RISK ANALYSIS ON EPIDEMIOLOGICAL MODELS AS A BASIS FOR THE MODERNIZATION OF CURRENT MEAT INSPECTION

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SUMMARY

There is a concensus of opinion that current meat inspection is no longer adequate in protecting public health. Similarly, it is agreed upon that there is a lack of knowledge with regard to the actual magnitude of risks to be associated with the consumption of meat. Scientifically validated (quantitative) assessments of risks are, however, prerequisites for the design of a really effective and flexible long-term system of safety and quality assurance of meat. The completion of highly structured, elaborate descriptive epidemiological models from stable to table can be considered as the first logical step in conducting such quantitative risk analyses. The advantage of this approach is that it not only facilitates validated estimations of the effects that certain control measures may have, but also, when risks can not exactly be quantified, makes it possible to use more semi-quantitative approaches of risk analysis and risk management, such as the HACCP approach. Some results of an epidemiological model of *Salmonella* spp. in the Netherlands are used to illustrate this.

INTRODUCTION

The methods and design of Western European meat inspection originate from the beginning of this century, when it became clear that meat could play a role in the transmission of disease, and that consumers and commerce, viz. free trade of animals, meat and meat products, needed some sort of safety and quality assurance. Especially in the past decades, however, there have been such enormous changes in the industrialised countries regarding animal husbandry and thereby associated public health risks, that current meat inspection procedures can no longer be considered adequate in protecting public health. In addition, there is a substantial lack of knowledge concerning the actual magnitude of human health risks to be associated with the production and consumption of meat. It is therefore agreed that current meat inspection procedures should be reviewed, and that future safety and quality assurance systems should be designed on the basis of formal (quantitative) analyses of consumer health hazards (Anon. 1985, Anon. 1987, Hathaway et al. 1988, Hatahaway and McKenzie 1991, Berends et al. 1993, Snijders et al. 1993a,b, Berends and Snijders 1994). Alhough several expert panels have suggested that descriptive models regarding the fate of potentially harmful agents in the entire chain from stable to table may be considered as one of the most powerful tools for analysing and managing human health hazards to be associated with the consumption of meat (Anon. 1985, Anon. 1987), very few attempts have been made to verify whether such an approach would be feasible and which "methodology" this would require (Hathaway et al. 1988, Hathaway and McKenzie 1991, Berends et al. 1993, Berends and Snijders 1994). As a result, there is no actual experience - let alone a standardised "methodology" - concerning the analysis of human health risks associated with the production and consumption of meat via descriptive epidemiological models (Berends et al. 1993, Berends and Snijders 1994). Because of this, the Department of the Science of Food of Animal Origin of the Faculty of Veterinary Medicine of Utrecht University in the Netherlands decided to start the research project "Risk Analysis as a Basis for the Modernization of Meat Inspection Systems".

Some results of the first phase of this project will be discussed in this paper. The main goals of this phase were: 1. to determine whether the completion of highly structured, elaborate descriptive epidemiological models from stable to table would be a feasible and practical approach, 2. to develop a more or less standardised working method and terminology for this proces of model building and subsequent risk analysis, and 3. to determine to what extent it would be possible to quantify certain health hazards, or, if an exact quantification would appear to fail, to determine whether the approach followed would be suitable for a more semi-quantitative analysis, such as with the HACCP approach. For this, the actual completion of a highly structured descriptive epidemiological model for *Salmonella* spp. from stable to table in the chain of pork production in the Netherlands was used as a "test-case".

MATERIALS AND METHODS

The project is mainly based on literature research. In this first phase the search for literature concentrated on a period that stretched from the mid-fifties up to and including the nineties, with emphasis on the past fifteen years.

To ensure that practically all relevant literature would be included, the search made use of both the nationwide network of the computerised literature data bases of the Dutch universities and the commercially available CD-ROM based systems of FSTA; AGRICOLA; CURRENT CONTENTS; MED-LINE and CAB.

For the first phase a total of approximately 6000 papers and book texts were screened in 4 steps. Ultimately, the data of circa 400 papers and book texts were used.

RESULTS

The developed general approach

Concerning the construction of models especially intended for the assessment and management of risks associated with the production and consumption of meat, figure 1 displays the developed "general aproach". Especially the practical experiences with the completion of the model for *Salmonella* spp. have contributed to this.

