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Acting in Times of Crisis and Crisis Prevention

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Acting in Times of Crisis and Crisis Prevention

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Acting in Times of Crises and Crisis Prevention

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Foreword

Dear Readers,

The symposium “Acting in Times of Crisis and Crisis Prevention” was organised jointly by the Federal Institute for Risk Assessment and its two sister authorities in France and Denmark, the French Agency for Food, Environment and Occupational Health & Safety (ANSES) and the National Food Institute at the Technical University in Denmark.

I would like to extend my sincere thanks here once again to my colleagues from France and Denmark for their very good and efficient cooperation. It was no coincidence that the first joint symposium of the three consumer protection authorities which specialise in health risk assessment and risk communication should start with this topic. The word crisis is in great demand these days and for this reason, the two food crises from 2011 – dioxin in animal feed and the EHEC crisis – should merely be regarded as the reason for our symposium.

What distinguishes a crisis? When a bank collapses, it may well be dramatic for the customers, employees and shareholders, but it’s not a crisis. This only happens when one bank after another goes bankrupt and the whole borrowing and lending system appears threatened. A product crisis doesn’t occur either when a solitary product risk is detected, if you consider that rapid alert messages are sent all over Europe and the rest of the world every day via the RASSF system for food and the RAPEX system for consumer products. Even if these cases are sometimes fatal, a crisis does not necessarily break out. Product crises only occur when a large number of people are affected by an incident and the impression arises that a large-scale problem has been encountered which cannot be overcome by the state or society.

For this reason, our internationally aligned event deals not only with questions of responsibility in times of national and international food crises, as well as the role of the state and institutions and collaboration between authorities and scientific bodies during crises and in peacetime, it also pursues the question of what has to be done in a crisis and what has already been done. I am sure that a lot can be learnt here not only for our routine dealings with risks but also on how to overcome crises within Europe. With this in mind, the Federal Institute for Risk Assessment also prepared this event in its role as the national Focal Point of the European Food Safety Authority (EFSA) and, with the help of a network consisting of the Member States, EFSA and other national and international institutions, it has compiled public documents on crisis management which you will find in these conference proceedings.

I wish you interesting and stimulating reading.

Professor Dr. Reiner Wittkowski

Vice-President of the Federal Institute for Risk Assessment

Welcoming Address

Professor Gérard Lasfargues,

Scientific Director of the French Agency for Food, Environment and Occupational Health & Safety (ANSES), Maisons-Alfort

Ladies and Gentlemen,

As Deputy Director General of the French food safety agency, I would like to begin by thanking the organisers for their kind invitation to speak at this event. It is a great pleasure for me to meet up with Professor Reiner Wittkowski, Vice-President of the Federal Institute for Risk Assessment and Dr. Jørgen Schlundt, Director of the National Food Institute in Denmark. This is the first joint event of our three institutes and there are of course many common topics to discuss in areas such as risk assessment and health.

Let me begin with a definition of the term crisis. A health crisis is by definition a situation characterised by two criteria: it is an emergency and the inherent risks have not been identified in nature up to now. In addition to this, all crises can trigger a wave of public reactions. In France, there have been a great many controversial health scandals in the past, such as asbestos contamination and BSE in cattle. In situations of this kind, it's important to have organisations dedicated to risk assessment in order to clearly separate risk assessment and risk management. They must also be independent of government ministries, because the crises of the past have resulted in a loss of trust in the authorities by the general public. The data on public perception we have show that this is evident in the nuclear area as well as in crises involving medical products and pharmaceuticals. Where food and nutrition are concerned, trust among the general public is slightly better.

This poses several challenges for public institutions: first of all, a suitable answer has to be found regarding the urgency of the threat. Secondly, we need suitable methods for crisis analysis and risk assessment to allow us to respond with an intelligent and well-informed crisis management. Thirdly, appropriate communication tools are required in order to clarify any uncertainties at the level of the health institutions and public opinion.

ANSES is an independent body for the assessment of health risks presenting various advantages. First of all, we cover a great many different areas (food safety, animal health, plant health, environmental health and occupational health). We conduct our own research and risk assessments, thereby recording the general state of health and the environment, thus enabling us to evaluate issues ranging from animal health to food as well as mobile communication system. On top of this, we are also capable of activating our scientists working in our labs very quickly, such as when pathogens in the food chain have to be identified. In addition, our network of external experts comprises more than 800 scientists working in our working groups.

Our national organisation is complemented by a strong network at an international and European level and our cooperation with the BfR and DTU food is a good example of this. This kind of networking is particularly important for the operation of efficient early warning systems. In addition to this, ANSES is open to the suggestions of everyone who can contribute towards the identification and solution of crises. All stakeholders are represented in the management board and the findings from human and social sciences are also given consideration in our expert reports and opinions.

Even though the European health safety system is efficient, we cannot assume that crises such as the EHEC outbreak will no longer occur in the future. I am nevertheless convinced that this symposium constitutes a good opportunity to strengthen the existing systems and deepen our know-how in the area of risk prevention.

Welcoming Address

Dr. Jørgen Schlundt,

Head of the National Food Institute of Denmark at the Technical University of Denmark (DTU), Søborg

Ladies and Gentlemen,

Denmark may be a small country but we have a saying in Danish that it is better to be small and proactive than large and inactive. We are participating in the cooperation project with our two sister institutions BfR and ANSES because we strongly believe that several events over the latest decade document the importance of European cooperation in times of crisis. We have seen again and again in the past that it is important to view risk assessment separately from risk management, though both of them should float in a 'sea' of risk communication; we must be able to communicate about both science and action in real-time. BSE and other crises have shown us that risk assessment must be independent of risk managers and politicians, and must be based in good science. We believe that our three European institutions have the same understanding of the significance of independent science. That is one of the reasons why we are attempting to advance a more formal collaboration, and this symposium is one of the results of this. We hope that more activities and campaigns will follow.

In Denmark, the separation of risk assessment and risk management has reached a point where our institute is now affiliated with a university, and fully functionally separated from the food safety authority. This makes sense not only to achieve independence, but also because if we want to provide excellent science we should be located at a place where the best research is done. We enjoy being at the Technical University of Denmark, and the environment is of benefit to us. It is very important to us to be independent and that is why we are pleased to collaborate with other European food safety institutions with the same attitude.

Of equal importance is also a common understanding among risk managers, politicians and consumers that the scientific assessment of health and food risks must be based in the national food research institutions with the most important task of the European Food Safety Authority (EFSA) being the combination of scientific risk assessments from the 27 EU Member States. In this way European research and expertise is used as the basis for all of the deliberations of the EFSA committees.

What is also true is that we have a great many good scientific approaches and results in Europe which should be spread all over the world. To do so, we need cooperation with global organisations such as the World Health Organization (WHO), the Food and Agriculture Organization (FAO) and others. We should not isolate ourselves, especially not when it concerns those areas where we have already found efficient solutions. Salmonella infections, for example, have been reduced by half in Europe and there are a great many other instances

where our scientific results could also be put to good use outside Europe, enabling safer food not only here, but elsewhere in the world too.

I would like to draw your attention to another point: our risk communication should in no way be allowed to convey the notion that outbreaks of diseases attributable to pathogens or contamination in food are the main cause of food related illness among the population in general. Quite to the contrary, compared to the entire burden of food related disease, the percentage caused by outbreaks such as EHEC is very small. I will deal with this in more detail in the course of my presentation. Nevertheless, outbreaks can show us the weak points in the system so that we can learn from them and make changes in order to avoid similar risks in the future.

The solutions we pursue within a national, European and – hopefully soon – global framework must be structured in such a way that they are built on a sound scientific basis. With a risk management system not based on scientific findings, we will very often come up with the wrong answers. Science delivers new answers and will also help us make food safer. That is precisely what our cooperation is all about. Thank you very much.

National and Social Crises: Responsibilities of Institutions and Individuals in a Crisis

Professor Christian Calliess,

Free University of Berlin and member of the German Advisory Council on the Environment (SRU)

Ladies and Gentlemen,

Many thanks for the invitation to this exciting symposium. The main thing the organisers have asked me to do is present the theoretical and constitutional foundations of state responsibility. I want to restrict myself to this, which means that in this regard, I will not be touching in any detail on our work at the SRU which involves state responsibility when dealing with "ignorance" and "uncertainty" using the example of nanomaterials.

In the past, it was often the case that the use of substances or products could only be restricted by the state once clear scientific evidence of harmful effects had been produced. For example up until 1981, the German Chemicals Act permitted the manufacture and marketing of new substances without any previous estimation of their effects on health and without any tests by the authorities. Working on the principle of trial and error, this approach, which only enabled state intervention under the conditions traditionally employed to ward off imminent danger, i.e. very late – sometimes even too late, as was the case with asbestos – came under increasing criticism. It was always the case here that the state and the scientific community only learned from the crisis at the cost of a perpetuating loss of trust among the general public.

In addition to a multitude of chances, the dynamic development of trade and industry, science and technology also brings with it as an unintentional side-effect new risks which extend way beyond the hazards of the first industrialisation phase. Some developments are connected with new environmental and health risks, the magnitude of which often cannot be foreseen or predicted. A current example of this is the use of nanomaterials (cf. SRU special expert opinion "Precautionary Strategies for Nanomaterials, 2011, Berlin 2012) in more and more consumer products. If risks of this kind materialise, however, the result is often fears in society which can develop into a crisis in the state and society when conveyed via the media.

I. Theoretical and constitutional foundations of state responsibility

Just like the European Union, the Federal Republic of Germany is a democracy with the rule of law written into its constitution. We have heard this often enough, but what does it actually mean in definite terms for our topic of how to handle crises in the state and society?

A state under the rule of law is defined by procedural specifications, such as separation of powers, reservation of statutory powers and effective legal protection on the one hand

and by the recognition of basic rights on the other. The pivotal element in this regard is the fundamental standard of our constitution – human dignity – which, as the key component of all basic rights, formulates through Art., 1 Para. 1, P. 2 GG (Germany‘s Basic Law) the elementary democratic obligations of respect and protection for the subsequent constitutionally protected resources of Art. 2 ff GG. The existence of a state’s duties to protect – where the object and legal basis of the protection are concerned, it is perhaps better to speak about constitutional obligations to protect – is generally recognised today in jurisdiction and in jurisprudence, even though there are disputes about many individual issues. Add to this the state obligations which arise from state objectives; Art. 20a GG is relevant to protection of the environment in this regard.

From a theory of state point of view, the state meets its obligation to protect by means of the state monopoly on the use of force as developed by Jean Bodin and Thomas Hobbes and thereafter implemented step-by-step in the historical context of the civil wars in France and England. The term monopoly on the use of force has its origins in the teachings of Max Weber, who defines the state descriptively through its specific means, the monopoly on the legitimate use of physical force. This concerns the monopoly on the use of physical force as expressed in the organised structures of the police, legal enforcement and the army. The decisive aspect here is the jurisdiction of the state, which has sole authority to use physical force. Based on this fact, the state organisation takes on a special quality which differentiates it from private organised forces.

The monopoly on the use of force imposes a sort of peace obligation on private individuals in the course of which – with the exception of instances of self-defence – they must refrain from using or threatening to use physical force and are obliged to settle conflicts purely within the framework of the law. This is balanced off by an obligation to protect on the part of the state which should be understood as a kind of compensation for the acceptance of the monopoly on the use of force. In this way, the theoretical contractual agreement “private non-use of force in return for state protection” becomes the theoretical state foundation of our polity. From a constitutional point of view, the state obligation to provide protection is given through the basic rights, as already mentioned.

Within the context of the state monopoly on the use of force, however, conflicts are not suppressed, they are channelled through state institutions and processes which guarantee certain co-determination, participatory and other procedural rights as a form of compensation. The state must ensure these on the basis of its obligation to protect. Viewed this way, the right to police intervention or the guarantee of access to justice is compensation in a constitutional democracy for the prohibition of unlawful intervention and self-administered justice.

Concerning the risk of misuse which is inherent within the monopoly on the use of force, on the other hand, sovereign force may only be exercised in a constitutional democracy within the framework of laws that comply with the constitution and above all, it must be restricted by basic rights in their classical dimension relating to the right of defence.

II. From a liberal night-watchman state to a welfare state?

II.1 Security between self-responsibility and state responsibility

The so-called “liberal night-watchman state”, which has a slightly scornful undertone, fundamentally reduced the obligation of the state to provide security to the guarantee of the physical security of its citizens. In addition to “classical” physical security, the closely related ecological security and further reaching social security have their place in modern industrial, service and communication societies. From the fragmentation of society into highly specialised function systems, however, (politics, law, trade and industry, science, technology,

health, ecology etc.), completely new challenges arise for the security that has to be provided by the state. In this regard, information and communication have become key terms which have taken on a networking function which the state must in turn guarantee. This corresponds with a social development which can be described – perhaps somewhat provocatively – with the thesis of the “dwindling legitimacy of state forbearance”. Accordingly, the guarantee of security has become more and more a comprehensive responsibility of the state in the eyes of many citizens and voters.

It proves to be a problem in this regard, however, that due to a lack of experience-based knowledge of all causes and consequences of damage, the state cannot make any precise and effective restrictions to prevent damage.

This means that the possibilities of science and research to comprehend the complexity and multi-causality of the environment are still very limited. Within the framework of accompanying risk research in particular, there are often considerable knowledge gaps and a lack of data.

Over and above this, there are multifarious difficulties in the field of measurements, which are often unreliable in light of the instability of many pollutants and uncertain materials cycles, with the result that the object that is subject to political intervention proves to be a variable quantity. Add to this the inadequacies of the measuring methods and assessments. The former either suffer from a certain lack of focus, which increases more and more the closer we get to the quantitation limit, or they fail right from the start because certain factors, such as the pollution caused by multiple introduction of pollutants, are not adequately illustrated and/or the real situation cannot be comprehended de facto. For this reason, schematisation and typing must be automatic within the scope of threshold and limit values so that the biological differences in the people and/or biosystems and the multi-causal effects of environmental pollution can only be taken into account to a limited extent.

Existing risk estimations and assessments are also frequently subject to changes. Supposedly well-known items of daily use, such as asbestos or formaldehyde, suddenly turn out to be harmful or other, perhaps new, assessment methods require an expanded scope of protection which the law cannot simply reflect. Add to this the fact that measures for observing and describing the environment are usually separated by media and uncoordinated. Above all, however, the effects and migration chains of harmful pollutants can only be predicted to a very limited extent in many health and environmental policy spheres of activity. Their accumulative, synergetic and antagonistic interactions lead to a structural obscurity of the relationships which make it difficult to determine linear functional chains and thereby the causes of possible damage with the legally required certainty.

The high degree of complexity described in this way combined with the multiple causes often makes it impossible to establish immediacy, accountability, responsibility and blame in a legal sense, and in light of the ubiquitous character of most cases of damage, there is no clearly identifiable perpetrator. The remoteness of damage which this involves makes it more difficult to apportion legal responsibility. As a result, the classical instruments of state control, state approval obligations and private compensation claims are bound to fail wherever, with a view towards the ubiquitous dimension of potential damage, either the perpetrator and causalities cannot be determined or the damage reaches a magnitude which cannot be financially replaced by the perpetrator.

The collectivisation of damage therefore stands in a paradox relation to the private responsibility of the individual. If individual compensation is not possible either due to a lack of proof of causality or inability to produce evidence of culpability, or because compensation solutions involving collective rights prove difficult, then the civil law instrument of compensation and related insurance coverage

also fails.

In a situation of this kind, in which it is not possible to attribute responsibility to an identifiable individual, thus causing the failure of private liability law as well as traditional laws to avert imminent danger, safety and security expectations are directed once again to state institutions from whom, as illustrated above, precautions to protect against damage can be justifiably expected.

II.2 From the averting of danger to risk management

Security is defined in a legal sense as the absence of hazards brought about by the state instrument of warding off danger. Decisive for identifying a danger is knowledge of the circumstances under which, by way of empirical rules and the prognosis that can be made from them, the likelihood of damage occurring to a legally protected interest can be presumed with a reasonable degree of certainty. This means that the "knowledge" of the potential occurrence of damage, which is based on general experience, stands at the centre of an effective security guarantee. The greater and more severe the former is, the lower the demands on the probability required to assess the danger, although the mere possibility of damage occurring is never sufficient for assuming a risk.

In complex legal areas, such as environmental and health law, the lawmakers have resorted to substituting these general empirical rules with scientific benchmarks and probability criteria which – after being conveyed via undefined legal terms such as "state of the art" or "in line with the latest scientific and technological findings" – are intended to provide an objectified decision-making basis for state intervention.

Where there are no experiments and scientific findings which confirm the cause of the damage, however, sufficient probability in line with applicable environmental provisions can no longer be justified due to a lack of the necessary decision-making certainty. If, on the other hand, certain indicators point to a distant contingency, the transition has been reached in law between danger on the one hand and risk on the other.

Due to a lack of knowledge, it will also be possible in future to apply the trial and error method in many cases under and as a part of the right to avert danger, even though this method is only appropriate for potential damage which is reversible. If, on the other hand, it can be expected and justified from the outset with certain projects, techniques and interventions that they will have irreversible effects, the trial and error method used in the state's duty to protect also reaches the constitutional limits outlined above.

Following on from the term "danger", the legal term "risk" describes the area in which the occurrence of damage merely constitutes an abstract possibility. Via the precautionary principle which corresponds with this term, the sphere of influence of the state institutions is expanded in such a way that protective measures can be taken in the event of an abstract concern and not only in the event of danger for which there is concrete evidence. In this regard, all that is required is reasonable suspicion with scientific justification. Only if damage is either completely uncertain or the likelihood of its occurrence is so slight that it can be practically excluded, can a democratically elected legislation decide that this so-called residual risk is acceptable. From a legal point of view, this genuine political decision is only relevant insofar as an obligation arising from the state's duty to protect (see above) exists to keep the residual risk as low as possible at all times in line with the latest level of available scientific and technical knowledge.

Consequently, the complex task of risk management – conveyed via the precautionary principle – has taken its place beside the state's duty to avert danger, which it was possible to

exercise on the basis of close attributions and linear causal progressions. Risk management is geared towards the control of risk situations defined by unpredictability and uncertainty. This is accompanied by resource management which pursues the goal of conserving environmental resources in the interest of their future utilisation by means of the under-use of the ecological limits. By doing so, “free spaces” are to be preserved in the structuring of “future living environments” for humans and nature and in the form of load reserves and capacity reserves.

The precautionary principle has embarked on a remarkable legal career in the meantime which began with and focuses on environmental, health and consumer protection law. And this does not only mean the law of Germany, which is often described as timid, anti-progressive and environmentally motivated, but also the law of the USA, EU, WTO and indeed international law in general. The precautionary principle is already recognised in German and European environment law as a decisive characteristic of the national policy objective of environmental conservation (cf. Art. 20a GG, Art. 191 Para. 2 P. 2 TFEU), as well as a consequence of the fundamental protection obligations of the state towards the individual as a constitutional principle. Over and above European environment law, the Commission and CJEU even regard it as a general legal principle of the law of the entire Union. From the standards already mentioned, a “prohibition of insufficient means” which is also recognised by the Federal Constitutional Court has followed which has to be taken into account because of the legislative development of an effective protection concept. Consequently, the precautionary principle is also explicitly anchored in many environmental laws.

