based on the ease of avoidability by industry rather than the risk presented by the classes of compounds. From the perspective of the government, prohibiting the use of an additive is much easier than removing a confounding contaminant or microorganism which will be difficult to locate in the food supply and which will be costly to control. In each case, the body responsible for generating the information and reducing uncertainty will depend on who is charged with 'owning' the uncertainty.

The relative stringency associated with HACCP-based systems can be modified by adding or eliminating one of the seven steps described above or, more modestly, by altering the level of effort expended at any of the seven steps. For example, a step could be added following the hazard analysis which provides for a qualitative or quantitative benefit-cost test. Such a step might revolve around attempting to ask two questions beyond whether or not a hazard exists, as follows:

- Are there any effective methods of controlling the hazard to reduce the existing risk by any meaningful degree?
- If such methods exist, does the cost involved exceed the private and societal benefits which would be derived from the use of these methods?
Alternatively, for example, some small firms with simple processes may not need to have a separate step to verify that the HACCP plan is being followed because the manager oversees every step on a daily basis. In this case, verification is taking place constantly and the costs of a formal weekly verification step would not necessarily exceed any possible benefits: therefore, the weekly step could be eliminated.

The latter possibility, that HACCP as a seven-step umbrella concept permits a broad interpretation for implementation at various margins, was suggested earlier (in the discussion of the reasons for a difference between a private voluntary programme and a mandatory government programme). Some of these margins include the following:
- selection of safety versus quality hazards as critical control points
- level of risk of the hazard which is to be managed
- frequency of monitoring
- severity of critical limits
- extent of back-up product testing
- number of people trained to perform tests and frequency of retraining
- severity of corrective action
- frequency and intensity of validation and verification
- volume of investment in good manufacturing practices (as a complement to HACCP).

From this partial list of variable HACCP margins, the vast potential for variation in the way HACCPs are implemented can be seen, even when the currently envisioned seven steps are applied. For example, the cost of monitoring critical control points may vary dramatically between plants, depending on how plants choose to monitor, what kind of monitoring technology is used, etc. Alternatively, many critical control points have fixed costs (costs which do not vary with the level of output) and these do not necessarily vary between large and small plants.

Hazard analysis and critical control points for seafood production

The Fish and Fishery Products Rule implemented by the FDA, effective on 18 December 1997, is the first attempt to impose, on manufacturers, the use of HACCP principles to control hazards in a product (7). The manufacturers affected by the rule include processors of all types of seafood, including finfish and shellfish. In addition to outlining the HACCP procedures which processors must follow, the FDA has provided processors with a 'hazards guide', which covers all types of seafood, together with possible hazards which should be considered in the hazard analysis to determine whether or not there is a reasonable probability of the presence of that hazard in the finished food product. The risks associated with seafood, as with other foods, involve considerable uncertainty and this has been reflected in the regulatory impact analysis which analysed the HACCP rule. Some risks are well documented and the number of cases is known with a greater degree of certainty: for example, the risk posed (primarily to immuno-compromised individuals) by the consumption of raw oysters harvested from the Gulf of Mexico during periods when the water was warm enough to support growth of the pathogen *Vibrio vulnificus*. Other risks, such as the number of cases of people affected by the Norwalk virus, are surrounded by considerable uncertainty. Many of the hazards associated with seafood, such as ciguatera, are somewhat unpredictable as they change with the conditions in the sea, which are difficult to monitor. Other hazards arise through mishandling by fishermen or processors: one such hazard is scombrototoxic poisoning.

Both the preliminary and final regulatory impact analyses of the FDA seafood HACCP rule estimated the likely numbers of the following:

a) the annual number of illnesses resulting from consumption of seafood products
b) the number of illnesses which might reasonably be reduced as a result of an HACCP programme
c) the economic benefits the implementation of the HACCP rule would confer to consumers.

This type of analysis, explained below, can be used to establish limits for the effort (costs) which is invested in HACCP programmes to cover social benefits. These estimates are reproduced in Table I.

From these estimates, the FDA experts on HACCPs and seafood attempted to estimate how effective HACCP programmes would be for processors in terms of reducing these illnesses. The FDA reported that:

'The agency followed three steps to quantify the safety benefits of HACCP for processors:

a) identify all significant hazards associated with seafood safety and establish the baseline number of incidents of each hazard in the population of the USA
b) estimate the reduction in the number of incidents of each hazard that HACCP is expected to accomplish
c) quantify the benefit of the reduced illnesses and deaths.

In all three steps, FDA acknowledges that there is substantial uncertainty' (6).

To estimate the number of cases which could be eliminated through the use of an HACCP programme, the percentage of
cases which are caused by retailers or consumers, or which arise only through recreational channels, must be taken into consideration.