The models as such can be expressed graphically, e.g. as a kind of flow diagram, or as text only. The advantages of a graphic presentation are that the appearance of risks at some stage in the chain from conception to consumption and the possible increases or decreases can be displayed clearly. On the other hand, only with a literal description of events it is possible to describe, analyse and quantify pathways, causes and effects as well as the underlying mechanisms in great detail. This is a prerequisite for an amply documented scientific validation of the model as well as the risk analyses. Only then will it also be possible not only to properly motivate possible choices made in risk management policy, but also to communicate them with credibility to the general public, for example.

The purpose of a *draft model* is to bring a first structure into the descriptive epidemiological model and ways of reasoning. Existing general knowledge about a certain agent or group of agents can be the basis. This can serve as a framework for the further completion of the model. To increase "workability" it is best to subdivide the entire chain of meat production and consumption into several links, e.g. the farm phase, the transport phase, the slaughter phase and so forth.

With *formalisation of the model* it is meant that the draft model becomes filled in with as much valid quantitative scientific data as can be found. The purpose is to document the state of the art in knowledge concerning epidemiological pathways, dose-effect relationships in humans and animals, the measure in which the agent is present at certain stages from conception to consumption, factors that influence its presence or absence, and so forth. Because quantification of causes, effects and risks is an important goal, only the data of research that is satisfactory concerning statistical and methodological aspects may be included in the model (Anon. 1985, Anon. 1987, Tardiff and Rodricks 1987, Berends et al. 1993).

Implementation of the formalised model is here defined as the actual systematic analysis. It must be aimed at: i) the identification of the moment(s) the agent enters, or can enter, the chain of meat production and consumption, ii) the identification and quantification of the effects certain factors have, or may have, at the presence or absence of the agent in a particular stage, and/or iii) the effects certain factors have, or may have, at dose-effect relationships, and iiii) the assessment of the probability that consumers, or certain vulnerable subgroups of consumers, will experience adverse health effects (Anon. 1985, Anon. 1987, Tardiff and Rodricks 1987, Berends et al. 1993,).

At least as important is, however, that the analysis indicates where there is a lack of knowledge. This is not only needed to set priorities regarding necessary further research, but also to indicate which margins of uncertainty have to be taken into account.

Which statistical/epidemiological method can be used for an analysis is entirely dependent on the amount and quality of the data obtained. This may lead to the situation that "black box" approaches or educated guesses are needed to determine certain relationships between causes, factors and effects. This is permitted, provided that the assumptions made are specified into detail and amply supported by data from the formalised model.

In addition, mathematical (simulation) models are here considered to be a numerical expression of an implemented formalised model.

An aspect of model building that is absolutely crucial is the *constant verification and validation* of the model itself. After all, the purpose of the model is that it displays an accurate picture of the current situation and that the subsequent analyses lead to ways of solving our current problems concerning the safety assurance of meat. Validation and verification can be carried out by comparison of the model with other models, by comparison of the outcomes of predictions or estimations etc. with data from the formalised model (internal validation), and by consulting experts (external validation).

Secondary, or further use of the model is defined as the use of the implemented formalised model for, for example, the design of a set of control measures, codes of good manufacturing practices (GMP-codes) and the design of a set of criteria with which the effectivity of these control measures can be assessed. If it is possible to construct a plausible mathematical model, it will be possible to calculate the effects of certain control measures in advance, and thus indicate what the effects of these measures will be under a given set of circumstances. For example, in the case that small changes in the value of a certain parameter have a tremendous effect on the outcome of the mathematical model this may lead to the conclusion that control measures with regard to that parameter will be most effective. Mathematical models will also facilitate cost-benefit analyses.

Some results regarding Salmonella in pigs and on pork in the Netherlands

How a graphic expression of an implemented formalised descriptive epidemiological model may look is illustrated in figure 2. This is the model constructed for *Salmonella* spp. from stable to table in pig husbandry in the Netherlands. It summarises the results of analyses. What it tries to make clear is that 1. the ultimate consumer risks regarding infections with *Salmonella* spp. are principally formed in the farm-phase and that everything that happens thereafter is the direct consequence of this; 2. in the Netherlands the main underlying cause for the more or less constant stream of *Salmonella* spp. towards consumers is that autonomous contamination cycles exist on the farms of multipliers and finishers; and that 3. under the present circumstances a limited number of factors also have a statistically significant influence.