III. Provisions of the precautionary principle in a free constitutional democracy

II.1 The structure of the precautionary principle

With regard to its contents, which are outlined below, the precautionary principle can be structured into a state of affairs which is characterised by the determination and assessment of a reason for precaution (“if” question), and a legal consequence, which is defined by each precautionary measure to be taken (“how” question), supplemented by the determination of a precautionary addressee.

The reason for precaution should be understood as a set of circumstances in the course of which preventive measures can be decided. To establish a reason for precaution, it is sufficient to have an abstract potential for concern and therefore reasonable suspicion in theory only – as opposed to purely speculative suspicion supported by scientific plausibility grounds – which does not have to be well substantiated empirically or even scientifically proven in the sense of a majority opinion. In this regard, what is required to begin with is the comprehensive, and where possible exhaustive, investigation of all information applicable to the reason for precaution. In the first step, therefore, scientific investigations have to be made to identify in a continuous process where the risk potential lies, what it consists of and how extensive it is in each instance (preliminary scientific risk determination). Only then can it be assessed on this basis whether each respective risk potential can be accepted or not and what measures should be taken to counter it in line with the sliding scale (danger – risk – residual risk) of safety dogma (preliminary political risk assessment). This assessment is the responsibility of the legislative authority which has a certain amount of scope with regard to estimation, assessment and prognosis within the framework of the constitutional parameters mentioned above.

On the basis of relief and concern criteria, which are to be established with scientific help, formulas can be developed which serve the determination of this reasonable suspicion. On the basis of formulas of this kind, concrete rules for the prevention-orientated handling of uncertainty can then be formulated (cf. SRU, special report “Precautionary Strategies for

Nanomaterials", June 2011, Berlin 2012 P. 189 ff. and 290 ff. = No. 435 ff. and 718 ff.). In the context of the determination of the reason for precaution, the precautionary principle implies a reversal of the burden of evidence which can take effect in line with the model of a rebuttable presumption of danger with observance of the limits of the rule of law.

With regard to the precautionary measures to be taken, stages of intervention into the constitutionally guaranteed economic freedom – each with a different level of intensity – can then be identified on this basis under consideration of the principle of proportionality. In this respect, this does not involve preventive bans with authorisation requirements right from the start, but often the generation of information which is suitable for clarifying the existing uncertainty as an accompaniment to provisional risk estimation. Transparency should then be ensured and traceability enabled for the event that a product containing a substance initially regarded as harmless turns out to be dangerous on the basis of new findings.

II.2 Precaution through processes

If an appropriate level of protection cannot be derived directly from scientific findings due to lingering uncertainty, there is a growing necessity to back up precautionary decisions with procedural rules. The decision-making process assumes an important compensatory significance above all if scientific risk determination does not produce clear assessments; it must be "socially resilient". Only in this way can social acceptance be ensured. For this reason, the precautionary principle is also interpreted in the literature as a process requirement in the course of which various procedural requirements are formulated.

- **Transparency**

The purpose of procedural regulations is to ensure that the given estimation and assessment scopes are disclosed during the assessment of the scientific data and findings. A transparent decision-making process requires that during the substantiation process, the entire bandwidth of scientifically tenable risk assessments – from optimistic to pessimistic assumptions – is presented and alternative solutions are prepared. Consideration of the entire spectrum of scientifically tenable positions also includes qualified minority opinions. Only when precautionary measures are justified in the political process with a sufficient degree of transparency, can a loss of credibility be avoided, as can happen when adjusting to new findings, for example. To improve the political assertion of measures, missing scientific findings have to be discussed for this reason. The prerequisite for this is a change in political risk culture.

- **Appropriate participation of social groups**

In light of the political character of risk assessment, the decision-making process not only has to be made transparent, it must also enable a pluralistic discussion of values, which should be held under the institutionalised involvement of representatives of social groups which participate in public life. The decisive aspect here though is that the political and scientific-technical level are appropriately linked with each other procedurally so that each side can fulfil the function it is assigned. The institutionalised involvement of social groups increases the political legitimacy of decisions and is intended to ensure that a wide range of risk assessment criteria are taken into account.

- **Lowering of the standard of proof**

The question is often asked what is supposed to happen in cases in which the existing uncertainty has not (yet) been determined due to a lack of adequate research, or cannot be lifted with the available investigative means due to the existence of a dispute among experts. If, as in conventional instances of emergency response, the sufficient likelihood of the occurrence of damage has to be proven, then the burden of producing evidence and the burden of proof lies with the party potentially affected by the risk in question or – based on the obligation of

the state to provide protection in line with Art. 20a of Germany‘s Basic Law and the fundamental rights outlined therein – with the state.

This is why there have been calls outside the sphere of jurisprudential debate (in the field of philosophy, for example, which deals with issues such as environmental ethics) for a general reversal of the burden of proof (“in dubio contra projectum“) to address the risks of new technologies. A risk decision of this kind pushes the rule-of-law limits of our liberal constitution. As a result, the precautionary principle can only be employed in conformity with the rule-of-law concept if it is based on the model of a rebuttable presumption of danger. In order to successfully challenge this presumption, the risk originator is required to present factual evidence and to prove with reasonable probability that his substance, production method or product does not pose a threat.

If we adopt the idea of apportioning the burden of proof based on the theory of spheres, an idea that also corresponds to the “polluter pays“ principle in the field of environmental law, this appears justified if for no other reason than it is the substance or product producer who confronts the public at large with a potential risk. The risk originates in his sphere of influence, as do the questions of fact that cannot be answered and hence also the grounds for precaution. Due to his proximity to the matter at hand, the person in whose sphere of influence the uncertainty arose has a “knowledge edge“, and it is only logical to require that this additional knowledge be presented. This “burden of proof reversal“ can incentivise the risk originator to conduct his own effect and risk research parallel to his product development research so that he is in a position to rebut the presumption of danger in legal proceedings which are instituted by the legislator and which also take into account the concerns of those affected by the risk in question.

III. Outlook

Back in 1792, Wilhelm v. Humboldt wrote wise words when he noted: “There is no security without freedom“. If there is anywhere that freedom and security belong together, then in the constitutional state; this is an aspect that is not always sufficiently taken into account in the current debate. With its twofold function, the constitutional state principle can “control“ the degree of security at any particular moment in time. To this extent, the rule-of-law premises are the state monopoly on the legitimate use of force, the constitutional obligation of the state to protect its citizens and the “freedom-preserving“ constitutional right of defence. These three premises form the basis for a multipolar concept of constitutional law that paves the way for a kind of “freedom compatibility check“ of planned precautionary measures.

The precautionary principle (together with the rebuttable presumption of danger that is inherent to it) legitimises regulatory action by the state. It can provide for the enactment of precautionary regulations and permit the authorities to intervene based on a rebuttable presumption of danger – for example by ensuring the appropriate wording of the relevant approval procedures.

In the absence of a formal legal regulation, the authorities have only limited options to secure a reversal of the burden of proof and only in individual cases. Reversal is only possible by utilising the leeway allowed by the law in question. This leeway must be gauged based on the risk assessment of the lawmakers as expressed in the law, and this assessment must in turn be determined in consideration of the overall conception of the law in question. It may not therefore be deduced solely from the wording of an individual provision, as the wording of such provisions is often more of a random nature. Determination of the assessment of the lawmakers must additionally take account of the constitutional aspects of a burden of proof decision – and not just of the rights of defence of the originator of the risk but also of the duty

of protection vis-à-vis third parties. If they abide by these restrictions, the authorities may take precautionary measures when new substances and products are brought into circulation even if no information is available at the time on the potential risk of these substances and products. It must be ensured, however, that the producer of a substance or product can bring these on to the market if he successfully challenges the presumption of danger for the product/substance.

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Discussion

Question: Professor Calliess, you've confused me a bit with your definition of risk. I have always understood risk as a consilium up to now in the sense that danger is a risk, albeit a particularly high one. That's why I'm all for substituting the term risk with concern and the term danger with damage. Can you say anything about this? The second question concerns the term "prohibition of insufficient means". Is this a juridicial turn of phrase or does it have a legal basis?

Prof. Calliess: Thanks for asking that question. In actual fact, the terms danger and risk are disputed among the various disciplines. I focused on the legal terminology which is mainly used in German and European law and which has also been confirmed judicially. The term danger orientates towards a sufficient probability of damage occurring and on the avoidance of damage. The term risk aims ultimately at avoiding damage too of course, but the mere possibility of the occurrence of damage is sufficient here and this mere possibility is defined by abstract concern.

Question: Is that a legal term?

Prof. Callies: Abstract concern actually is used as a benchmark in risk law, but it must of course be defined more precisely. Abstract concern requires scientifically justified reasonable suspicion, because the lawyers agree that there cannot be precaution for the sake of precaution for constitutional reasons. That is a very big difference to sufficient probability of danger which makes it necessary to avert the danger. Although the general rule is the greater the possible damage the lower the requirements on probability, it must be scientifically proven in this case that this damage will occur in all probability. This is often impossible with new technologies such as nanomaterials due to the knowledge gaps that exist.

Regarding your second question, the prohibition of insufficient means is no more expressly anchored in the constitution than the prohibition of excessive means. Where basic rights are concerned, however, the jurisdiction of the Federal Constitutional Court has construed the prohibition of excessive means as a right of defence against state action, but certain basic rights collide here. On the one hand, there is the free market economy where the state should not interfere so that the companies can market their products. At the same time though, the state must protect its citizens from the possible negative effects of these products. This obligation of the state to protect as a basic right brings with it the prohibition on the use of insufficient means, which the Federal Constitutional Court introduced and defined in its judgments: the state must prove that it has developed an effective protection concept.

Question: How do you view the regulations on the level of the WTO? You know that we had that famous argument about hormone-contaminated meat over ten years ago where there were different scientific opinions and the World Trade Court ultimately had to reach a decision. Do you see any deficits here?

Prof. Callies: I'm very pleased that you asked me that because it really is a problem. We are coming more and more to the conclusion that there is a European context which distinguishes the precautionary principle as a comprehensive legal principle. This also produces latent conflicts in EU legislation, as illustrated very well by the example of nanomaterials. Consensus in WTO law is even more difficult, because different risk cultures collide here. The American risk culture is different from the German and the Chinese versions. The hormone meat dispute makes it clear that the European interpretation of risk cannot be simply transferred to the WTO, whose dispute arbitration institutions have had a hard time precisely defining the precautionary principle as we see it here.

Moderator: Many, many thanks. The next presentation is being delivered by Dr. Angelika Tritscher, who currently heads the food safety department at the World Health Organization and gained previous experience in the food industry. Due to global trade flows, incidents can spread rapidly nowadays. Together with the FAO, the WHO has developed the INFOSAN programme to promote the cooperation of countries in food crises. How does this programme work?

Lessons from Crises of the Past

Dr. Angelika Tritscher,

World Health Organization (WHO), Geneva

Ladies and Gentlemen,

We have already heard today that action at local level is the precondition for the local protection of food supplies. What is equally true, however, is that the volume of global food supplies is increasing at a dramatic pace, and this means that the local protection of the population calls for global action. Before I turn to INFOSAN, I would like to talk about a mechanism that the WHO uses in this connection.

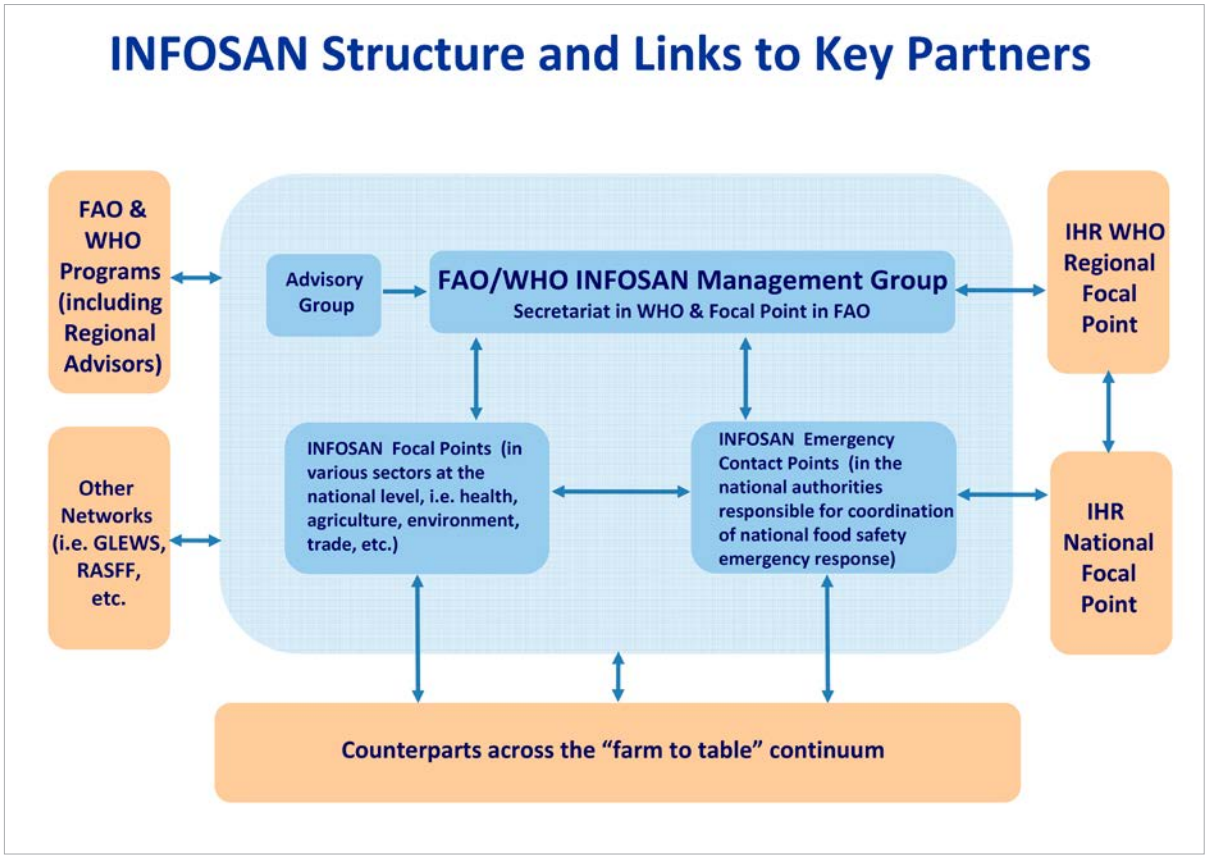
We too have recognised the importance of scientific findings for crisis management, and this is why systems are in place for risk monitoring and risk assessment. These steps are followed by response and a final analysis that shows us what lessons can be learned from the crisis and from the management of the crisis. International health regulations, so-called IHRs, provide the legal framework for our activities. A new IHR was introduced in 2005 detailing all public health problems of international significance – in other words, not only just a small number of infectious diseases such as plague and cholera. The Member States are under an obligation to report all emergencies in the area of public health with international impact to the WHO. This notification sets the mechanisms in motion that are necessary to inform the global networks and pave the way for global action. Moreover, the WHO has a mandate to initiate certain actions within a predefined period of time.

That these global mechanisms now also encompass food safety is a relatively recent development. What makes the incidents in this field so unique? First, they call for cooperation between different partners and fields of knowledge in different countries. The central task is to identify potential public health problems. A further aim is to predict the impact on trading activities and the economy as a whole. And this is why we need a multidisciplinary and multisectoral approach to food safety incidents. The increasingly international nature of the food trade calls for a global strategy; an extremely rapid response and seamless cooperation between the national and international networks are key to ensuring the effective exchange of available information. Moreover, countries need to share their experiences so that we can respond faster and more efficiently in future. This in turn requires a platform that can facilitate cooperation between the various partners – hence the creation of the INFOSAN network as a joint initiative of the WHO and FAO.

INFOSAN stands for International Food Safety Authorities Network; it was founded in 2004 and has been steadily expanded ever since. The mission of INFOSAN is to contain the international spread of contaminated foodstuffs and the diseases caused by these foodstuffs. A

further aim is to promote the rapid exchange of information as well as partnerships and co-operation between the various countries. This means that communication between the member countries is not solely via the INFOSAN secretariat; our aim is rather to bring together the countries in different regions so that they can handle food safety crises more effectively and also take preventive measures in future.

177 countries are currently members of INFOSAN; communication is via an internet platform and is geared towards exchanging and documenting information on incidents and practices. The INFOSAN Management Group has a secretariat at the WHO and a Focal Point at FAO; it also uses the services of an external advisory group made up of experts from the various authorities. INFOSAN consists of two branches: the emergency branch with official contacts in the governments of the various countries and the second branch with local contacts in numerous national authorities (fig. 1.1). With certain restrictions, the INFOSAN network also facilitates the flow of confidential information.



.Fig 1.1: The structure of INFOSAN and contacts with the most important partners.

What is also important are links to other European networks like the Rapid Alert System for Food and Feed (RASFF) and other international networks such as the Global Early Warning System for major animal diseases (GLEWS).

These different sources of information form the basis for an internal assessment and review, which in turn provide the necessary information for decisions on further action, with a final follow-up at the end of the process.

The following examples illustrate the modus operandi of INFOSAN. I'm a toxicologist, so I'll start with a chemical example, melamine. This chemical was deliberately added to food, diluted milk for example, in order to feign high protein content. This fraudulent activity extended to a whole range of products, including baby food; the extremely serious effects on human

health resulting from the use of this chemical were well-known from earlier incidents and investigations. A total of 47 countries reported melamine-contaminated food products. The greatest health concerns were in China, where 22 million people were screened; 300,000 children fell ill, and six fatalities were confirmed.

INFOSAN was quick to react to this dramatic situation with case definitions, epidemiological data and the description of possible courses of action. The WHO conducted a preliminary risk assessment for melamine and published the findings on its website; it also supplied information on relevant testing methods for various products. During the months after the contamination problem became known, INFOSAN collected information from the various countries and compiled lists of contaminated products and batch numbers to facilitate their identification and also investigated the relevant sales channels. We pinpointed the countries to which these products were supplied so that they could be taken off the market as rapidly as possible. We helped to interpret analytical results in numerous countries, and we also published experience reports outlining the differing national limit values for the various products. It soon became evident that there was insufficient scientific information on the level of concern that is appropriate in this connection. We therefore provided expert consulting services to enable an effective risk assessment, based on which we were then able to make suitable recommendations for action.

I can‘t emphasise often enough what Mr. Schlundt has already said: we need scientific findings if we are to make the right decisions. The previous speaker also rightly pointed out that we sometimes have to make decisions even when little or no information or knowledge is available. Neither EFSA nor the WHO conduct their own scientific activities. Our job is to bring all the parties together to draft and then publish recommendations. We also identify knowledge deficits, which are then resolved by scientists.