The preliminary regulatory impact analysis of the seafood HACCP rule also stated that:

"Risk from seafood may be introduced at any stage from water to consumption. The source of the most significant risk varies from species to species. However, all seafood is harvested from either an aquaculture or a "wild" environment. Reduction of risk at the harvest stage relies on, among other things, current identification of waters that are high risk and avoidance of fishing in those areas. Processors may exercise control at this stage by purchasing from harvesters that exercise appropriate controls, by analytical testing, or by taking advantage of Federal or State monitoring activities. Risk introduced at the processor stage is controlled by process control. Finally, both consumers and retailers may introduce risk by handling and cooking errors. Of course, fish must be transported between each of these three stages and hazard may be introduced at the transportation stage as well." (5).

### Table I
Significant hazards associated with seafood from both recreational and commercial sources (5, 6)

<table>
<thead>
<tr>
<th>Hazards</th>
<th>Reported cases (annual)</th>
<th>Estimated cases (annual)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anasakis simplex</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Campylobacter jejuni</td>
<td>2</td>
<td>200</td>
</tr>
<tr>
<td>Ciguatera poisoning</td>
<td>800</td>
<td>1,600</td>
</tr>
<tr>
<td>Clostridium botulinum</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>Clostridium perfringens</td>
<td>7</td>
<td>200</td>
</tr>
<tr>
<td>Diphyllobothrium latum</td>
<td>Unknown</td>
<td>1,000</td>
</tr>
<tr>
<td>Giardia lamblia</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>Hepatitis A virus</td>
<td>9</td>
<td>1,000</td>
</tr>
<tr>
<td>Norwalk virus</td>
<td>12</td>
<td>100,300</td>
</tr>
<tr>
<td>Vibrio spp. (excluding V. vulnificus)</td>
<td>43</td>
<td>1,000</td>
</tr>
<tr>
<td>Paralytic shellfish poisoning</td>
<td>13</td>
<td>10</td>
</tr>
<tr>
<td>Non-Typhi Salmonella</td>
<td>2</td>
<td>200</td>
</tr>
<tr>
<td>Scombrotoxin poisoning</td>
<td>796</td>
<td>8,000</td>
</tr>
<tr>
<td>Shigella</td>
<td>7</td>
<td>200</td>
</tr>
<tr>
<td>Vibrio vulnificus</td>
<td>24</td>
<td>60</td>
</tr>
<tr>
<td>Other marine toxins</td>
<td>48</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>1,772</td>
<td>113,630</td>
</tr>
</tbody>
</table>

Determining a point in the system at which risk can be controlled creates a need to know the harvesting and marketing methods used for fish. Table II illustrates these methods (5).

### Table II
Harvesting and marketing methods for fish in the United States of America (5)

<table>
<thead>
<tr>
<th>Origin and type of fish product</th>
<th>Volume of total fish sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recreational fishing</td>
<td>20%</td>
</tr>
<tr>
<td>Commercial fishing</td>
<td></td>
</tr>
<tr>
<td>Frozen</td>
<td>47%</td>
</tr>
<tr>
<td>Canned</td>
<td>15%</td>
</tr>
<tr>
<td>Raw</td>
<td>14%</td>
</tr>
<tr>
<td>Smoked or brined</td>
<td>2%</td>
</tr>
<tr>
<td>Cooked but not canned</td>
<td>2%</td>
</tr>
<tr>
<td>Other</td>
<td>2%</td>
</tr>
</tbody>
</table>

### Ciguatoxin: a sample problem
The naturally-occurring toxin, ciguatera, is used here to demonstrate how risk assessment and benefit-cost analysis can be employed effectively within the HACCP umbrella.

Ciguatoxin is produced by microscopic organisms which grow on the surface of marine algae commonly found in reef areas of the ocean. The poison enters reef fish which feed on the algae, and can then accumulate in larger fish as these in turn eat the reef fish. The toxin is most common in certain tropical reef areas, such as the Caribbean region. Ciguatoxic fish cannot be detected by appearance, taste or smell, and neither raw nor cooked whole fish, or fillets or parts of the fish, show signs of spoilage, discoloration or deterioration. Furthermore, the toxins present cannot be destroyed or removed by cooking or freezing.

The symptoms of ciguatoxic poisoning include the following: numbness and tingling around the mouth, hands and feet; joint and muscle pains with weakness or cramps; vomiting, diarrhoea, chills, itching, headaches, sweating and dizziness; reversal of temperature sensation, where cold objects feel hot and hot objects feel cold. The symptoms may last a week or many months. There appears to be a positive dose/response relation and this is supported by the evidence that repeated exposures tend to make the symptoms more intense and appear faster after exposure, normally two to five hours after consuming the fish. There is no known treatment except to make the victim comfortable and to ensure that the symptoms are not aggravated by consumption of fish, fish sauces, shellfish, alcohol or nuts for several months after the incident (4).