The amount of risk represented by a certain factor is in the model expressed as an odds ratio (OR). If the OR of a risk factor is estimated to be 3, this means that in those cases were the factor is present the amount of infections or contaminations will in general be three times larger than in those cases were the factor is not present. When the OR of a factor is estimated to be 1, or if 1 lies within the 95% confidence limits of this estimation, there is no proof of a relationship between the factor and the effect. In the event that the OR of a factor is estimated to be(significantly) smaller than 1, the presence of the factor appears to have a preventive effect on the occurrence of infections or contaminations.

Depending on the quality of the data, odds ratios can be estimated with the use of two by two tables or with more sophisticated methods, such as with logistic regression analysis. In this model virtually all odds ratios were determined with two by two tables.

DISCUSSION AND CONCLUSIONS

As illustrated by the figures, the activities in the first phase of the project have shown that it is indeed possible to construct an elaborate descriptive epidemiological model especially intended and designed for the analysis of (consumer) risks to be associated with the consumption of meat, and to develop a certain methodology regarding this approach. With the model it has been possible to determine and formally document: at which moment and in which link of the chain from conception to consumption a certain risk appears; where and at which moments the risks may increase or decrease; to identify and quantify up to a certain point which factors are, under the present circumstances, of major importance regarding the presence or abcense of that risk; and where there is a lack of knowledge, allowing for an indication of the exactness of estimations and the setting of priorities regarding further research needed.

Because of its very elaborate nature, the implemented formalised model can easily be used as a "reference manual" for conducting further analyses, such as the HACCP approach, and the design of a set of control measures and GMP-codes (Berends et al. 1993, Snijders et al. 1993b, Berends and Snijders 1994). This includes a determination of the role meat inspection has to play in this and what instruments need therefore to be at its disposal.

However, the structural and systematic listing of relevant epidemiological data and the subsequent risk analyses is also a very time-consuming business. That is especially true for the acquisition and evaluation of data from literature. This, together with the amount and diversity of risks that need to be evaluated, make it necessary that an analysis of all consumer risks to be associated with the consumption of meat be carried out internationally. Different institutes from different countries should thereby conduct parts of the whole analysis. EU or Codex Alimentarius Commissions could act as coordinators for these activities, for example.

It is important to realise that risk analysis is a cyclic process. Whenever relevant new data regarding certain harmful agents appear, or, for that matter, formerly not as such recognised risks for the consumer become known, and whenever changes in circumstances or ways of production occur, the analysis of risks has to be carried out again. This is also the strength of this approach, because only on this basis will it be possible to design and maintain a system of safety assurance of meat that can continuously be adapted to all the sorts of changes that might occur. At the same time the approach will also ensure that in different countries and regions the same level of safety can be reached without the necessity for a fixed list of hazards being controled with identical control measures and meat inspection procedures followed. After all, the situation regarding prevalent zoonoses, environmental contaminants and veterinary drugs used in one country or region does not necessarily have to be the same in another country or region.

Be that as it may, there are some matters which need to be addressed before risk analysis can really be the basis of the modernization of meat inspection. For example, most countries do not have a monitoring system for effectively detecting the prevalence of human health hazards in slaughter animals and the incidence of disease caused by these agents in the human population. If there is no insight into these matters, both risk analysis and the assessment of the effects certain control measures have becomes very difficult. Another problem is that there is, as yet, no consensus regarding how to evaluate certain health hazards, thus hindering the setting of priorities regarding the hazards to control. That is to say, there is no consensus regarding the question whether a human health hazard that has a very low incidence in the human population, but that has severe consequences, such as meningitis caused by an infection with *Streptococcussuis* type II, must be regarded just as serious than an in general less severe infection with a much higher incidence, such as infections with *Salmonella* spp.. Maybe the introduction of internationally accepted weighing factors could solve this matter.

In conclusion it can be said that if these matters can be overcome there is a real future for the modernization of meat inspection based on risk analysis on elaborate descriptive epidemiological models from conception to consumption.

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