What lessons did INFOSAN learn from the melamine crisis? It was the first global crisis during which INFOSAN played a key role as a worldwide information platform, paving the way for an extremely rapid response in close cooperation with the member countries; we were able to organise an expert hearing at short notice, enabling the definition of an international standard for melamine in food, feed and in particular baby food based on the work of the Codex Alimentarius Commission within an extremely short space of time. Up to that time, this was the fastest an international food standard had ever been defined following a crisis. Our experiences also show, however, that the resources of INFOSAN are limited, and that‘s why we had major problems getting to grips with this incident. If a product was suspected of having been contaminated with melamine, we always had to check whether the batch number was the right one. This entailed painstaking and time-consuming research at national level. We need to be better prepared in terms of laboratory capacities and resources so that we can provide more rapid information to the authorities in the various countries.

I would like to provide a further example, an outbreak of *Salmonella Oranienburg*. It began in Russia with 60 cases of salmonellosis, mainly among infants. The product that caused the problem was also marketed in Russia; when the infection was traced to its source, it was discovered that the infected products came from Belgium and had not only been supplied to other countries but also distributed by aid organisations. Three WHO regions were affected, and the product we‘re talking about has an extremely long shelf life. We immediately contacted the company, which – thank God – had an excellent traceability system and was able to recall the affected products extremely quickly. This helped to minimise the economic impact of this outbreak and prevent further exposure.

I don‘t need to talk about the EHEC crisis in any detail; I‘m sure you all recall it well (fig. 1.2). The European Food Safety Authority EFSA and the BfR were involved in tracing the problem

back to its origin, ultimately identifying fenugreek seeds as the source of infection. This illustrates the complexity of this type of crisis. What have we learned from the EHEC outbreak? We struggled with the system-based delays in the reporting procedures, and this is certainly something that must be improved. The entire information flow also needs to be optimised. And last but not least, risk communication is of paramount importance. It's not about naming and shaming the guilty party. What's far more important is to underpin the long-term credibility of national decision-makers in the eyes of the consumer.

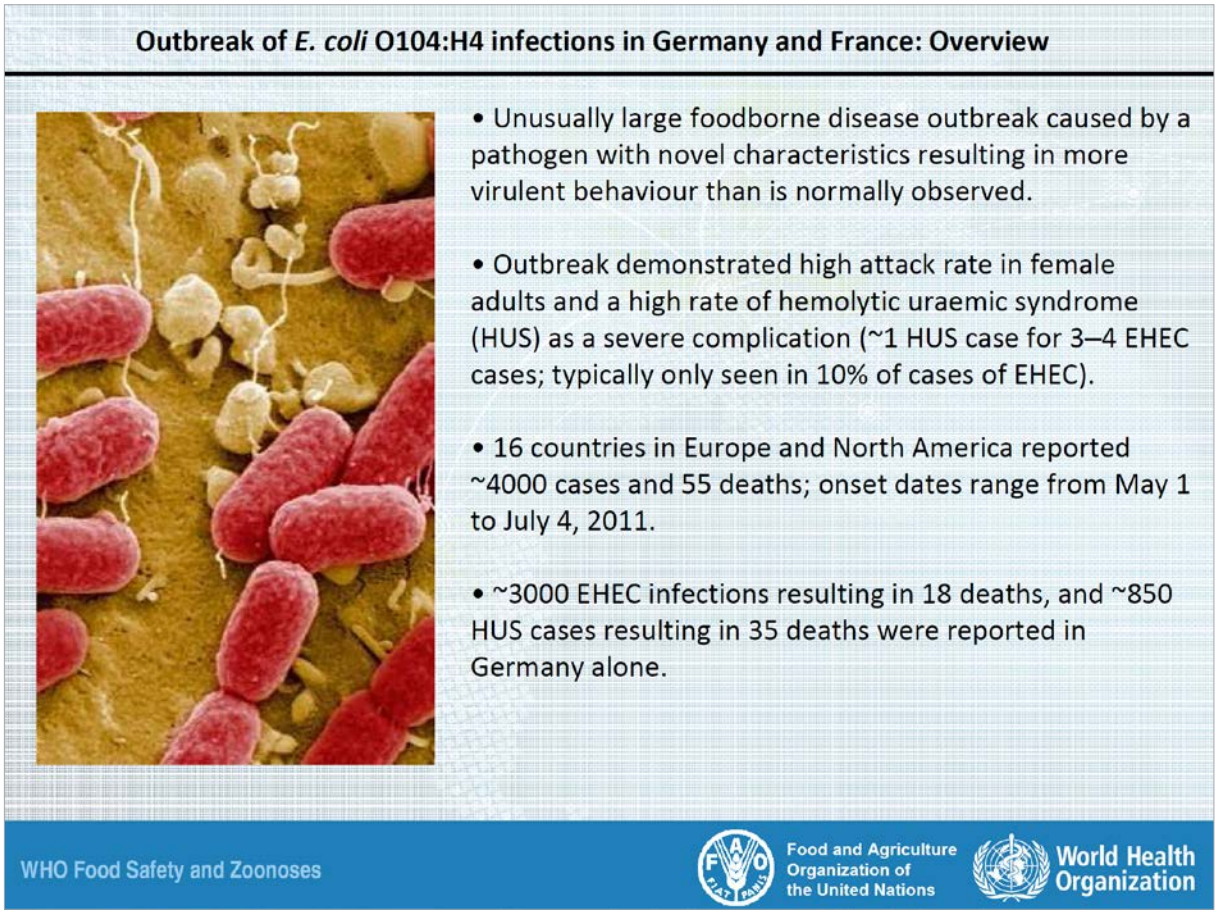


Fig. 1.2: Outbreak of *E. coli* O104:H4 infections in Germany and France.

These examples show that a local outbreak can fast turn global due to the many international sales channels. We need emergency plans in each individual country. There is no agency or institute responsible for all aspects of the food chain. This is why a concerted and coordination strategy is so important: the response plans must be descriptive, but also flexibly adaptable. International cooperation and exchange of information are key. As food crises have tangible consequences for industry and the retail trade, risk communication is of central importance. Then there are various categories of food like fruit and vegetables that pose greater risks and require particular attention.

How does the WHO react to these findings? We have drawn up some guidelines for national authorities: framework guidelines for emergency plans and application guidelines for risk analysis and procedures in food crises. Then there are the national food product recall systems, which need to be optimised; we will soon also be publishing a document on this topic. In preparation for this, we have defined five key messages for fruit and vegetables with the aim of achieving improvements in the production field. Like I said, the idea is to implement an integrated monitoring system. In order to do this, we need to merge the existing systems. Thank you for your attention.

Discussion

Question: I am the spokeswoman of Bonn.realis, a cluster initiative focusing on similar issues that has already proposed a number of ways of handling crises in Europe. What is the status of funding for INFOSAN and how do you contribute to ongoing projects in Europe? The EU is inviting tenders for several projects in the area of crisis prevention and crisis management both within the framework of Horizon 2020 and also within the context of the programme that is currently ongoing.

Dr. Tritscher: Cooperation with the EU is anything but trivial for us for contractual reasons. It‘s generally relatively difficult for us to become involved in the EU framework programmes, not least because we don‘t have any internal resources for large-scale programmes. But we do participate in individual work packages within the context of programmes of this kind. Funding is always a problem and, to be honest, I would be delighted if the EU were to approach us and signal their interest in our involvement. The world is indeed bigger than the 27-plus states, and the EU has far more money than the WHO. That‘s why I‘m happy to play the ball back to you: talk to us, we‘ll be happy to listen and to play our part.

Moderator: My next question follows on from the previous one. Apart from collecting information, reacting and bringing the various authorities together, how do you communicate, for example, with the agricultural sector or the food industry?

Dr. Tritscher: We are trying to cooperate more closely with the private sector, but this is not without its problems. There are many facets to the communication process, and the WHO plays a central role in defining norms and standards. It is in particular in this area that cooperating with the private sector is not always easy. This is why our Director General recently set up a working group to explore the potential for cooperation specifically with this sector. The communication aspect is part and parcel of this evaluation. It goes without saying that we also do our best to ensure targeted communication with the press, the public at large and the consumer protection organisations.

Moderator: Thank you very much. We now come to our next presentation by Dr. Tobin Robinson from the European Food Safety Authority EFSA, where he is responsible for scientific strategies and coordination in the event of new incidents. His career history means he is also familiar with the world of food production. His presentation will focus on the following questions: How quickly are the relevant EU bodies aware of the current status of research and how soon do they pass on this information to the competent bodies in the individual countries? And to what extent is it possible to anticipate future risks based on past events or experiences?

European Cooperation in Times of Crisis and Peace: European Value-added

Dr. Tobin Robinson,

European Food Safety Authority (EFSA), Parma

Ladies and Gentlemen,

Many thanks to the organisers for giving me the opportunity to speak here about some of the EFSA activities in the fields of risk assessment and crisis communication. I'd like to start off with some information on the subject of EFSA and science, however. EFSA is the risk assessor at European level for safety issues related to the food and feed chain. As such, EFSA's work involves carrying out science based risk assessments. EFSA's staff of 450 includes around 300 scientists. These are, for the most part, coming to us with experience gained in public institutions in the Member States.

The bulk of the risk assessment work at EFSA is carried out by the thousands of experts that make their specialised knowledge available on a voluntary basis, from institutions, authorities and agencies from all over Europe and beyond. This expertise and also the data used in our risk assessments, which are vital to the functioning of EFSA, is generated through the scientific activities in the Member States to which reference was made in the previous presentations. To enable EFSA to do its work, it is therefore vital that the Member States maintain an active and vibrant scientific capacity in the area of risk assessment.

I would now like to deal very briefly with the preparation for and response to crises and give a few examples of so-called urgent requests. I do not use the term crisis here in the same way it is officially defined by the EU Commission and I would like to illustrate our responsibilities by giving you a practical example, namely the EHEC outbreak in 2011 and the measures initiated by EFSA in this regard.

When preparing for crises, EFSA has several functions. In terms of crisis preparation, EFSA has two main actions: the preparation of procedures for dealing with urgent requests, and training in crisis response. The procedures are updated once a year or as necessary. The review of the procedures is based on our experience with urgent requests and from training exercises. These exercises are conducted once a year in conjunction with the Member States, the European Commission and our sister institutions in Europe. We also try to involve international organisations, such as the WHO and FAO.

Our procedures are summarised in the so-called "Emergency Manual" (EFSA's procedures for responding to urgent requests) and are generally activated in response to urgent requests from the European Commission or an EU Member State. The manual establishes who is involved and what their roles and responsibilities are and determines how incoming information

is to be handled and documented. These practical deliberations extend to the facilities and equipment of the “crisis room” and the provision of EFSA staff to help with the coordination.

With longer lasting crises, we must also ensure the continuity of our work, not only in the response team but also in our other activities. This places high demands on our planning, both in the provision of staff as well as the setting of priorities. Finally, another important step once the crisis has ended is its evaluation: what did we do right, where can we improve in future?

The training mentioned above is enacted in crisis-free times, because as I’m sure you will agree, it’s better to be ideally prepared. The main purpose of the simulation exercises is to improve cooperation between the European Commission and the Member States and sister European agencies. They consist of a series of exercises during which particular aspects of the crisis response are examined. This extends all the way through to the testing of conducting a video conference. It may sound banal, but communication is only possible in crisis situations if the right infrastructure has been put in place and tested.

Where communication in a crisis is concerned, a clear message at the right time can have a very calming effect. The longer the period of time without any information, the more speculation there will be. This causes unnecessary stress and concern among the general public. It is very important that the recommendations we make are scientifically independent. Risk assessment and risk management should therefore be separate activities performed by separate institutions. The quick response times show how well the cooperation between the EU Member States, EFSA and the European Commission can work where communication is concerned. To the extent possible, we attempt here to work with the same messages with all stakeholders, because it is highly undesirable that the various groups involved communicate different messages to the general public, who would naturally find this very confusing.

Let me give you a concrete example now. In the ten years of our existence we have received, over the last six years, in general roughly two urgent inquiries per year. Most of these concerned risks involving chemicals: melamine in baby milk, mineral oil in contaminated sunflower oil, dioxin in pork, nicotine as an insecticide in wild mushrooms and chlormequat in grapes (fig. 2.1).

Inquiries to the EFSA	Response Time (in days)
Melamine in baby food and animal feed (2007)	30
Mineral oil in sunflower oil (2008)	<1
Melamine in baby milk (2008)	5
Dioxin in pork (2008)	2
4-methylbenzophone in breakfast cereals (2009)	13
Nicotine in wild mushrooms (2009)	10
Chlormequat in table grapes (2010)	1
Volcanic ash (2010)	6
E. coli in sprout seeds (2011)	7
Schmallenberg Virus (2012)	10

Fig. 2.1: Response times to inquiries made to the EFSA.

As a result of the volcanic eruption in Iceland in 2010, we also received an inquiry from the European Commission about the health risks of volcanic ash for human health by exposure through the food and feed chain. This was followed by the EHEC outbreak in 2011.

With urgent inquiries of this kind, the response time is dictated by the institution making the request, e.g. the European Commission. In practice, this deadline has been between 24 hours and one month. By way of comparison: with normal risk assessment procedures, it takes anywhere between three months and two years to reply to a risk assessment inquiry, the time required depending on the complexity of the issue. Although the questions are, in general, simpler in a crisis situation, we have to speed up the process considerably while usually having to get by with less available.

Our most extensive inquiry to date, both in terms of the duration as well as the possible health consequences, involved Shiga-toxin-producing E. coli bacteria (STEC) of the serotype O104:H4. As the main facts of the matter are generally well known, I will only deal briefly with the circumstances surrounding them. One of the challenges of this crisis was that the characteristic features of the organism did not permit any clear conclusions about the source (human or animal) of the pathogen. The pathotype was rare in Europe and historical data showed that it had previously occurred mainly in the Middle East, Central Asia and North Africa.

The epidemic began in Germany in early May 2011. Germany notified the EU Member States and EU Commission about the outbreak on May 21, whereupon the Commission convened a video conference with the Member States. A second outbreak was reported by France on June 24, which led to the involvement of the European Food Safety Authority. If an outbreak of this kind only affects a single EU member the intervention of the EFSA is only exceptionally requested, but we were called in here once the problem had been detected in a second country.

In the first phase of our work we hadn't received an official request; nevertheless, in anticipation of our eventual involvement we started summarising background information that was already available, in collaboration with the European Centre for Disease Prevention and Control (ECDC). At this point in time, the source was still unknown, but fresh salad vegetables were under suspicion. For this reason, the presence of enteric pathogens in plant material was examined and we summarised the data that had already been reported within the EU.

The second phase began with a request from the German authority and the European Commission for support in investigating the outbreak in Germany. This was the first time that a national authority had approached us with a request of this kind. We then sent several staff members to Germany to assist the German task force with their investigations that led to the identification of sprouted seeds as the source of the outbreak. Of course we were pleased that we were able to offer our help, but I don't want to give any false impressions here or take credit for the achievements of others. National investigations of this kind are always the main responsibility of the Member State in question and their resources are many times greater than those available on our side.

In the third phase of our cooperation, the goal was to find the common source behind the outbreaks in France and Germany so that we could eliminate it from the European food chain. On behalf of the European Commission, we set up a task force from the interested Member States, ECDC, the European Reference Laboratory for *E. coli*, the WHO and FAO and in this way, fenugreek seed was identified as the common source. Only with the additional data provided by the French outbreak were we able to identify the precise food material (fenugreek seeds for sprouting) linked to the EHEC outbreaks, and only thereafter was it possible to take the necessary risk management measures.

Finally, as for all urgent requests we are involved in, we carried out a review of the response. To this end, we published a document taking stock of the situation by summarising the response at the European level in connection with the outbreak, and a second report detailing the lessons learnt.

This brings us to a point which received an awful lot of attention in the press: how could we be sure that the right source had been found? Rather than positive bacteriological tests, the evidence in this case was based on epidemiological findings which, although very compelling, were not concrete enough for some people. The resolution of the outbreak solely through the use of epidemiological data came as no surprise because there are many outbreak cases which cannot be connected with positive bacteriological findings. This can be explained by a low infectious dose connected to this EHEC outbreak being expected, and a low level of contamination being most probable in the food. On top of this, the contamination was likely only affecting a part of the batch, which means that a huge amount of bacteriological tests would have to be conducted to have a chance of finding one positive result. Furthermore, experience from testing similar materials (seeds and grains), particularly in the area of animal feed, tells us that it is very difficult to detect bacteria in this type of material. The European reference lab is currently working on refining the methods used for the detection of this type of pathogen in this type of matrix. The convincing factor was, however, that once the source had been identified and successfully traced and removed from the market, there were no further reports of cases with this strain.

We reported on the activities undertaken during all phases and the same applied to the ECDC and European Commission. We all informed the general public with the same carefully coordinated message and we conferred with the Member States to ensure that communication on the subject was not contradictory, nor came as a surprise to any of the public institutions involved. One of the things we learnt from this was that we sometimes tend to focus too much on the affected Member States, thereby losing sight of those not directly involved.

I would like to emphasise once again that due to our preparatory work outside the crisis periods, we are well prepared for a real crisis, thanks in part to the routine systematic gathering of data that takes place across the Member States. Routine collaboration in “peace time” also builds networks, confidence and trust that are vital for successful crisis resolution. And in this context, EFSA currently coordinates 13 Member State networks covering different scientific areas. Many thanks for your attention.

Discussion

Question: Was EFSA criticised for its communication strategies in the EHEC outbreak? From discussions with the Danish authority, I got the impression that they would prefer to receive notification from the EU Commission rather than from EFSA. EFSA is not an authority and the communication channel usually runs from the EU Commission to the national authorities. Perhaps the reason behind this is the fear that national peculiarities would not be taken into account, so it could be important that the communication channel from authority to authority is maintained.

Dr. Robinson: EFSA’s founding regulation clearly states that, in liaison with the risk manager, EFSA has obligations concerning risk communication.Transparent communication is a part of our responsibility which we exercise in close coordination with the EU Commission. As a matter of course, we talk to the risk managers before we make any announcements to the general public. In the EHEC case, the issue was discussed in the Advisory Forum Wor-

king Group on Communications, which is the group EFSA coordinates to address communications issues with the Member States and the European Commission.

Moderator: Many thanks. The next presentation deals with the question of how cooperation works between the national government and the governments of the federal states in Germany and between the federal states themselves. Professor Eberhard Haunhorst, President of the Lower Saxony State Office for Consumer Protection and Food Safety, is a veterinarian by profession. Professor Haunhorst, what are the obstacles in the way of smooth cooperation and how can they be overcome?

Cooperation Between the Various Government Levels in a Crisis: Point of View of the Federal States

Professor Eberhard Haunhorst,

Lower Saxony State Office for Consumer Protection and Food Safety (LAVES), Hanover

Ladies and Gentlemen,

I'd like to start by thanking you for the invitation. As president of the Lower Saxony State Office for Consumer Protection and Food Safety, I would like to explain to you how we are organised and what advantages and disadvantages this brings with it. By way of example, I will use the dioxin incident, with which we in Lower Saxony in particular were confronted in 2010/2011. I will also touch briefly on the EHEC outbreak.

Our structures in Germany are federal, which means that each of the 16 federal states and not the national government is responsible for food monitoring, the public veterinary control system and the health system. The organisation and conducting of control, monitoring and examination activities is therefore the responsibility of the federal states. The national government also has its responsibilities, of course; the Federal Ministry of Food, Agriculture and Consumer Protection represents this field towards the EU Commission and other Member States. And then there is the Federal Office of Consumer Protection, which attends to risk management matters on a national government level, the BfR and several other institutions. It should be noted though, that responsibility for monitoring lies with the federal states.