There are three points at which control measures might be instituted to control ciguatoxin, as follows:

### Harvest
The main areas in which ciguatoxic fish have been caught are tropical to subtropical Pacific and Caribbean islands. Reported illnesses also indicate that southern Florida, southern California, Hawaii, the United States Virgin Islands
and Guam are the principal areas of the USA in which fish from these tropical sources are consumed. On a local level, there are on-going efforts by authorities to keep records of the reefs on which commercial fishermen have found ciguatoxic fish. The most reliable information on the location of ciguatoxic reefs is derived from the experience of commercial fishermen. One control step is to ensure that sports fishermen (who sometimes sell their catch) remain informed. In addition, marine researchers can continue to study the species which seem to be most affected.

Many species of fish have been implicated as carriers of the toxin. However, additional careful study may help assign probabilities to those species most frequently contaminated, which include barracuda (Sphyraena spp.), snapper (e.g., Lutjanus spp., Etelis spp., Pristipamoides spp.), amberjack (Seriola spp.), surgeonfish (Acanthurus coeruleus) (in the South Pacific only) and grouper (e.g., Cephalopholis spp., Epinephelus spp., Mycteroperca spp.). These species are generally found near coral reefs between 35°N and 35°S latitude. According to Travel Health Online, the documentation, verification and utility of a reliable ciguatoxic fish list is seriously compromised by the diversity of fish species and variable nomenclature. For example, local fishermen may refer to a variety of fish as ‘jacks’ or ‘snappers’ when these are actually mackerel, wrasse or other species. Certain species of snapper and grouper are never implicated in ciguatera, yet their popular reputation suffers from species misidentification.

Thus, at the harvest control point there are a number of investments which could be made, for example:

- research into determining the probabilities that various species will be contaminated with the toxin
- more sampling and up-to-date identification of contaminated areas
- better dissemination of knowledge from commercial to sports fishermen in areas which have been identified as contaminated
- enforcement by authorities to ensure that fishermen do not fish in those areas.

**Receipt**

The possibility remains that some sports fishermen, and perhaps even some commercial fishermen, will not have up-to-date information or, alternatively, may prefer to fish where fish are abundant because no one else is fishing there, i.e., on ciguatoxic reefs. Thus, another control point is the point at which retailers, restaurants and processors receive fish. These groups can insist on seeing records that document the location of the catch (this is in fact obligatory under the new FDA rule). Investment could include:

- tests to check whether or not the fish is contaminated
- inspection of records to determine whether the fish has been taken from a safe area.

**Consumption**

Consumers affected by ciguatoxic poisoning may aggravate the symptoms by consuming more ciguatoxic fish, thus the choice can be made not to eat these fish. Some consumers may prefer not to eat any fish associated with ciguatoxic poisoning caught in waters which may harbour ciguatoxic fish. Labelling fish which may potentially contain this poison helps consumers make risk choices. Investment in this critical control point could include:

- studies to determine whether there is a sensitive sub-population
- education for consumers regarding the risk of ciguatoxin poisoning from certain fish and also the risk of exacerbating an intoxication by receiving another dose
- labelling fish in restaurants and retail establishments according to the risk of ciguatoxic poisoning.

Risk assessment can help determine, at each critical control point, which activities are likely to be effective in controlling the risk.

In the final regulatory impact analysis of the seafood HACCP rule, the FDA estimated that 1,600 cases of ciguatoxic poisoning occur in the USA each year. There is considerable uncertainty about this number and the true range may be between 500 and 8,000 cases. The estimated cost per case amounted to US$12,875, so that the annual economic benefits which would result from the elimination of this problem range from US$6 million to US$103 million. These figures represent the upper bound expenditures which society, governments, academia, consumers and the industry should expend collectively to eliminate this problem. In other words, the combined costs of all critical control points, research and government expenditures should equal but not exceed these amounts. However, if the assumption were made that research could solve the problem in one year, the discounted value of the benefits ranges from US$92 million to US$1,471 million, which would justify a considerable amount of research.

Ideally, the net benefits of investments to control ciguatoxin should be maximised, or:

\[
\text{Max NB} = [q_h(R)\nu_i - c_h + [q_r(R)\nu_r - c_r + [q_c(R)\nu_c - c_c]
\]

where:

- \( q_h \) = the estimate of the amount by which the risk can be reduced from the baseline risk, \( R \) at step \( i \) (i = h, r, c)
- \( \nu_i \) = the value of the risk reduction at step \( i \)
- \( c_i \) = the cost of the risk reduction at step \( i \).

