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Quantitative risk assessment

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Background:
The production of safe food is increasingly more based on the use of risk analysis. Risk analysis is used to set (internationally) fo safety criteria. Also risk analysis can be used by food producers to quarantee that the criteria are met. For the first purpose Codex Alimentarius Commission has recommended a method for risk analysis. For the second purpose some elements of this method a useful, which can be used as a validation or extension of the HACCP-system.

Objectives:
To apply the Codex Alimentarius appoach for risk analysis for a agro food chain and to modify and extend some elements to determine the risks for food companies. Several risk analysis are carried out for one production line as well as for a agro food ch of which two case-studies are described.

Method:
Risk analysis consists of risk assessment, risk management and risk communication.

- Risk assessment is the scientific estimation of the likelihood and severity of harm resulting from exposure to a hazard. Th risk consists of the probability of occurence of a hazard in a food product, the probability of consuming a certain ammou and the probability of illness given an exposure.
- Risk management is the process of weighing alternatives in the light of the results of the risk assessment. Control measu and measures for improvement, if required, should be selected and implemented. A cost-benefit analysis of options can a support risk management.
- Risk communication is the interactive process of exchange of information and opinions on the risk among risk assessors, managers and any involved parties.

Consumer's risk and producer's risk

In hazard characterization a dose-respons relation should be incorporated. For a food company this is too excessive and expensiv Food companies have to adhere to criteria set by governments, set by clients or set by the company itself. If those criteria are exceeded, there is a probability that e.g. consumers will become ill, that clients claim, or that the company has to do a recall.
In exposure assessment, the probability of intake is quantified which requires information about the food consumption. Food companies are rarely the final link in the food supply chain and are not solely responsible for the level of exposure.
Further, food companies always have to deal with changes in products, processes, suppliers of raw materials and characteristics (new) hazards. Because the quantitative effect of changes at risk factors can be predicted, an up-to-date risk assessment is essent product and process development. Therefore, TNO has developed a method for the assessment of the food producer's risk.

Consumer's risk	Producer's risk
protection of the consumer	production of safe food in a cost-effective way
te set criteria	te meet criteria
management by Codex and governments	management by food company

From worst-case to probabilities

The risk factors can be quantified by application of a worst-case, a what-if or a statistical approach.
The worst-case approach is a succession of extreme situations in the process and unfavourable events, all with a small probab occurring. If the result following from the worst-case estimate is below the critical limit, the product can be considered as safe. other cases, the results should be reconsidered because the risk is always over-estimated.
The what-if approach is a succession of what-if scenarios. It is flexible, so the influence of a risk factor can be estimated. Diff scenarios can be chosen, e.g. average values and even some worst-case values. In every scenario the calculation is based on one at each riskfactor. This leads to one value as an answer. This is not realistic because each value at a riskfactor has a probability.
The statistical approach is a succession of probability density functions. In the calculations values are sampled from the proba distribution functions. The outcome is not one value, e.g. the average or an extreme value (worst case), but several values each certain probability. From a cumulative probability function the probability of exceeding a critical limt can be calculated. This is only approach in which the risk can be really quantified.

CASE-STUDY 1 *BACILLUS SUBTILIS* IN A PASTEURISED MEATPRODUCT

The meatproduct consists of meat, spices and herbs and other ingredients. It contains nitrite salt, has a wateractivity of 0,97 and a pH of 6,3. The product is pasteurized (P-value of 40 minutes at 70°C). The product should be stored at 7°C maximum. The company wants to know the risk of a spoiled and unsafe product when the product is stored at 15°C for 12-16 hours. If necessary, the company is interested in the effect of options for improvement.

All vegetative bacteria are eliminated during pasteurization. The spores of the pathogenic *Bacillus cereus*, *Clostridium perfringens* and *Clostridium botulinum* are not able to germinate and grow because of the nitrite salt. Some spores can grow, but very slow at 7°C. Storage at 15°C increases the growth rate of spoilage-organisms. *Bacillus subtilis* is identified as the most significant organism. The critical limit at the time of consumption is set at 6 log cfu / g.
The use of probabilities gives insight in the distribution of *Bacillus subtilis* in the raw materials, resulting in a probability of occurence in the mixed raw product. The growth characteristics of the organism is modelled, resulting in a lag-time of 7 hours (mean) and a generation time of 0,2 hours (mean). From these inputs the probability of exceeding the critical limit (spoilage by *Bacillus subtilis*) is calculated at 100%.

Two measures for improvement are proposed:
- decontamination of the spices and herbs by steam treatment, which reduces the initial count.
- change the pH of the product to 5,3 or 5,7, which increases the generation time of *Bacillus subtilis*.

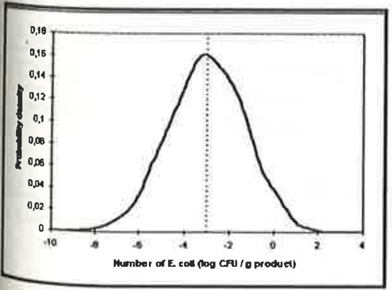
The results are given in the table below.

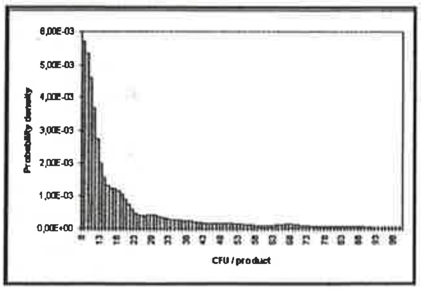
steam treatment spices and herbs	pH	probability of spoilage
no	6,3	100 %
yes	6,3	100 %
yes	5,3	< 10^{-7} %
yes	5,7	0,01 %
no	5,7	25 %

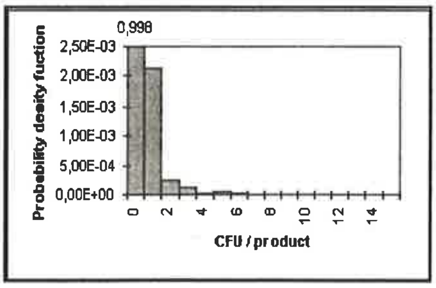
CASE-STUDY 2 *E. COLI O157:H7* IN A RAW FERMENTED MEAT PRODUCT

The risk of *E. coli* O157:H7 in raw fermented meat products is assessed. Statistical calculations are made including the distribution of the pathogen on the beef meat, the ammount of beef meat in the mix of raw materials and the distribution of the pathogen when making portions (sausages) of the mix.
A reduction is observed during fermentation and storage. This depends on the a_w and the pH of the product as well as on the storage temperature. The probability density of E. coli O157:H7 in the product at different processtages is given in the figures below.

E. coli O157:H7 in the raw product mix; in the product after fermenting; in the product at the time of consumption







CONCLUSIONS

In the case of *Bacillus subtilis* the management can make a decision based on the risk relating to costs of the steam treated spices herbs and the acidity of the product (flavour). In the case of *E. coli* it can be concluded that 0 E. coli O157:H7 are te be expected in 99,8% of the products; 2 of 1000 products can have 1 bacteria; no numbers of more then 10 in a product are to be expected.
Uncertainty and variability at different riskfactors can be analysed so control measures and measures for improvement in the food chain can be proposed.