In Lower Saxony, the Ministry of Food, Agriculture, Consumer Protection and Regional Development with its headquarters in Hanover is responsible for this. Our State Office for Consumer Protection and Food Safety is as least as old as the BfR and Federal Office of Consumer Protection and Food Safety (BVL). I believe we may even be a bit older, because we celebrated our tenth birthday last year. 42 communal offices for the veterinary control and food monitoring system currently exist in Lower Saxony and they conduct most of the on-site checks. There are more than 400 offices of this kind throughout Germany.

Figure 3.1 shows the structure of the administration in Lower Saxony. You'd be forgiven for thinking that the structure is a strictly hierarchical one with the Ministry on the top, the State Office for Consumer Protection in the middle and the communities on the bottom, but unfortunately it's not as simple as that. Lower Saxony has a two-level administration, with the Ministry supervising the administrative and technical activities of the Lower Saxony State Office for Consumer Protection and Food Safety, which means that our organisation is directly subordinate to the Ministry.

In addition to this, the Ministry is responsible for the technical supervision of the 42 community veterinarian and food monitoring offices in Lower Saxony. The administrative supervisor of

these offices, however, is the head of each district authority as the chief executive of the community, and not the Ministry. This was different up to 1978 and it is also regulated differently, at least in part, in the other federal states.

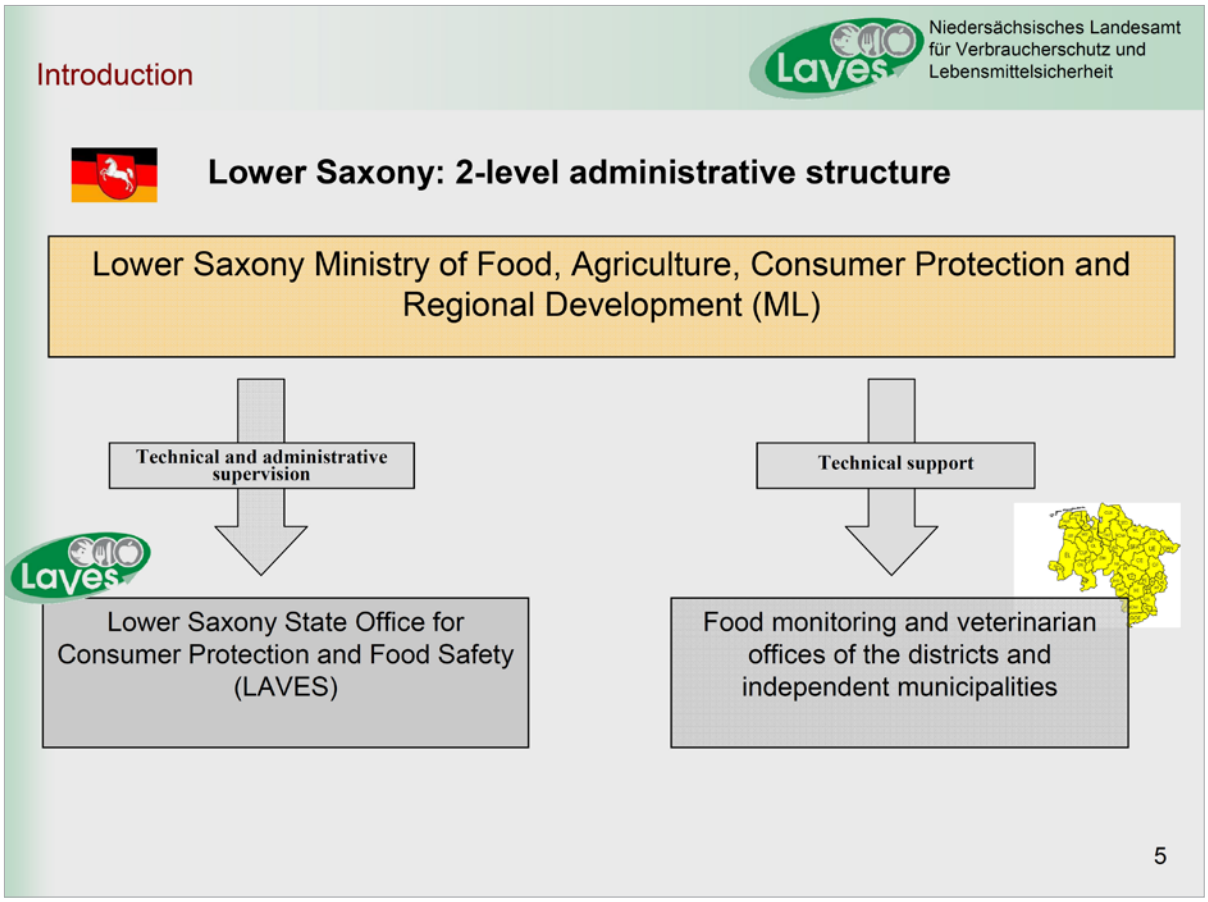


Fig. 3.1: Two-level administrative structure in Lower Saxony.

Why is Lower Saxony often the focus of food scandals? One could easily come to the conclusion that it's because we don't do our work very well, but the cause in the majority of cases lies in the fact that huge amounts of livestock are farmed in Lower Saxony: 47 % of all porkers in Germany – roughly ten million pigs – come from our federal state and the poultry numbers are approaching the 100 million mark in the meantime. If all of the agricultural businesses with mandatory registration are included, which means that they at least have to be inspected at certain intervals, we arrive at a total of over 50,000 feed companies. Over 3,000 larger-sized feed companies produce more than 40 % of the compound feed in Germany. According to the latest report, we have over 110,000 food businesses, including the gastronomy sector, which are subject to monitoring. The total of eight million consumers, on the other hand, is fairly average, but Lower Saxony nevertheless has a strong position in agro-business. That was another reason why the State Office for Consumer Protection was set up: food and feed crises and animal epidemics have an immediate and enormous effect, which will in all probability not only affect consumers in Lower Saxony, but also the entire economy.

The State Office for Consumer Protection was therefore created to take on food safety and animal health tasks. We have our own examination institutions and implementation tasks, which I will touch on briefly in the course of this presentation. De facto, the Lower Saxony state office examines all official samples in the livestock, food and feed sector, as well as performing a wide range of advisory functions. We are a purely state-run organisation, an office

with a staff of almost 900 and a national budget of 53.4 million euros. Our institution has its headquarters in Oldenburg, thus underlining our intention of locating the head office close to the largest agricultural businesses in Lower Saxony, along with branches throughout the state.

I'd now like to use the example of dioxin and EHEC to explain risk management in Lower Saxony and identify what we did well there and what could still certainly be done with some improvement. Maybe you can still remember what caused the dioxin crisis in 2010 and 2011: feed fats were mixed with technical fats which were contaminated with dioxin and this had the result that 25 compound feed producers had delivered feed which could not be classified as safe to approx. 4,700 agricultural businesses. Food products from animals which had eaten these feedstuffs could not be marketed for this reason. Of the 4,700 affected businesses, 4,468 were from Lower Saxony. Figure 3.2 shows the course of the crisis. After a relatively sharp decline in the number of suspended businesses, the number of businesses that we had to suspend rose again slightly in January until it eventually petered out at the end of April 2011.

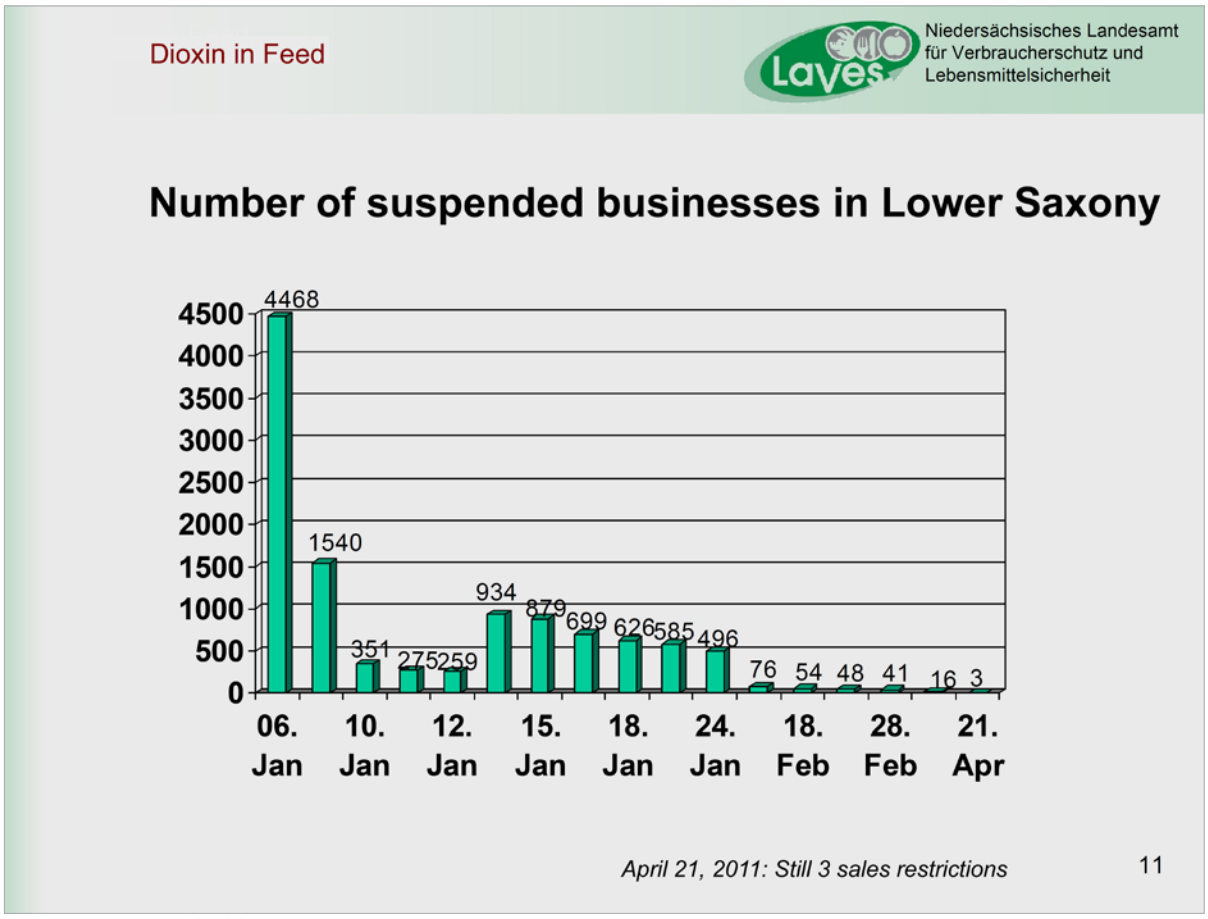


Fig. 3.2: Dioxin crisis 2011: Number of suspended businesses in Lower Saxony.

What tasks was crisis management faced with? Feed monitoring is the responsibility of the State Office for Consumer Protection, not the administrative districts and independent municipalities. This proved to be of great advantage, because in this way the on-site checks and subsequent inspections were all conducted from a single source. We of course had to establish quickly whether all 4,468 businesses had actually received contaminated feed, or whether the suspension could be lifted on some of them. Anyone who has seen a laying hen business will know that large quantities of eggs accumulate quickly when the business is suspended, and these eggs may have to be disposed of. The same problems occur in pig

production. To give us a significantly larger number of samples as a decision-making basis, we linked our examination results for feed and food for the first time with the results of the self-checks that were conducted within the sector. This cooperation was hugely important. We of course cooperated closely with the federal authorities, the BfR, BVL and the ministries too, in order to make estimations as quickly as possible. Unfortunately, it took a relatively long time to make it clear to the consumers that even if they were to eat two eggs with four times the maximum dioxin concentration every day for a year, the total concentration in the body would still be lower than it was 20 years ago.

So, what concrete measures did we take? The risk assessment was made on the basis of a traffic-light system which in turn was based either on the actual dioxin concentration detected in a feed in the course of our investigations or a worst-case contamination scenario of 61.6 ng of dioxin per kg of feed, a value we had calculated on the basis of the examination results from the business responsible for the fat admixture. If our test showed an admixture of over 0.5 ng per kg, the feed was classified as unsafe and the business was not allowed to continue delivering its products. Businesses for which we did not have a safe result were also suspended initially. Businesses with contamination levels of less than 0.5 ng per kg were classified as safe and permitted to deliver their products. The value of 0.5 ng per kg constitutes the so-called trigger value; the legally determined upper limit for dioxin contamination is 0.75 ng per kg. It proved worthwhile to use the trigger value as the critical limit, because there actually were a few isolated cases in which the contamination level in the feed lay between 0.5 and 0.75 ng per kg and the upper limit with the eggs was exceeded nevertheless.

We used this traffic-light system with as many evaluations as possible, but not all businesses could be evaluated in this way. There were pig farms, for example, where it was not clear how the contamination would develop. For cases of this kind, we developed a system in collaboration with the BfR and Lower Saxony ministry which enabled us to estimate when the contamination in the animal tissue would drop below the critical limit. This system was successful.

We were also heavily involved in risk communication, with a hotline, relevant interviews and several statements. We have developed a new concept in Lower Saxony in the meantime to ensure that different people don’t make different statements in a crisis of this kind. We are on the way towards uniform risk communication. It worked quite well in the dioxin incident due in no small part to the good working relations with the administrative districts, which are responsible for food monitoring, and the close cooperation between industry and the authorities. Overall, the Food and Veterinary Office (FVO) awarded us a good rating during an inspection for our crisis management in this dioxin crisis. Despite this, I believe as I cast my eyes over the representatives of trade and industry in the audience, that we will need better methods in future to enable us to identify contaminated feed batches even more clearly. We had 4,468 potentially contaminated businesses, but it took us weeks to identify them, because the computerised lists with the delivery addresses of feed producers do not match up with our own lists of agricultural businesses. There are interim dealers and distribution channels which require a lot of laborious research here. There is still an awful lot of homework to be done in this area if we don’t want to have to manually check up on more than 4,000 businesses again when a new case crops up.

I hope you will allow me a few final remarks on the EHEC outbreak, which also had a very strong effect on Lower Saxony, with 15 fatalities. In my opinion, the error in communication was that the difficulty of identifying an EHEC infection via the pathogen was not emphasised right at the beginning of the crisis. Carefully conducted epidemiological examinations are conclusive per se in 80 % of cases but unfortunately, I have often heard people comment what a pity it is that it was not possible to detect the pathogen directly.

During the EHEC outbreak, the national government deployed a risk management taskforce which also included LAVES personnel. The cooperation between the authorities still has room for improvement in my opinion. This affects the interface between human health and animal health on the one hand. Although this worked very well in some offices and on a federal state level, it can be said that cooperation on community level was not quite as simple. If, for example, someone from LAVES wanted to talk to a community authority in another federal state, this was sometimes refused with the request that compliance be observed with official channels, namely from community authority to community authority. In short: thought should be given to the standardisation of the structures in risk management. I know that many people don't want to hear this message, but in light of the different levels of competence of the state authorities and two or even three-level administrations, it must at least be clearly regulated who is to communicate with whom. This issue should be dealt with before the next crisis, because it cannot be the case that the communication channels are only determined once a crisis has broken out. The various degrees of competence among the authorities are also more of a hindrance in a crisis. We do not have technical supervision over the authorities on community level, for example, which means that we cannot tell them what to do. This is not the case in North Rhine-Westphalia and Bavaria.

I'd like to summarise briefly before I finish: there are still great problems with data management. I already spoke about the lack of a network so that industry can control itself with regard to identifying consignments or businesses, for example. There are also deficits in the networking of the federal states in my view. Although this network is being built up, it is still at the project stage. Where communication structures are concerned, we in Lower Saxony are pretty far advanced, but we still need fast and direct communication among the specialised authorities with responsible contact persons and a common data pool. Work is currently being done on this.

For this reason, a taskforce for the food sector is to be formed in Lower Saxony where a similar group has been in existence in the field of animal epidemics for ten years. On top of this, there is a corresponding technical crisis department at the agriculture ministry which has the task of coordinating crisis activities better than was possible in the past. Many thanks for your attention.

Discussion

Question: How long do you think it will take until a common data pool and better networking have been achieved? Is the conversion from paper to computer to be made soon or is this still a long way off?

Prof. Haunhorst: It's still a long way off.

Moderator: May I ask a completely different question which I am sure is of interest to many here in the audience: the food authorities of the communities – there are more than 400 of them – say that they are lacking the necessary financial and personnel resources. Is that so?

Martin Müller, Federal Association of Food Inspectors, Germany: Unfortunately, this is not just moaning for the sake of moaning, we really do need more food inspectors to perform the distinct task of food monitoring. This is a fact. Risk-based control specifies an inspection frequency which unfortunately cannot be complied with. Some of my colleagues in Germany have to attend to as many as 3,500 businesses.

Prof. Haunhorst: I can only back up what Mr. Müller is saying. There are certain areas in which more personnel are required, but before that happens I see the obligation for better organisation. If an office only has two or three people to cover the entire spectrum, it's very

difficult. It doesn't necessarily have to be huge units – there are well-functioning veterinary inspection offices of a limited size which specialise in a particular area – but there is a great bandwidth here and that includes Lower Saxony.

Question: You argue in your presentation that information to the public should be issued from a single source. Can you prevent colleagues in Lower Saxony from regarding themselves as experts and airing their opinions?

Prof. Haunhorst: Of course we can't prevent that, but we have developed a concept on how risk communication should be handled. This involves the state office preparing a daily report summarising the most important information. When the minister publicises this information, it is given to the heads of the district authorities and LAVES at the same time so that we all have the same information status which we can then communicate accordingly. These reports contain a date, time and submission deadline so that it is clear what data were taken into consideration. If ten other businesses are suspended five minutes later, it is clear that this information will only be able to be included in the next position report. I believe this will produce more clarity in future.

Moderator: Maybe I could add something to this from my own professional experience. I think it has become clear that official bodies must become better and more uniform in their communication. On the other hand, we are dealing with science here, a field where there are many different opinions, including minority opinions. I admit that my journalist colleagues occasionally interview outsiders too, so that they can then question the basis of their scientific findings, but it's difficult to put a stop to this.

Question: Can I return the ball to your court? What possibilities do you see concerning quality assurance in journalism?

Moderator: Very few, to be honest. As in many other sectors, the financial resources of the publishing companies, which form the basis of carefully researched, knowledgeable quality journalism, are becoming ever scarcer. Attempts have been made by professional associations and trade unions to establish quality assurance in journalism and some of them have been successful, but not all of them. I'm afraid that in the same way that we all have to live with shortcomings in science and politics, you will just have to live with the shortcomings of my profession.

But let's move on to the next presentation. Adjunct professor Dr. Gaby Fleur-Böl is responsible for risk communication at the BfR. There are several pitfalls in this area: firstly, real danger and risk perception are not always one and the same thing; secondly, reporting in the media is not always sufficiently based on the facts; thirdly, not all authorities act with the necessary transparency and fourthly, there is the problem of the variety of responsibilities which has already been mentioned many times. The biggest problem, however, could be that a thorough and substantiated scientific search for causes takes time. Dr. Böl, how do you bring all of this together?