An alternative way to approach the above model is that society should allocate up to \( q_t(R)\nu_i \) for marginal benefits to equal marginal costs. Note the value for each critical control point, as follows:

\[
q_t(R)\nu_i - c_i > 0.
\]
If the value is less than zero, the implication is that spending any amount of money on the particular critical control point is not worthwhile. The fact that each $q_i$ is a conditional probability distribution, dependent on the effects of other $q_i$ values, should also be noted. Thus, if a rapid and inexpensive method is developed for testing for ciguatera, expenditure to control the preparation of seafood products for this toxin may not be cost-effective.

In this example, trial values can be assigned to determine how this exercise might work. If:

$q_h = 0.05$ to $0.15$
$q_r = 0.01$ to $0.05$
$q_c = 0.005$ to $0.01$

the potential benefits for society of the critical control points would be those demonstrated in Table III.

### Table III

<table>
<thead>
<tr>
<th>Critical control point</th>
<th>Minimum value (US$)</th>
<th>Maximum value (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvest</td>
<td>322,000</td>
<td>15,450,000</td>
</tr>
<tr>
<td>Receipt</td>
<td>64,000</td>
<td>5,150,000</td>
</tr>
<tr>
<td>Consumption</td>
<td>32,500</td>
<td>1,030,000</td>
</tr>
</tbody>
</table>

Although many species have been associated with ciguatera poisoning, a limited number account for the majority of illnesses. Those species, as mentioned above, include barracuda, snapper, amberjack, surgeonfish and grouper. Annual consumption of these fish in the USA is approximately 3,000,000 kg. Taking these data into account, the amount which should be spent so that marginal costs would equal marginal benefits for each of the critical control points is shown in Table IV.

For example, in accordance with the sample figures given above, the receipt critical control point should spend between US$0.02 and US$1.89 per kg of fish each year to ensure that the seafood originates from safe reefs. These margins may be sub-divided further into the different potential investments within each critical control point where something is known of the relative efficiency of the various investments. The exact amount to be spent within this range would need to be established, but at least risk assessment and benefit-cost analysis would establish boundaries on the debate.

### Table IV

<table>
<thead>
<tr>
<th>Critical control point</th>
<th>Lower bound (US$/kg)</th>
<th>Upper bound (US$/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvest</td>
<td>0.11</td>
<td>5.72</td>
</tr>
<tr>
<td>Receipt</td>
<td>0.02</td>
<td>1.89</td>
</tr>
<tr>
<td>Consumption</td>
<td>0.01</td>
<td>0.37</td>
</tr>
</tbody>
</table>

### Conclusion

There is a natural division between parties which are profit maximisers and parties which must account for all social effects involved in the amount of money to be invested in food safety. That division grows larger as the firm is further removed from accountability in the market or in the courts. The problem is then how to determine how much should be invested in food safety when uncertainty exists concerning the probability that a hazard will occur. Risk assessment and benefit-cost analysis can help determine the parameters of the debate. Ultimately, the amount to be invested within the range of uncertainty will most probably be decided according to which party is responsible for overcoming the uncertainty. If a firm must prove that a product is safe before marketing is permitted by government, more will be invested: if government must prove the product is unsafe, less will be invested.

### Acknowledgements

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La méthode de l’analyse des risques, points critiques pour leur maîtrise en santé publique : l’exemple des risques liés aux produits de la mer

R.A. Williams & D.J. Zorn

Résumé
Les auteurs montrent comment les deux composantes de l’analyse des risques — à savoir l’évaluation et la gestion des risques — peuvent être utilisées en association avec la méthode de l’analyse des risques, points critiques pour leur maîtrise, afin de déterminer les ressources devant être affectées en priorité à tel ou tel point de contrôle critique. Pour illustrer leur démonstration, les auteurs prennent l’exemple des risques que peuvent présenter, pour la santé publique, les fruits de mer et en particulier l’intoxication par la ciguatera.

Mots-clés
Analyse coûts-bénéfices — Analyse des risques — Analyse des risques, points critiques pour leur maîtrise — Ciguatera — Gestion des risques — Produits de la mer — Santé publique.

Sistemas de análisis de riesgos y control de puntos críticos aplicados a los riesgos de salud pública: el ejemplo de los alimentos de origen marino

R.A. Williams & D.J. Zorn

Resumen
Los autores describen la forma en que los dos componentes del análisis de riesgos — la evaluación de riesgos y el manejo de riesgos — pueden utilizarse y combinarse con el concepto de análisis de riesgos y control de puntos críticos para determinar la distribución óptima de recursos en posibles puntos críticos de control. Se ilustra este concepto en el contexto de los riesgos que plantean los alimentos de origen marino para la salud humana, especialmente en lo que se refiere a la ciguatera.

Palabras clave
Alimentos de origen marino — Análisis de costo-beneficio — Análisis de riesgos — Análisis de riesgos y control de puntos críticos — Ciguatera — Manejo de riesgos — Salud pública.
References