Risk Communication in Times of Crisis

PD Dr. Gaby-Fleur Böl,

Federal Institute for Risk Assessment (BfR), Berlin

Ladies and Gentlemen,

When the talk is of food and eating, one would assume that most people would have positive associations, but surveys conducted throughout Europe show that people tend to be uncertain in this regard and that they believe food to be a great risk. This leads us directly to the question as to why the food sector is so susceptible to crises in the first place. Some of the reasons are obvious: eating is an elementary need and we have daily contact with food, but amidst all this we detach ourselves more and more from the production process. Our analysis methods have improved an awful lot and we are capable of detecting even the slightest contamination, even if it does not automatically constitute a health risk, as with dioxin.

The causes of food crises include contamination, new scientific findings which attribute a hazard potential to foods previously regarded as harmless, and simple confusion among consumers due to false declarations. Ultimately, public perception plays a decisive role here too. It is often very different from the way we scientists view things. As you all know, words as well as images can often have a very strong effect. Looking at pictures of Japanese children after the reactor accident in Fukushima, people in Germany were dramatically unsettled and began to demand more and more iodine preparations, which turned out to be counterproductive in this instance because no health risk existed for the German population and increased iodine intake posed more of a risk.

We are nevertheless often confronted with stark images and we as scientists are faced with the challenge of responding to this and taking the concerns of the general public seriously instead of hiding behind the argument that their concerns are not really justified.

We've talked about various crises, but we don't always have to deal with a sudden crisis that crops up quickly and ends just as quickly. They very often come in waves or they creep up slowly and all of a sudden public interest soars. We have to be able to respond to this appropriately and in good time.

This brings me to the decisive question of how to communicate in a crisis. It goes without saying that we have to act quickly without losing sight of our strategic alignment, which means that we have to formulate rules of thumb for the affected sections of the general public so that we can issue instructions very quickly to bring the situation under control. Risk communication, on the other hand, is all about communication before the crisis, in quiet times, in the hope that the crisis can be avoided before it even happens thanks to an

appropriate measure of participative risk communication. It is recommended here to deal with the question of how people perceive risks. We have analysed this using the example of nanotechnology and defined different perception types: people who act pragmatically can be approached in a completely different way than people who give up hope more quickly or get important tips from their doctor or pharmacist. The goal is to enable controllability not only for those who have to handle the crisis but also for the population in general.

Where there is a risk, toxicologists ask: How poisonous is the substance in itself? The fundamental level of danger of a substance can be determined in this way. The question also arises as to how much poison will actually enter the human body. Do huge quantities perhaps have to be ingested before a person even reaches the limits of possible danger? The spatial and chronological expansion of the damage must also be taken into account, but the fact that risks can be calculated using parameters of this kind does not mean in any way that consumers will understand us when we present these deliberations.

The basic principle is that as soon as consumers' options are restricted by the occurrence of a crisis, their risk perception rises sharply. It does so too if the impression arises that they themselves cannot control the risk. Just think about swine flu and the simple tip on how to wash your hands. Advice of this kind may sound obvious but it is very useful for adjusting the population to the crisis and providing some help. Of course it also matters how terrible the damage is, how trustworthy the institution that gives the advice and who is ultimately responsible for the crisis.

This leads us to the question of how a risk should be communicated in the first place. There are recommendations on this, such as those issued by the Environmental Protection Agency (EPA) and World Health Organization (WHO), the initial goal of which is to involve and listen to the general public. The media should then be approached with caution using clear language that the public can understand. The use of definite images can be very helpful here. Scientific uncertainties should be mentioned. If a responsible person really is unsure, he or she should state this clearly while continuously researching all new information.

I would like to return to the example of the EHEC outbreak in 2011 in this regard. The images that were shown in the media were highly charged with emotion. Everyone asked themselves: what do we really know and what don't we know? I would like to digress here briefly and touch on a theory that I consider important. It deals with the communication of scientific uncertainty. According to Socrates, there is unspecific ignorance on the one hand, which is characterised by the notion that what we do not yet know is unknown and that there are still a great many shortcomings. People talk in general about a risk technology and do not know the probabilities for the occurrence of damage. Unfortunately, situations of this kind still exist to this day, but luckily they tend to be seldom. The rule of current scientific practice is specific ignorance, which means that we are aware that we may not yet know something. We can tell the general public precisely where we still have to acquire knowledge. We can give estimates and make provisional risk assessments.

What communication strategies are there when dealing with ignorance? I'll sketch out three different possibilities for you: in all of the countries represented at our symposium, it used to be the case that uncertainty in science tended to be denied. What was known was published, the rest did not exist, in line with the motto "uncertain results aren't results". The second option is to admit that although uncertainty exists, it should not be discussed in public. The train of thought behind this is that science is the opinion leader and that its knowledge is of no importance to the general public. We all hope that we have changed and are willing nowadays to disclose and openly discuss uncertain results. This means that the expectations of politics and society with regard to certainty could possibly clash with the uncertainty of science.

Despite this, we should deal openly with this, admit knowledge gaps and also correct recommendations where necessary.

The problem here though is that the media often don't communicate scientific results precisely enough and turn preliminary results into certain results. In the EHEC case, the vast majority of the public fully understood and accepted the correction when the recommendation not to eat certain foods was switched from cucumber, lettuce and tomatoes to sprouts. We and many other institutes published articles on this. One Hamburg institute expressed the suspicion that cucumber could possibly be the EHEC carrier. The wording of the statement issued by the BfR on this was very cautious too: "The detection of EHEC in Hamburg in cucumber from Spain and other places led to several warnings via the European rapid warning system. It cannot be excluded that other foods are also a possible source of infection". The wording was intended to point out that uncertainties still existed and that other foods could not be discounted as EHEC carriers. As you know, we issued this statement jointly with the Robert Koch Institute and the Federal Office of Consumer Protection and Food Safety. We also recommended as a precaution that people stop eating raw tomatoes, cucumber and leaf lettuce until further notice. Our final statement also contained the careful formulation that fenugreek seeds were responsible for the outbreak with a high degree of probability.

What this means is that, as natural scientists, we can define what we know and what we don't know. Our internal guidelines contain formulations which express specific ignorance and which the general public can understand. But as you know, the press communicated this state of affairs completely differently: "Spanish cucumber is to blame". The economic and diplomatic consequences this had internationally are well known in the meantime.

We talked before about how there are and always must be many different expert opinions. Several of them suspected that antibiotics in animal feed were allegedly to blame for these dangerous intestinal bacteria. Others said that vegetables just had to be thoroughly washed. And others still surmised that the germs had been spread deliberately. As an institute, you have to live with statements of this kind; you can't publish a counter-opinion every day and there is no need to do so either.

If you look at the results of a representative population survey on the EHEC crisis, the following can be seen:

- The question "Have the responsible authorities in Germany done enough to protect the general public in your opinion?" was answered with "yes" by an astonishing 71 %. The communication measures were so successful here that they got through to the general public.

- Asked whether they had changed their habits as a result of EHEC, 50 % answered with "yes". Most of them stopped eating the foods we had listed in the consumption recommendation. We would also like to have seen better acceptance of the corresponding hygiene recommendations which were only heeded by a small percentage.

- 74 % of the German population was able to understand our consumption recommendations and also approved of them, even though for technical reasons a different recommendation was given at the start of the outbreak than at the end.

- Although the sprout recommendation still applied for quite some time, 60 % of the respondents returned to their old consumption habits at the end of the crisis. This is typical behaviour after crises.

- If we compare the risk estimation of the EHEC outbreak with that of the dioxin incident in 2011, however, we ascertain that the dioxin problem was perceived as a crisis by the

general public, even though it most certainly was not a crisis. 40 % estimated both risks to be equal and 30 % assessed the dioxin risk as higher than that of EHEC despite the fact that EHEC caused the loss of human life (fig. 4.1). This means that the public perceive chemical risks as more of a threat while biological risks are regarded initially as less of a threat.

- I would like to touch very briefly on the dioxin incident which did not constitute a genuine crisis situation. From the point of view of the media, however, it definitely was a crisis which stayed with us for over six weeks. We reacted quickly by producing a chart which was intended to show that the level of dioxin that we all have in our body was three times higher 20 years ago than it is today. Even if consumers had eaten two of the contaminated eggs every day for a year, their dioxin levels would only have risen by a small margin far removed from the 30 pg/g body fat that used to be the average value. In spite of this, our message was scarcely heard by the media, and consumers were calling us up to ask if they should dispose of the eggs in question as special waste. There was great uncertainty.

- The example of dioxin shows clearly the role that news factors play for the media (fig. 4.2). On the one hand conflicts are made a subject of discussion, which in this case concerned the criticism levelled at the German government by the consumer organisation Foodwatch. Quantities are thrown about which can often be inconsistent. The local aspects of a crisis are emphasised, instances of noncompliance with standards are picked up on and attributed to individuals wherever possible. A report with the headline “Why Dioxin Again?” unsettles the general public. The maximum permitted values have been set in such a way in this regard that we will have to read reports of this kind in the future too. Add to this the serialisation of the incidents: “First Eggs, Then Pork” (fig. 4.2).

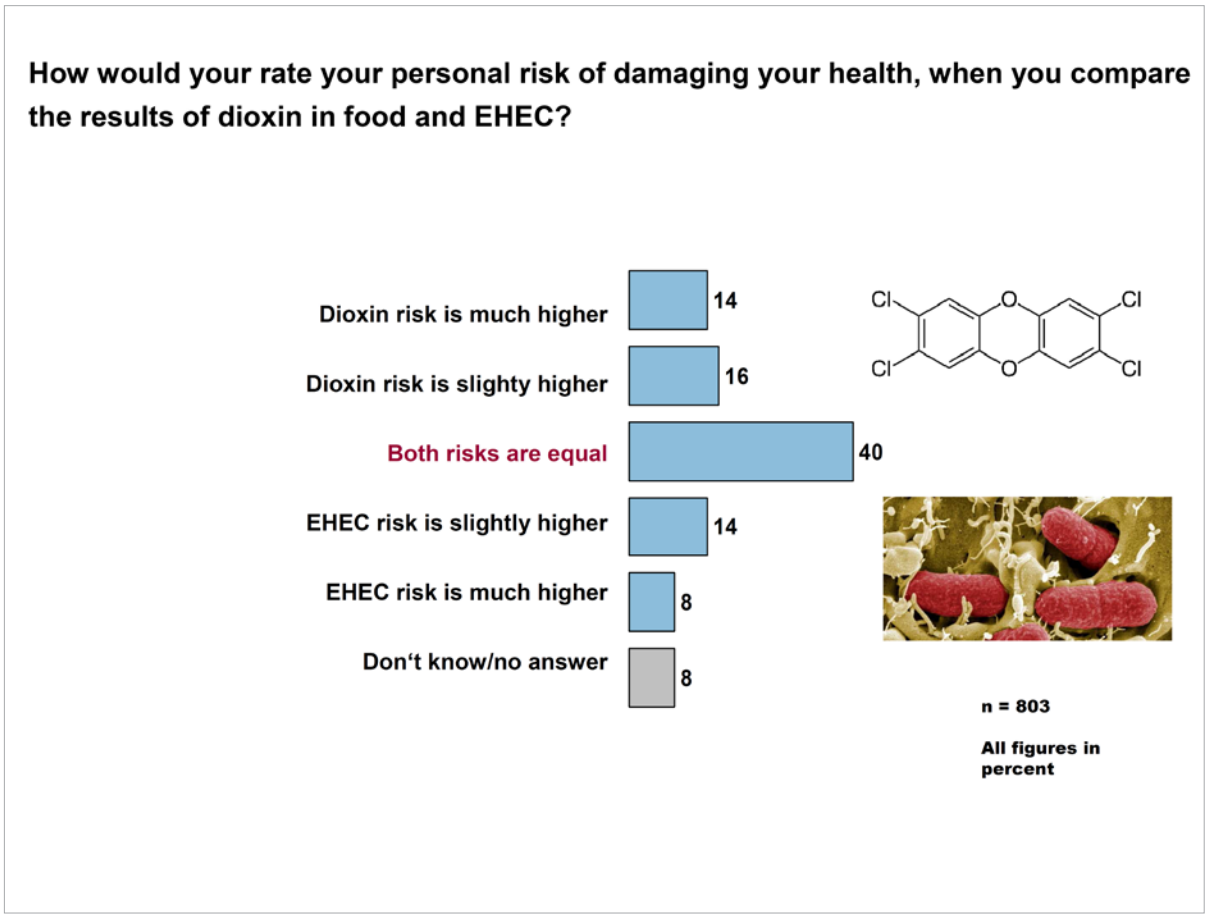


Fig. 4.1: Comparative risk estimation: EHEC versus dioxin.

News Factors	Dioxin Incident 2011
Conflicts	"The consumer organisation Foodwatch attacks the Federal Government in the dioxin scandal. They are guilty of serious neglects and are not strict enough in their dealings with the feed industry." (Handelsblatt Online, 09 Jan, 2011)
Quantities	"Some samples contained almost 78 times more dioxin than allowed." (Berliner Zeitung, 08 Jan, 2011)
Local aspects	"This affected 1,000 laying hens and poultry and pig production businesses in Lower Saxony alone. The authorities shut down a pig breeding business in Brandenburg as a precaution." (Berliner Zeitung, 04 Jan, 2011)
Noncompliance with standards	"There was criminal energy at work here." (WAZ online, 04 Jan, 2011)
Personalisation	"This guy put toxic fat into our food." (Bild online, 04 Jan, 2011)
Topicality	"Why is dioxin back again in eggs and meat?" (Tagesspiegel, 16 Jan, 2011)
Serialisation	"First the eggs, now the pork." (Stuttgarter Zeitung, 12 Jan, 2011)

Fig. 4.2: News factors in the dioxin incident 2011.

The socio-cultural criteria which characterised people's emotional reaction during the dioxin crisis were many and varied: people were personally affected because they had contact with the foods. They were involuntarily exposed to the risk. Although they could avoid eating eggs and pork, they had no control over matters initially. On top of this came the worry that the consumption of large quantities of foods contaminated with dioxin could have long-term effects. Responsibility for the problem was not to be found in nature – people would have been more willing to accept that – it was man-made. That's why the risk was generally estimated to be higher.

In synopsis: adequate risk communication should anticipate possible evasive behaviour in a crisis. Consumer typing helps here to improve understanding of people's emotional reactions to a crisis. The different needs of these target groups have to be taken into account when selecting the multipliers and information channels. Consumption recommendations and other clear recommendations for action are important aids for consumers which they can use for orientation purposes in a crisis. What is required first and foremost, however, is transparency in order to promote participation and a proactive response so that crises can be avoided before they arise. Many thanks for your attention.

Moderator: Many thanks, Dr. Böl. We'll move along now to our next presentation. Ms. Boutrais will be speaking on behalf of ANSES, one of the co-organisers. She is a sociologist and will be telling us about what social and human sciences can contribute to risk management and risk prevention.

The Role of Social and Human Sciences in Crisis Prevention

Régine Boutrais

French Agency for Food, Environmental and Occupational Health & Safety (ANSES)

Ladies and Gentlemen,

I am very pleased to have the opportunity to present the various ways in which ANSES is promoting the contribution of social and human sciences to health risk assessment and the dialogue with civil society in order to try to prevent crises. ANSES was founded in 2010 and upon its creation, the transparence, independence of expertise and access to stakeholders were central to the Agency's activities. I am a sociologist and I work in the Risk and Society Unit which belongs to the Department of Information, Communication and Dialogue with Society. This unit is composed of four employees, having qualifications in the fields of sociology, economics, and political science. In order to secure a more comprehensive approach of risk assessment, we have established four main goals:

- Implementing the opening up of expertise by entering into a dialogue with the stakeholders.
- Developing knowledge in social issues and involving social and human scientists in the assessment committees.
- We also carry out a watch on the interfaces between science and society.
- and we contribute to public debate by communicating and explaining the opinions and reports delivered by the Agency.

In 2011, ANSES and five other public organisations involved in the field of health risk assessment signed a charter aiming at improving the transparency with regard to expertise and assessment methods; sharing with stakeholders scientific findings and uncertainties, including minority positions and possible controversies among experts, and finally building up capacities of stakeholders to understand the assessment process.

I would like to remind you of ANSES's areas of competencies. We came into existence through a merger of the former AFSSA, the French food safety agency, with AFSSET, which covered the environment and occupational health fields. Our agency is therefore set on a very broad basis: human health and safety in the fields of environment, work and food, as well as animal health and welfare, and plant protection. This means that we have to deal with a wide array of stakeholders involved in these various fields – NGOs, industries, trade unions, etc. Their participation is legally required in the governance bodies, such as the Board of Directors and the thematic orientation committees. We also launched on a voluntary basis two dialogue committees on hot issues: "nanomaterials and health" and "radiofrequencies and health".

One of the particularities of ANSES is that NGOs are entitled to request risk assessments from us. The NGO must be approved or certified by the French government to be entitled to solicit a risk assessment by the Agency on a specific topic. We can also receive requests from trade unions, environmental associations, consumers' organisations, industries and of course ministries.

You can see that this approach goes further than risk communication in times of crisis and means a commitment to try to prevent crisis by upstream engagement of stakeholders all the way through the expertise process up to the downstream information.

In order to create the prerequisites for fruitful discussions, we organise information meetings which convene roughly twice a year. We choose transversal topics, such as pesticides in food and the environment, water quality, plastics, nutrition, cancer, microbial pathogens, antibiotic resistance and allergens. Whenever possible, we also take into account lay knowledge which might be produced by NGOs, such as surveys, consultations; we make interviews and hearings in the course of risk assessment. The Risk and Society Unit also conducts a watch on networks and social movements at a national and international level.

Our second goal, the production of knowledge on social issues regarding environmental health, is not only pursued internally but also in close cooperation with external scholars and academic research centres. I'll give you two examples of these collaborations: the "Group of Pragmatic and Reflexive Sociology (GSPR)" at the School for Advanced Studies in the Social Sciences (EHESS) is specialised in detecting early warnings and studying controversies on the long-term through a computerised, semantic analysis of texts and data published on these subjects (official reports, media, etc.). Large databases have been compiled over the years on various issues: asbestos, bees, nuclear power, Bisphenol A, polychlorinated biphenyls, dioxin, genetically modified organisms and much more. It also enables the analysis of transversal themes such as low doses, conflicts of interest, expertise, etc.

We have also established a collaboration with the Centre for the Sociology of Organisations (CSO) connected with Sciences-Po and the National Centre for Scientific Research (CNRS). We have jointly prepared a questionnaire for sociological framing of risk assessment. The outcome of this collaboration will also probably result in the building up of an international network of experts in social and human sciences in the fields of environmental health who can exchange their knowledge and approaches.

Within ANSES too, we promote the use of social sciences in risk assessment. We conduct socio-economic analyses, for example, to investigate the effects of poor indoor air quality or the socio-economic factors underlying the substitution of CMR chemicals. To the greatest possible extent, social and human sciences are involved in our multidisciplinary working groups dealing with risk assessment of endocrine disruptors, noise pollution, pesticides, nanomaterials, animal welfare, to name but a few.

In addition to this, we are planning the deployment of a specific expert working group composed of social and human scientists to be launched in November 2012. It will comprise various disciplines: economics, sociology, law, philosophy, etc. This committee aims at making literature reviews and recommendations on societal issues linked to opinions rendered by the Agency, at conducting case studies and more generally at improving methods and procedures used.

These various initiatives, both on an internal and external basis, generate socially relevant knowledge and understanding of societal issues to produce a more robust risk assessment. The next step involves the close follow-up of the gaps between science and society. In doing

so, we follow in particular the criticism of science and emerging technologies (nanotechnologies, radiofrequencies, synthetic biology) and take interest in raising issues such as unexplained syndromes: multiple chemical sensitivity (MCS), chronic fatigue syndrome (CFS), intolerance to fragrances, sick building syndrome or electrohypersensitivity (EHS). We are also observing cross-sectional topics, such as conflicts of interest, the precautionary principle and public participation in health and environment risks.

The last goal is the contribution to public debate and regular information on the statements and reports produced by ANSES. We also conduct internal debates three to four times a year open to the Agency staff and to our stakeholders and partners where social scientists present the results of their research. We have dealt with issues such as the asbestos crisis, a comparison of the nano debates in Europe, nutrition and obesity, the prevention of occupational health risks etc. In cooperation with Sciences-Po, we also organise prospective colloquia which are open to the general public on topics such as the governance of uncertainties, environmental justice and health inequalities or the internationalisation of food systems.

It has been our experience that the human and social sciences make a significant contribution towards improving the quality and robustness of risk assessment. Potential controversies can be more easily anticipated because all stakeholders are involved right from the start of the risk assessment process. This is important, because crises not only require top-down communication but also a bottom-up pro-active approach. This promotes transparency and creates trust. In France in particular, NGOs are open to the idea that there are scientific uncertainties and a lack of knowledge in certain areas. On the basis of our joint analyses with cooperation partners, we gain awareness on alerts and early warning signals and improve our reactivity in potential future crises. A more precise knowledge of the social impacts of health and the environment, a better communication not only on risks but also on uncertainties and emerging issues, should enable us to better handle a crisis or a deep controversy which might arise. Many thanks for your attention.

Discussion

Question: Ms. Boutrais, this is the first time I have heard you talk about early warning signals and risk observation. You mentioned the nanomaterials in this regard, but which conceptual ideas are there beyond the discussion of nanotechnology in the early warning area?

Régine Boutrais: Where early warnings are concerned, it is difficult to give a definition. David Gee published a book on this recently called “Late lessons from early warnings”. I can only give you examples here. As far as the asbestos crisis is concerned there were many practitioners who identified an asbestos problem, and who could have alerted the authorities. There are no particular early warnings with nanomaterials but a lack of knowledge. We have only just begun the dialogue on the potential health risks coming from nanomaterials. We wanted to get all stakeholders to sit down around a table and discuss – trade and industry, the NGOs, the trade unions and the scientists – health risk assessment and orientations in the field of research.

Comment: I found both presentations very interesting with very good approaches. In recent years, pressure has increased to make risk estimation more transparent and to outline its uncertainty. While many projects on the communication of uncertainties in risk assessment are currently running, this pressure is all but lacking in risk management. Dr. Böl concentrated on communication with the public and defined certain formulations so that the general public can better understand risk management, but it is not only the media who distort messages and pass them on in a different way; the same thing happens on the political side too. I think

it's high time that risk management does its homework and makes efforts towards a better understanding of science.

Moderator: Dr. Böl, perhaps you would like to comment briefly on this.

Dr. Böl: You are right, I did concentrate on the messages for the public and the media. That was the focus of the presentation. Of course it is just as important that the various stakeholders – especially the public institutions, authorities and international organisations – produce formulations which are transparent and which match up with one another. With the request that you provide us to the extent possible with the corresponding guidelines and directives of your organisations we at least made an attempt to find an approach, because it is definitely dangerous if something goes wrong in the communication of the risk managers.

Moderator: I know you're not completely satisfied with the answer, but perhaps you'd like to ask your second question.

Question: Thank you. I didn't expect a concrete answer. I only wanted to address the matter. My next question goes to Ms. Boutrais: what role will the social and human sciences play in risk management?

Régine Boutrais: I think it is the way forward that the social and human sciences are becoming more and more involved in risk assessment, so why not in risk management too? The main focus should not be in terms of communication, but in delivering knowledge about society.

Moderator: Thanks, I've got a question for Dr. Böl. It goes without saying that every communication process demands transparency, honesty and speed in connection with crisis situations, but how are the extensive coordination processes brought in line with the demand for speed?

Dr. Böl: Very well actually. The fundamental advantage lies in the fact that in this way we are assured of internally coordinated answers and do not issue individual replies to the general public. The process is extremely fast: we only require seven to ten minutes with personal contact or per telephone for a reply coordinated over three hierarchy levels. Hierarchy systems that appear complicated do not have to be slow.

Question: My question concerns the communication of uncertainties. Is this not a double-edged sword? Of course these uncertainties should be conveyed but isn't there a risk that they could be instrumentalised to reject a risk estimation or recommended measure as completely exaggerated?

Dr. Böl: There is a risk, but it's a small one. People used to think that by admitting uncertainties of this kind, they were also admitting their own incompetence, but this attitude has changed a lot. This is shown by several social science studies. The public want multiple answers, even if they are uncomfortable. Credibility is very much higher if uncertainties are openly admitted and communicated, even if the opinions are controversial. I don't want to be misunderstood here; it's not about one hand not knowing what the other one is doing. It is essential that they all have the same level of information, but we have a federal system here in Germany in which the federal states have a say and where the BfR can also state its opinion as an independent institution in order to issue consumption recommendations and press releases.

Régine Boutrais: At ANSES, we don't communicate directly towards the general public, we work via stakeholders and particularly with NGOs. Explaining uncertainties often leads to greater commitment and trust in the results of expertise on the part of the NGOs.

Moderator: Thank you very much. The next presentation will be given by Dr. Helmut Tschiersky-Schöneburg, President of the Federal Office of Consumer Protection and Food Safety. Dr. Tschiersky-Schöneburg, which models do we need to enable us to handle the next crisis more quickly and more effectively, with better coordination and less uncertainty?

Risk Management and Coordination in Times of Crisis

Dr. Helmut Tschiersky-Schöneburg,

Federal Office of Consumer Protection and Food Safety (BVL), Berlin

Ladies and Gentlemen,

Many thanks for the introduction. When we speak of crisis management it is extremely important that everyone is aware of the role they are playing in helping to overcome the crisis. To this end, a structured development plan and an operating plan are needed and I would like to go into this within the scope of my presentation. I would also like to explain which possibilities exist to improve crisis management and which of these can actually be used.

Professor Haunhorst has already said a fair amount with regard to crisis management from the perspective of the federal states. I represent the national perspective. My place of work, the Federal Office of Consumer Protection and Food Safety, is a partner and affiliated organisation of the BfR. We are responsible for a whole number of steps along the value chain in the field of risk management. Amongst other things, we are also the competent national approval authority for genetically modified organisms or GMOs.

Please allow me to start with a brief overview of the legal framework. When looking for the appropriate legal provisions with regard to crisis management, there are surprisingly few regulations to be found. In the basic regulation there are some articles concerned with the European Commission Emergency Plan and with the crisis unit. This task was implemented in the 2004 decision. In the EU control regulation 882/2004 there is an obligation in Article 13 that EU Member States must set up alarm and emergency plans. In Germany, this obligation was met with a clause in the general administrative regulation on framework monitoring according to which the federal states have to establish such plans. Some provisions in the German Food and Feed Code (LFGB) supplement this regulatory framework.

Although the term risk is defined in the Basic Regulation, there is unfortunately no direct answer to be found with regard to the definition of a crisis. However, an indirect approach is to be found in the formulation of Article 55 of EC Regulation 178/2002. In this case, however, it is only a question of those crises caused by foodstuff-induced factors. For this reason I also found the presentation by Régine Boutrais very informative, as in my opinion it makes sense to discuss whether food crises cannot also be triggered by socio-ethical factors, through problems of sustainability, climate change and by political factors. The fact that media perceptions and political factors can at least fuel a crisis has been highlighted very well by Dr. Böl.

The dioxin incident caused an unbelievably strong reaction in the media without there actually having been any noteworthy impairment of the health of the population. So in this regard

it took a completely contrary course to the EHEC crisis. Politics seizes on these moods and uses them. Politicians freely admit in the meantime that they use the climate of public opinion in order to profit politically from it themselves. This makes it difficult for independent scientific opinion, as represented by the BfR for example, to make itself heard, because even though it is represented in dialogue with policy makers, it could well be that they do not accept this scientifically-based risk communication.

This morning it was clearly emphasised that both in Europe and in Germany we have a strict separation of risk management and risk assessment. In Germany, my organisation is responsible for the management side and in this field we work in close cooperation with the BfR. This means that we provide the BfR with the necessary data so that it can conduct the risk assessment on its own. Both institutions are in a close relationship with the respective European level and communicate with each other so that, as a consequence, the networking of national and European level is guaranteed in a crisis situation.

So which classical instruments do we actually have at our disposal on the management side? Because of European legislation, we differentiate between four classical instruments: traceability, the previously mentioned emergency plans, the Europe-wide Rapid Alert System, and of course the network of European reference laboratories. These European tools are supplemented at national level by a situation report, which is generated by a situation centre within my organisation via appropriate data management and a system of national reference laboratories, which cooperate closely with the European reference laboratories.

What experience have we had with these tools? The most important impulses for crisis management were produced by the tragic events in conjunction with the outbreak of the shiga toxin-producing *E. coli*-infection following the consumption of bean-sprouts. What was so special about this event? The EHEC crisis resulted in more than 3,000 cases of severe gastro-enteritis. There were complications in 885 of these and 53 people died, so this crisis struck with unbelievable force. The duration of the crisis in this form was unique. It began at the beginning of the second week in May of 2011 and was not over until the beginning of July 2011. This means that all institutions and authorities involved were really put to the test. It was further aggravated by the fact that, in contrast to the food crises we had managed before, we were not aware of the causal source of the infection. We had no appropriate, validated methods of investigation and were thus unable to conduct any classical form of traceability controls. Consequently the risk-based inspection along the food chain initially failed to yield a positive result and neither did the use of classical epidemiological methods to establish the events surrounding the outbreak. On top of this, we were subjected to enormous pressure from the general public.

What was the first step towards solving this problem? Ms. Tritscher mentioned it in her presentation this morning: the authorities closed ranks. In order to solve the EHEC crisis, an EHEC taskforce was created for the first time as part of which the experts from risk management and risk assessment, the federal government – represented by the Federal Institute for Risk Assessment (BfR), the Federal Office of Consumer Protection and Food Safety (BVL), the Robert Koch Institute (RKI) and the federal states – all cooperated closely and took the necessary steps. This was novel, in particular because a start had been made to link the results from an epidemiological investigation with the classical instruments of flow of goods analysis and traceability. This process eventually led to success; starting from initially five outbreak clusters a potential outbreak location was established using a tracing strategy, and this result was confirmed using a “trace forward approach”.

It was problematic that this taskforce was only able to work using comparisons because all necessary tracing information was only available in paper format on delivery lists with hand-

written additions. It is extremely important that we think about how this approach can be improved upon. Nowadays, everyone has a smartphone and it is very hard to understand why we cannot also use communication devices of this kind with an appropriate app for the purpose of tracing in a matter of seconds and generating digital data in food monitoring.

During the EHEC outbreak, this taskforce became part of the overall national risk management concept. There was a central crisis unit at the ministry, which was in daily contact with the federal states responsible for food monitoring. This crisis unit was directly supported through the work of the taskforce.

With the taskforce having proven itself as part of the EHEC crisis, it would seem to make sense to institutionalise it. What could an institution of this kind look like? Firstly it should bring together the participating experts, as has already been the case with EHEC. From our point of view it is important that there is direct cooperation with the situation centre that meets in the BVL, because the findings which come together from the federal states in the situation centre can be directly used for the taskforce, and this is of course also true for the opposite case. In addition, a taskforce of this kind can also be helpful with regard to communication in a crisis. Finally, an institution of this kind, which is in direct contact with federal state authorities, can give valuable tips for work by the authorities on the ground.

In the process of institutionalisation, care should be taken to ensure that the appropriate framework conditions are selected. This relates to the place in which it is established, the availability of the necessary information and communication technologies, the securing of direct cooperation with the situation centre and the distribution of roles in a crisis. To this end, regular exercises must be held in order to practice procedures and to ensure direct cooperation between the institutions, both at a national level as well as a federal state level. This also includes the setting up of a network of experts and appropriate training to ensure high quality. In the event of a crisis, it is also important that the necessary data is provided via a system of knowledge and data management, including rapid alert reports.

How can we further develop our crisis management and crisis coordination with the help of these insights? A decisive factor is that the data is made available more quickly for tracing purposes and that appropriate digital systems are developed to this end. A participant asked earlier how far on we are with this. I believe we still have an awfully long way to go and active cooperation is also required, above all from business, to help ensure the digitalisation of traceability data. Professor Haunhorst correctly noted earlier that the exchange between the various authorities and levels involved – that is between the human (i.e. health) side and food monitoring agencies – has to be guaranteed and developed further at all levels. To this end we require an adaptation of the regulatory framework conditions. Finally, the generation of databases is also a part of further developing data management systems. I would like to present one such example to you: “eFI” is an electronic, early-detection and information system into which the federal states can feed their monitoring data. In the future eFI could be used for early detection of risks and in case of crisis for developing a picture of the situation on the ground.

What form would further developed crisis coordination take? Precisely this point is currently being debated by consumer protection ministers of the individual federal states in Hamburg. Basically it is a question of a treaty in which the government and the federal states agree how they will cooperate in the case of a crisis. This also requires a strategic tier that bears the political responsibility. The decision will also be made at this level as to how communications are to be conducted in a time of crisis. This strategic, political tier will be supported by an operational level, which will be responsible for crisis management on a case-by-case basis and in close cooperation with national government and federal states. The crisis unit

will be located here and will make the necessary operational decisions to control the crisis and ultimately also resolve it. If required, it will also be supported by a taskforce, but also in any event by the situation centre and the methods of data management, as well as of course by scientific evaluation on the part of the BfR.

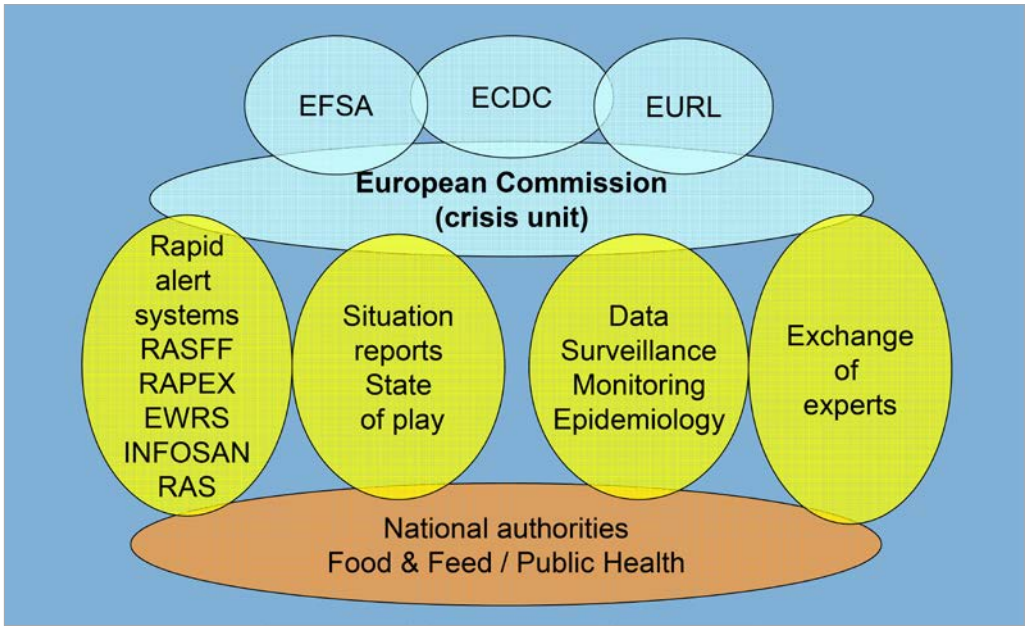


Fig. 5.1: The interlinking of European institutions with the national authorities in risk and crisis management.

At European level institutions are linked as shown in figure 5.1. Here too there are various interlocking instruments such as the European Commission “Crisis Unit”. The various authorities are also integrated here in the decision-making process at European level. Should a crisis occur in Germany, a daily situation report would be generated, data sent to the EU Commission and expert opinions exchanged.

Please allow me to venture an outlook. I hope it has become clear that we need to create coordinated structures to cope with challenges. Apart from this, I hope that the consultation today and tomorrow will lead to a positive outcome so that, in the national arena at least, we are able to build such a structure for crisis coordination. However, this also includes the need for these structures to be practiced. It is extremely important that response times are drastically reduced. Each day can save lives. In this context, the exchange of information with the food industry plays a very important role.

Much has already been said today about communication in time of crisis. Coordinated crisis communication boils down to a distribution of tasks. At government level it would seem appropriate that nationwide aspects are communicated. This includes risk communication on the part of the BfR. For logical reasons it would appear more appropriate that individual federal states would communicate regional aspects in a time of crisis. These, I believe, are the fundamental key parameters needed to further develop crisis coordination in the future. Many thanks for your attention.

Discussion

Question: Mr. Tschiersky-Schöneburg, you mentioned the subject of databases in connection with early detection. Which data did you have in mind and does data protection play a role here?

Dr. Tschiersky-Schöneburg: Data protection always plays a role when generating databases; and of course it is also being observed in this pilot project. It is a question here of the surveillance data from the federal states, or the data from the field of food inspection and sample analysis. Using this data from the federal states and special algorithms, certain investigations can be carried out with this database. There is a whole series of possibilities and applications in which a database of this kind can be helpful. However, the most important would in fact be that it would be used to produce a picture of the situation and for the early detection of risk. At this time, however, the electronic early detection and information system or "eFI" is still in the pilot phase.

Statement: For some years now, the University of Bonn has been collaborating on several pilot projects to develop databases in the field of crisis management. At the end of this we will have a mock crisis exercise involving the federal states as well as the government authorities, additional departmental research institutions and two universities. This is a similar path to that taken in the Netherlands and Denmark. The most important aspect of the cooperation with universities is that in this way the experts who will have to make the decisions in crisis situations in the future can be appropriately trained.

Question: Will these databases be established at national, regional and international levels?

Dr.Tschiersky-Schöneburg: In this case, at a national level.

Question: Are AFSSA, WHO and FAO not conducting similar projects? It would indeed be important that these databases were able to communicate with each other. Are there any ideas for a joint template or at least four to five common search terms? We harmonised our system with the AFSSA, for example. What are your thoughts on this?

Dr. Tschiersky-Schöneburg: Of course we have considered how it would be possible to establish data management systems at European level. At the beginning of December I gave a lecture on precisely this topic to the Advisory Forum of the AFSSA in Wiesbaden. Unfortunately, the 16 federal states that provide data all have different systems. In order to be able to extract the data, the laboratory data information systems have to be coherent with the data reporting portal. Once this difficulty has been mastered at a national level, the next problem has to be addressed, namely cooperation in the EU. We are certain to advance more quickly here because we will then be working with fewer partners, but there are barriers to progress here too. It is therefore definitely going to be a few years yet until data management is running smoothly.

Moderator: Are you not conversely able to profit from the experience of FAO, WHO and AFSSA?

Dr. Tschiersky-Schöneburg: We would dearly like to profit from this, no question about it. But FAO will hardly be able to help us with an incident in a cowshed in Lower Saxony.

Moderator: It is surely about the compatibility of the databases – that was the question.

Dr. Tschiersky-Schöneburg: But the question is how this database instrument can be utilised for a crisis which first breaks out in Germany? Once the database is established, it

will then be definitely possible to link national and international data levels with each other as well.

Question: What is this taskforce permitted to do and what can't it do? Of course, risk management has something to with measures that have to be taken. I often have the impression that the individual states are not prepared to surrender responsibility in the case of cross-border problems.

Dr. Tschiersky-Schöneburg: In my somewhat rough sketch it was perhaps not possible to see how the federal states, for example, might be included in a "Crisis Unit". The taskforce would assist and decisions would be made at the operational crisis management level. In this way the connection would be made between the work of a taskforce, the decision-making of the crisis unit and implementation within the federal state.

Moderator: Thank you very much. The second co-organiser of this conference is the National Food Institute of Denmark at the Technical University of Denmark. The director of this institute, Dr. Jørgen Schlundt, is a doctor of human and veterinary medicine and before he joined the DTU he was at the WHO and is a specialist for zoonoses. Is it easier in this field to make provisions on the basis of existing experience?

Crisis Prevention: Control of Zoonotic Diseases

Dr. Jørgen Schlundt,

National Food Institute at the Technical University of Denmark (DTU), Søborg

Ladies and Gentlemen,

A glance at the WHO figures on the burden of disease caused by diarrhoea shows incidence rates of almost 4 billion cases a year and roughly 1.8 million people – most of them are children – who die of this disease every year. Bear in mind here that diarrhoea is only one of many symptom complexes transmitted by food (including water). Please bear in mind too that while diarrhoea relates to microorganisms, we know virtually nothing about the burden of disease caused by chemicals in food. In addition to this existing burden, new issues continue to add to the problems. We know that roughly 75 % of the newly occurring infectious diseases are zoonoses and more than 25 % of them are transmitted through food. This also shows, that in general a very large fraction of the general burden of disease is in some way connected with zoonotic pathogens transmitted through food.

I said at the beginning of this symposium that we should try to avoid focusing only on the terms outbreak or crisis in connection with risk communication related to food. The case numbers related to outbreaks only account for a very small fraction of the real problem, since most foodborne disease cases occur sporadically, i.e. not in outbreaks. 15 years ago, hardly anyone knew about the Campylobacter bacterium because it almost never occurs in outbreaks. Today we know that most foodborne disease cases in Europe and throughout the world are caused by Campylobacter, which shows that we make mistakes by focusing too much on outbreak cases. What should really count for public health – and for political decision makers – is the total number of people who are actually sick from food, and the effect of such illness, not the small fraction of these cases that are related to outbreaks. This reminds me of the story of the drunk man who is looking for his keys in the light of a street lamp. When asked where he lost his keys, he points to the other side of the road. “Then why are you looking here?” he is asked. “Because the light is better over here,” he replies. In other words, we should start to analyse not only the tip of the iceberg representing the outbreak cases that are in the light and easily detected but we should actively look for the real disease burden that is presently hidden in the shadows.

Why is this so difficult? The agenda in the field of food safety is dominated by many different interests, rules and stakeholders: the global trading agreement of the World Trade Organisation (WTO), the economic interests of the big trading partners in the USA and Europe, the processes of global food supply, the profit margins of the retail sector, the considerations of science, the concerns of consumers and the media. In an emergency, they all come together. Emergencies of this kind shouldn’t really be so important for scientific work but they dominate

everything in the real world. As scientists, we should take note of these emergencies, but we should not let the agenda be dominated by them.

It is often said that we can learn an awful lot from outbreaks. It may sound exaggerated to you, but I maintain that this is not the case. If we take a closer look at the EHEC outbreak in 2011, it has to be asked whether zoonotic pathogens in vegetables were really something new. No, they were not. Are infections caused by verotoxin-producing *E. coli* pathogens (VTEC) on bean sprouts perhaps a phenomenon that no one has known about until now? No, all the way back in 1997 there was a very big outbreak in Japan which affected tens of thousands of schoolchildren, caused by exactly this problem. We even had a VTEC outbreak in little Denmark which was caused by the consumption of sprouts. In all of the investigated cases, the contamination was caused by faeces, manure or indirectly contaminated water applied to the green plants used for seed production – the seeds that are then used for sprouting. In other words, the argument that we have never been confronted with such disease outbreaks before and cannot deal with them because they have not been properly researched, are simply not correct. We most certainly could have assumed that they would occur. The bigger issue for us should therefore be not that this outbreak occurred, but rather that it could have been prevented, and what we need to change to avoid the next one.

Possible preventive measures could consist, for example, of avoiding contamination from manure and waste, introducing tests for sprout seeds, helping developing countries to improve their production practices and improving legal requirements. The problem and necessary countermeasures were outlined after the Japanese outbreak, but were these measures implemented globally? I think the answer has to be: no!

Following the terror attacks of September 11, 2001, there was a great deal of discussion about how terrorist attacks could be prevented. There were even at this stage deliberations about setting up a separate food control system aimed at dealing with terrorist attacks involving the poisoning of food. Someone at the USA Centers for Disease Control and Prevention commented on this idea by stating that it would be just like establishing two fire brigades, one for normal fires and one for arson. But how can you know in an acute emergency whether a fire is caused by arson? This can only be determined, if at all, once the fire has been put out and everything has been destroyed, so then why would we need two different fire brigades?

It's the same with food safety. A separate system dealing solely with outbreaks and another one with responsibility for the rest does not make sense. Several proposals for the improvement of our crisis prevention have already been put forward: more tests, more care, better communication. I could easily add many more items to this list, but I am fundamentally of the opinion that these measures will not work. What we should do is ensure that our preventive system responds to problems as comprehensively as possible, not only to those that we actually detect, the ones that are reported in the press or the ones related purely to outbreaks.

I would like to set out three theses in the following paragraphs which we could then discuss:

- **Rethink the testing regime**. First of all, blind trust in tests has to stop. Why? Havelaar hits the nail on the head in his publication in 2010: it is pretty inefficient to rely on the detection of pathogens in the final product because not enough samples can be tested to avoid health risks in this way. I can back this up using a concrete example: Denmark is Europe's largest exporter of pork, including cold cut meats. If we assume that one in every 1,000 of these products is defective, that would equate to a defect rate of 0.1 %, which means that if we took ten random samples, there would only be a 1 % likelihood of finding the bad piece of meat. Despite this fact, politicians keep demanding more and more tests in the belief that this will make food safer.

- **Create one integrated system.** So how can we achieve efficient prevention if we are not to have blind faith in tests? I maintain that the prevention of outbreaks caused by food, or diseases transmitted via food, depends on the creation of integrated systems. Several countries have set up zoonosis centres and this is only one of many ways to establish an integrated system of this kind. Zoonosis centres receive all of the monitoring data from animals, food and humans, and use the combination of these to find trends and suggest solutions. Everyone outside Europe is now talking about the One Health concept, which really suggests that you need to look at the link between animal and human infections. Since zoonosis research in Europe has been practiced for quite some time now and an EU Zoonosis Directive has been in existence for many years, I find it strange that several EU countries are rediscovering the One Health idea at this stage. One Health is in this case just another word for zoonosis prevention – farm to table.

- **Assess the risk – and reduce it.** It is clear that we need monitoring at the level of primary production, because diseases in humans can be prevented by intervention in livestock farming. The long-standing example of eradication of brucellosis in bovines, and the following eradication in humans shows that this strategy can be successful. If we can acquire more information on the disease, the contamination and the connection between the two, the risk can also be assessed better. We can isolate the most important foods involved in disease cases and we can determine efficient ways of intervention. Ten years ago, the prevalence of salmonella in poultry in Denmark was at 40–80 %; following the implementation of action plans to control salmonella in poultry, this figure is less than 1 % today. This also means that the risk of human salmonellosis from Danish poultry has been reduced at least 40fold.

If we have a better understanding of human diseases caused by food, we can improve prevention in this area. Overall, this development would also have positive economic effects, partially because of a reduction of health costs and partially because of a potentially increased export revenue for safer products.

In relation to these considerations we should also remind ourselves of the new technological advances, presenting us with new opportunities for prevention. Based on improved knowledge, more efficient interventions to manage and control risks will likely be developed, implemented and documented so that positive results can be shared with other countries. It is important in this regard to set clear objectives or targets for reduction, and to strive for constant improvement to achieve optimisation. The involvement of industry is also important and experience in this area shows that a good outcome is often linked to processes where all stakeholders are involved in the planning and where all pull together in one direction. The positive development in Danish poultry breeding was only possible because industry paid for a significant part of the measures. If a win-win situation for both sides can be found, industry will join in.

A last word about the outbreaks: thanks to the use of new methods in molecular biology, it is very probable that we in the future will be able to connect many of the cases previously designated as sporadic as parts of outbreaks. For instance, it will be possible in the near future to use genetic fingerprinting to diagnose and link cases, and to attribute disease more efficiently back to food and primary source – using whole genome sequencing techniques. This means that it has to be assumed that there are a great many more outbreaks than we can currently see. This was already found in the late 1990s when scientists in the USA began to examine the links between the various salmonella strains in food and in humans using the then new pulsed-field technology. Many more cases could be linked and thereby outbreak detection and prevention received a welcome boost. Whole genome sequencing is likely to give a similar boost for researching all pathogens – and now at a global level.

Using these new methods, the cross-border exchange of data and information on microorganisms will be much easier in the future. Huge volumes of data can be handled and exchanged directly by working with barcodes and DNA sequences. We should also attempt to trace things back because that will help us to predict the future (fig. 6.1). Kierkegaard, the Danish philosopher, once said: “Life can only be understood backwards, but it must be lived forwards”. That’s exactly what we’re talking about here.

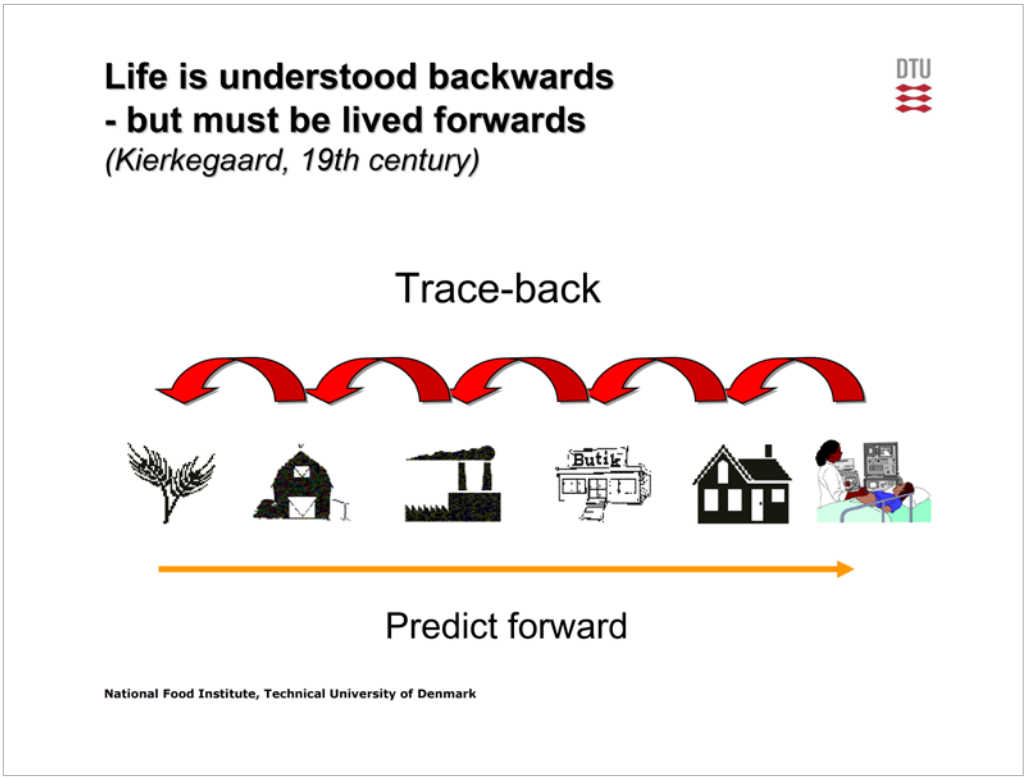


Fig. 6.1: Tracing of food risks.

If we really want to improve food safety in a country, there is no other option than to include global aspects. This also affects our relations with developing countries. We should not simply take up the stance that because developing countries cannot comply with certain standards, these standards have to be lowered. The notion that people will just have to consume a few more salmonella bacteria if they are starving is not only cynical, it is simply wrong. If anything, a starving population has a lower level of resistance to salmonella and would thus actually need higher standards! The way forward is for us to help developing countries to comply with the existing standards, because food safety should be the same everywhere. We can significantly reduce the burden of disease by applying good solutions, thereby improving economic development in many parts of the world. This means that risks have to be avoided globally, something which cannot be achieved by only relying on testing at the borders. We have to focus on the food safety systems and optimise them. Food safety, nutrition and the related illnesses should be viewed collectively and ultimately, we will have to intensify our global efforts so that standards are improved in developing countries too. Thank you very much.

Moderator: Many thanks for those critical and clear statements. The next presentation will be a bit more technical. Laurent Laloux is head of the food safety laboratory at ANSES. Not only biological and chemical food risks are examined there, the department also develops test methods and serves as a reference laboratory on French national government and EU level.

The Role of the Reference Laboratories in the Crisis

Laurent Laloux,

French Agency for Food, Environmental and Occupational Health & Safety (ANSES), Maisons-Alfort

Ladies and Gentlemen,

The food safety laboratory at ANSES performs numerous reference functions on both the national and international level. Based on our experience in this field to date, I will be describing some of the remits and tasks of the Reference Laboratories in general and also talking about some of the concrete measures implemented in connection with the EHEC crisis.

Together with all the member states, the European Council and the European Commission have created a scientific and technical support network for the prevention and management of health risks. First of all, there are several European agencies in the field of public health, including in particular the European Centre for Disease Prevention and Control, the ECDC, as well as EFSA, the European Food Safety Authority.

In times of crisis, a part of the organisational structure is based on the Reference Laboratories of the European Union. These laboratories implement the relevant codes governing animal health and food and feed. All in all, there are 17 EU Reference Laboratories in the field of animal health and 21 laboratories for food and feed. Each of these EU laboratories has a specific core area of activity (fig. 7.1). Some of them are involved in specific biological and chemical hazards, some others in specific food or feed like in France with the Reference Laboratory for Milk and Milk Products.

The responsibilities of the European Reference Laboratories in the food and feed sector are outlined in EU Regulation 882/2004. They must coordinate a network of National Reference Laboratories and define standards for the characterisation of hazards. This information is disseminated within the National Reference Laboratories network. The networks are required to provide proof of their expertise in tests and to implement the latest analytical methods. This is an extremely important point, as we need a common methodological expertise, efficient and responsive to all European countries. The European Reference Laboratories therefore organise proficiency testing and training programmes for employees of the National Reference Laboratories but also offer courses for experts from developing countries (fig. 7.1).

A further key task is the provision of scientific and technical support to the European Commission in times of crisis. This is an area in which we also work together with laboratories which are responsible for testing feed and food in third countries. This cooperation ensures early access to information on food-related problems that can be found on the European market later.

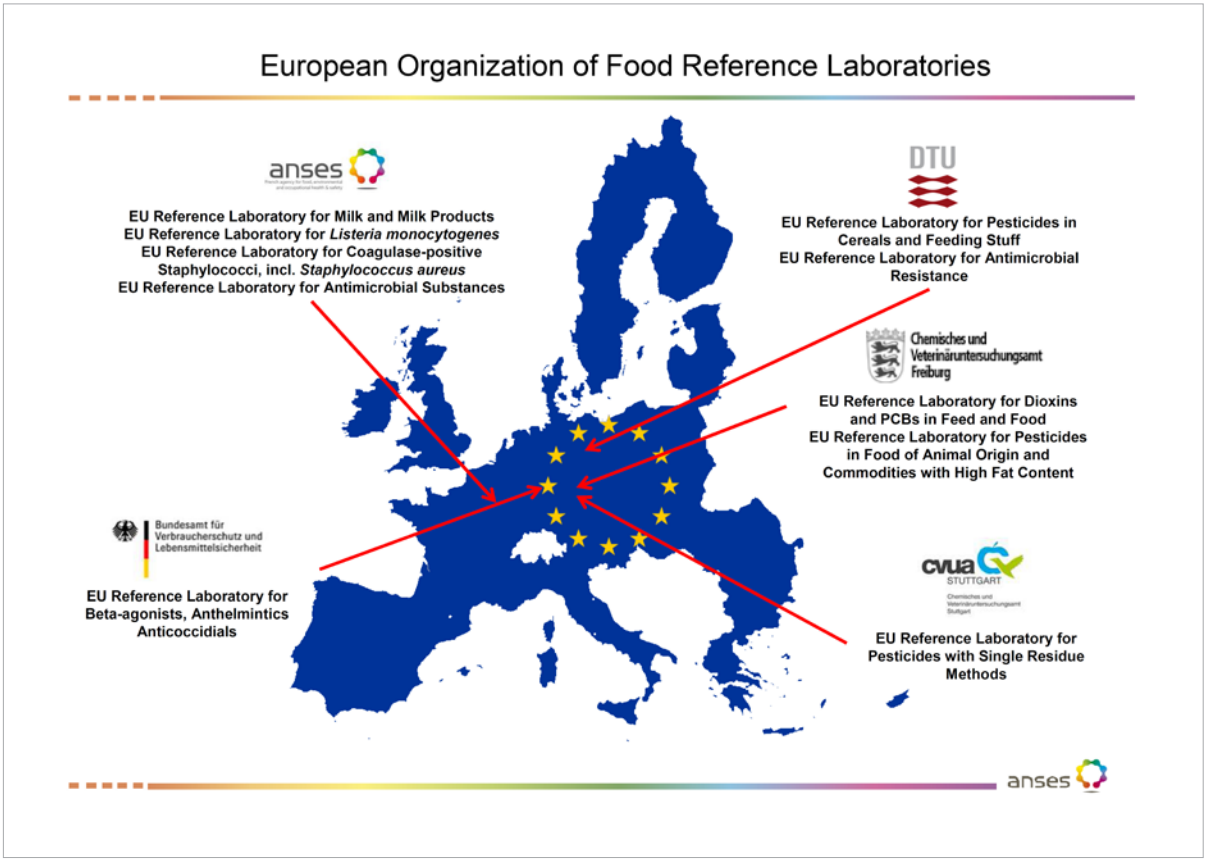


Fig. 7.1: The organisation of European Reference Laboratories in the food and feed sector in three countries (France, Germany and Denmark).

A food crisis has three characteristic features: it creates uncertainty, it occurs unexpectedly and it poses a threat. The European Reference Laboratories can assist the competent authorities in handling each of these issues. We have excellent analytical methods at our disposal that allow us to react to the uncertainties in the monitoring and inspection of food sources. The European network also has significant capacities for the testing of a high volume of samples. In addition, we operate databases for the purpose of hazard characterisation and can use bioinformatics tools to identify the relevant signals and then issue warnings. We also possess wide-ranging know-how in the field of food hazards, and this know-how can serve as the basis for etiological research or the development of hygiene control measures.

In closing, I would like to look at some of the measures taken by the European Reference Laboratory during the EHEC crisis. It is an Italian laboratory that, together with the network, developed a method to identify the outbreak strain. Why was it possible to develop and distribute this test so rapidly? The network of National Reference Laboratories uses a large range of methods for the characterisation of a pathogen, and the European Reference Laboratories try to derive the most effective screening method from these activities. In this case, the method is a biomolecular technique (PCR) that was forwarded extremely rapidly to the National Reference Laboratories, which then validated the technique. The laboratory also provided ongoing support to the Directorate General SANCO in the form of scientific and technical know-how, and they were involved in the inspections performed by the food and veterinary authorities in Egypt. During this period, several scientists participated in numerous working groups and initiatives.

The conclusion I draw from all this is that, in the European and National Reference Laboratories, we have at our disposal an effective network of scientists who exchange information and data to ensure mutual support among the various countries. This network is made up of

committed scientists who are involved in research projects and who can also provide extremely effective tools that help us to master and prevent crises.

In future, we need even better hazard databases and bioinformatic tools and a more effective exchange of information with other countries outside the European Union and worldwide. This would enable us to optimise our overall range of testing options and prevent future crises. Thank you for your attention.

Discussion

Question: Shouldn‘t the role of the Reference Laboratories be to provide an overview rather than to itself develop reference tests?

Dr. Laloux: The tasks of the Reference Laboratories are outlined on regulatory level; it is not clearly stipulated that the Reference Laboratories should also develop new tools, but we possess the requisite knowledge and we also participate in research projects that can be of great benefit for subsequent reference work. I am convinced that a Reference Laboratory needs an extremely broad expertise base on different levels because it has to process so much information. In the case of new incidents, it is particularly important that we are in a position to conduct further investigations in order to combat the crisis, but this is not really part of our statutory remit. Nevertheless, we should discuss with the Commission about the option of extending the remit of the Reference Laboratories in order to pave the way for more analytical development.

Question: It was just explained that there is a separation between risk management and risk assessment on European level. Do you see the job of a European Reference Laboratory as being more in the field of risk assessment or rather in the area of risk management?

Dr. Laloux: The contribution of the European as well as the National Reference Laboratories is more in the field of risk assessment: their job is to provide data and information. The European Reference Laboratories by their expertise are only a part of the risk management process.

Question: Then who should crisis managers turn to if they need additional information from laboratories?

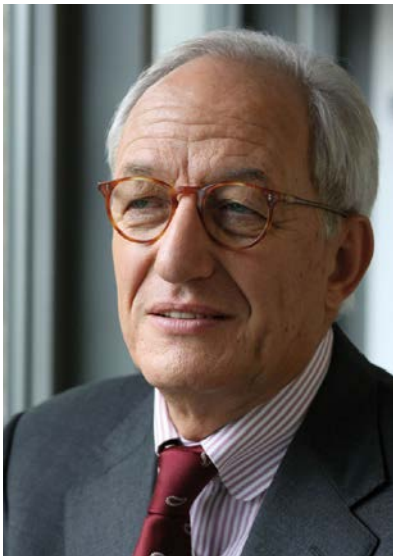
Dr. Laloux: The laboratories can naturally act as sources of important data in a crisis, but there must be close cooperation between the risk managers on national and European level. The European Reference Laboratories are organisations of the European Commission. If help is needed in an emergency, then we‘re naturally willing to provide assistance. In general, however, we‘re the ones who generate scientific data for the risk assessment experts.

Moderator: Thank you very much. Professor Matthias Horst is Managing Director of the German Federation for Food Law and Food Science, the BLL – a German producers‘ organisation with offices in Berlin and Brussels. He will be talking about what the food industry does to avoid scandals and how it responds to crises.

Crisis Management and Prevention Tools in the Food Industry

Professor Matthias Horst,

German Federation for Food Law and Food Science (BLL), Berlin



Ladies and Gentlemen,

The members of BLL, the German Federation for Food Law and Food Science, include federations and companies along the entire good chain, from the feed sector, agriculture, the trades, industry and the retail sector through to large-scale consumers and all supply sectors.

I would first like to briefly profile the German food industry. With over four million employees, gross value added of 133 billion euros and a huge tax yield, it is one of the country's biggest economic sectors. Moreover, the food industry is the single biggest industry in the European Union, far ahead of the automotive and other sectors (fig. 8.1).

BLL

The German food industry in 2010

With gross value added of 133 billion euros in 2010, the German food industry accounted for 6% of total gross value added in Germany. It exported goods worth around 55 billion euros. A total of 736,000 farms and companies provided jobs for 4.1 million employees and 305,000 apprentices, which means that 10% of the German workforce is employed in the food industry.

Sector/2010*	Enterprises	Turnover in mio euros	Employees	Apprentices
Agriculture	300,700	47,000	648,000	38,500
Agriculture wholesale	7,600	55,000	58,000	3,500
Craft-based food industry****	36,500	38,400	573,000	52,000
Food and drink industry***	5,900	152,000	542,000	36,000
Food wholesale	18,300	163,000	252,000	15,000
Food retail	97,000	162,000	960,000	64,000
Out-of-home market	272,500	64,300	1,170,000	97,000
Food industry overall**	**736,000**		**4,100,000**	**305,000**

Notes:
* All figures rounded for easier comprehension
** The totals are adjusted to avoid duplication due to different sector demarcations (industry – craft; craft – out-of-home market)
*** Industry comprises enterprises and their employees from a size of 20 employees
**** Craft segment comprises companies listed in the register of craft enterprises

Sources:
BVE, DBV, DEHOGA, DFV, DKB, ZDH, BGA, BMELV, Federal Statistical Office, Federal Employment Agency, BiBB, ndpgroup

3

Fig. 8.1: The German food industry in 2010.

Crises affecting food safety often impact the entire food chain or at least more than one part of this chain. Sometimes the food chain is the victim of a crisis, sometimes a crisis is caused by negligence and – in extremely rare cases – by “black sheep”, perpetrators who act with intent. Above all, however, the food industry is one of the parties that try to prevent or overcome crises. Like the competent public institutions and the consumer, our companies are primarily interested in ensuring that crises don‘t happen in the first place and that any crisis that does occur is rapidly resolved.

There are real and perceived crises, and not every crisis is a scandal. The media and our politicians are very quick to use this word. I think calling the EHEC crisis a scandal is in poor taste. We talk about scandals when someone puts rotten meat onto the market or deliberately mixes dioxin-contaminated fats in with animal feed. EHEC was a disaster, a tragedy, but it wasn‘t a scandal. It is precisely because crises play such an important role in the world of politics and because the media instantly pick up on these crises that we need to make sure we differentiate when choosing terms to describe these kinds of incidents.

Even when we distinguish between real and perceived crises, the effect on consumers, the public at large and the companies involved may still be the same. We have already talked about the deficits in the area of crisis management today, deficits that seriously impact consumer trust, the credibility of decision-makers in politics and administration – and naturally also the affected companies and sectors. And this is why we need to work together to find ways of preventing crises.

Crises occur without warning, and there‘s little or no time to prepare. The most important thing is naturally to prevent harm to the population, but crises often also cause massive financial damage. During the dioxin incident, 4,500 to 5,000 farms were shut down for days or even weeks and there was an export ban on meat. A crisis can significantly harm the image of products, brands and companies but also – and this should not be forgotten – that of authorities and political decision-makers. Politicians and the food industry are generally way down in the credibility rankings. Last but not least, crises can also result in criminal charges if offences have been committed.

I would like to take a closer look at various food crises in Germany. It is important to differentiate between crises that affect the entire food industry or individual sectors and company-specific crises that impact the overall image of the industry due to the fact that people are quick to generalise. The Birkel incident caused by carelessness on the part of an authority in 1984 made legal history. Although the company won a compensation lawsuit against the state of Baden-Wuerttemberg, the incident spelled the end of Birkel as a family-owned business.

The Coppenrath & Wiese company was also seriously affected in 2003. A family was enjoying coffee and cake on a Friday afternoon when a child sitting in front of a piece of Coppenrath & Wiese cake died suddenly. The Hessen state government, in whose jurisdiction this incident occurred, initially had no choice but to issue a warning regarding the product in question. The all-clear was given on the following Tuesday after it had become clear that this tragic fatality was totally unconnected to the product. Even so, the next day – on Wednesday – another German state issued a warning concerning the company‘s products. As you can see from these examples, prevention is key.

But we always need to remind ourselves that the companies themselves – and no one else – are responsible for the safety of food products and for conformity to food regulations. The state defines the legal framework and monitors compliance, but food safety depends on the companies taking responsibility for the foodstuffs they produce. They need to be familiar with the

raw materials, fulfil their duty of care and constantly think about where new risks might arise. Moreover, they have to ensure traceability so that any occurring damage can be contained, and they have to train their employees accordingly.

Prevention takes top priority, but even the most detailed prevention strategy cannot totally rule out the possibility of a crisis. The best form of crisis management is effective preparation, both in-house and within the network. A crisis plan should be part and parcel of modern in-company quality management and should comprise updated data as well as coordination and cooperation with service providers, testing laboratories, lawyers, the federation and consultants. The names of both the suppliers and customers along the food chain must be known so that end consumers never even come into contact with the products in question in the event of a crisis. Regular crisis drills help to ensure that companies are prepared for the worst case.

Experiences gained in a whole series of crises underline the benefits of a network structure for crisis management, and one particular aspect was shown to be key during the Chernobyl disaster in 1986. When the accident occurred, the reports on radiation exposure levels were extremely contradictory. No one, neither the authorities nor the scientists, were able to provide any concrete data. We invited our members, the Ministry and the German Radiation Protection Commission to a joint information meeting – and they all came. Although this meeting didn‘t generate any specific new insights, it created a feeling of solidarity among the participants which made things a lot easier further down the line.

BLL has the necessary contacts to the authorities, is in constant communication with the political decision-makers and the media, and is equipped in organisational and personnel terms to perform professional crisis management. It enjoys the trust not only of its members but also of its partners in administration, politics and science. A few years ago, we set up the BLL crisis management database which meanwhile comprises 900 companies. This ensures that the responsible crisis manager at the production company can be reached – in emergencies even on a Saturday evening – so that the crisis can be addressed and resolved as quickly as possible. We have further expanded the database in recent years, and it now also includes the highest-level national authorities and companies in other European countries.

What expectations does the industry have of governmental crisis management? Dr. Tschiersky-Schöneburg has already outlined the processes that ideally take place on national level and in cooperation with Germany‘s regional states. Particularly in view of our integration in the internal market of the EU and increasing global trade, we can no longer think or act only nationally and certainly not within the confines of an individual regional state. Moreover, close cooperation between the authorities, the industry and the consumer organisations is key to professional crisis management. The authorities rely on the food industry, for example, when it comes to flows of goods or the question of the trading channels via which goods are supplied. And we are naturally willing to provide all the necessary information.

The consumer organisations also play an important role from the point of view of BLL, as they provide information on the expectations and fears of consumers. By the same token, we also expect the consumer organisations to pass on the findings of the authorities and in particular the assessments of the independent risk management experts to consumers, providing information and reassuring the public at large.

Governmental crisis management, the authorities, the industry and consumer organisations all have different duties, roles and resources but they all have the same goal – to overcome a crisis as rapidly as possible. This requires fact-based cooperation and in particular constant communication and information. Mutual reservations and distrust are the last things we need.

What are the potential areas of cooperation? The first thing that needs to be done is to establish the facts and answer legal questions. Which regulations have been violated? Is it only an infringement? Is there any evidence of criminal activity? We should pool our efforts to arrive at a common assessment of the situation and then communicate the relevant facts to the public at large. The most important job once the crisis is over is to ensure a joint follow-up and review process so that we learn the lessons that need to be learned.

One of the cornerstones of effective crisis management is a high-quality system of risk assessment free from the influence of industry, politics, NGOs or the media. What is also key is a clear-cut and easy-to-understand process of crisis communication that respects and communicates the findings of risk assessment. It is worth remembering that, during the dioxin incident, the BfR was quick to reassure the public that even people who had consumed large quantities of eggs or pork with dioxin burdens exceeding the permissible levels were not expected to experience any adverse effects on their health in the short or long term. This all-clear was ignored by the political powers-that-be for weeks, and as a result the crisis was drawn out from the end of December 2010 all the way through to the end of January 2011.

What should we learn from the crises of the past, above all those of recent years? One important aspect is that joint action has to be assured even in a country like Germany with its federal structure. Dr. Tschiersky-Schöneburg talked about the agreement between the national government and the regional states signed by the Conference of German Consumer Protection Ministers. This is a step in the right direction. What is also true, however, is that a joint taskforce has to first prove its worth in practice; and, if we‘re honest, we know that the effectiveness of a taskforce of this kind largely depends on the good faith of all those involved. In order to handle a future crisis resulting in major problems, what we would have liked to have seen is for the national government to be given greater powers in consultation with the regional states. But this is apparently not possible in Germany, and this is why we are calling on all parties to show self-discipline, to refrain from political jostling and not to exploit crises for their own political gain. The cacophony of opinions and statements that we have seen again and again in the area of crisis communication is a hindrance to rapid crisis resolution; it poses a potential threat to consumer safety and harms the industry and the companies in the sector. And it prevents modern crisis management. Thank you.

Discussion

Question: The crisis database is geared towards ensuring specific personal responsibility on the part of the decision-makers in companies. But what about transparency in the authorities, where there is high personnel fluctuation on the various hierarchy levels?

Prof. Horst: Each company that submits information to the database is responsible for ensuring that the data they enter is always up to date. We regularly ask database participants to update the information they enter. We‘re confident that everything works as it should because we haven‘t received any complaints. We as a federation make this tool available to participants.

Question: The reason I‘m asking is that I know from personal experience that the authorities tend to list positions and functions rather than the actual names of the relevant contact persons.

Prof. Horst: You‘re right, to the extent that it took some time for us to persuade the authorities in all the federal states to participate in the scheme. But we finally succeeded, and we regularly ask the relevant authorities to update their data.

Question: Is it really the case that people can reach someone at the competent authority on a Saturday evening in the event of a crisis?

Prof. Horst: The authorities in all the federal states in Germany operate a so-called „emergency situation centre“. If you are faced with a serious incident, this emergency system really will put you in touch with the relevant contact person.

Moderator: When new food-associated diseases occur, it is important that they are identified as rapidly as possible. Professor Frank Aarestrup conducts research into antimicrobial resistance and is a molecular epidemiologist at the DTU in Denmark. He is an advocate of ever cheaper and faster analysis of microbial DNA.

Global Data on the Real-Time Detection of Outbreaks of Emerging Diseases

Professor Frank M. Aarestrup,

National Food Institute at the
Technical University of Denmark (DTU), Lyngby

Ladies and Gentlemen,

Thank you very much for your invitation. “Next generation sequencing” is a relatively new technique and opens up huge potential in many different areas for those who use it. The decisive factor that makes it superior to earlier methods is that we can now sequence DNA far more rapidly and cheaply than was possible just a few years ago. Moreover, a modern DNA sequencing machine is around the same size as a PCR machine, and the next generation will have the dimensions of a USB stick. As a result, it is possible to take and use this technology practically anywhere.

I am an old fashion conventional microbiologist, and when it comes to the bioinformatic evaluation of sequencing data, my skills are limited to turning on my computer and calling someone if Windows doesn‘t start. My computer has many gigabytes of memory, costs 300,000 euros and is designed for the evaluation of small research projects. Computers used for genetic data evaluation within the context of health monitoring need to be far, far bigger and are in a different league. But I am sure that this problem is a solvable one.

I believe that health monitoring is of absolutely essential importance if we want to prevent health risks. This process begins with the central collection of global data. The Global Influenza Surveillance Network of the WHO in Geneva takes 200,000 samples every year, for example, uses these samples to perform genetic and immunological characterisation, derives trends and makes predictions for the next epidemic or pandemic. It uses this information as the basis for the development and utilisation of a vaccine. In Denmark, for example, anyone over 50 years receives a flu vaccination based on the work of this WHO group. We need a similar procedure for the identification of food risks. But this requires data, data and more data – representative data from all over the world that are also openly exchanged. This is not as easy as it might sound; nevertheless, food monitoring is of major importance in global terms.

Many speakers today have already talked about the EHEC problem, and this was a topic that even preoccupied us in Denmark. On 2 June 2011, scientists from Muenster decoded almost the complete genome of the EHEC pathogen for the first time and made their data available. It then took two and a half hours for the next genome analysis to be completed.

I think there were articles in around 15 leading publications, including The Lancet and New England Journal of Medicine, and many scientists in Germany assumed that successful sequencing also signalled the breakthrough in the efforts to tackle the illness caused by EHEC.

The opposite was the case. Sequencing data may have made quite a few waves in the scientific world but it didn‘t save any lives.

Why was this? Well, the results came too late. The outbreak had gone almost unnoticed, and no intensive measures were taken to address the problem until three weeks later. But what if all the diagnostic centres in Hamburg had already had access to sequencing technology at the beginning of May 2011? Then examination of the first three isolates would have shown that they are identical. This is not a guarantee of an outbreak but an indication. We would have probably been 14 days faster, provided that sequencing was not performed at the universities but at the location where the diagnosis was made and the data collated.

The EHEC crisis is an excellent example of the challenges presented by the global monitoring of food risks. The objective is not only to prevent outbreaks but also to detect them. This is why we need to refine the monitoring process with the help of molecular diagnostics. These novel diagnostics should also be easy to apply on the bottom tier of the health system and should supply valid information as rapidly as possible. Moreover, all countries must benefit from the advantages of this kind of monitoring system.

Whole genome sequencing could be a good way of achieving this. As recently as the early 1980s, it took one full-time technician and three years for the sequencing of a gene. Today, genome sequencing costs less than 100 euros and is so simple that even I can do it. The primary outcome of genome sequencing is the genetic code of many small DNA fragments that can be merged to depict the whole genome with the help of bioinformatic programs. As a committed epidemiologist, I leave this task to the bioinformatic experts. The decisive thing is that we now have access to a tool that makes it easier to monitor global health in real time. This is why we set up a Centre for Genomic Epidemiology, where we are developing a diagnostic process that is of use to those engaged in health monitoring and even for clinicians.

What does a tool of this kind need to offer? It must answer the following key questions: Which organism are we dealing with? How can the resulting disease be treated? Have I seen this organism before? Is it a new organism, is it especially prevalent at this particular moment in time or is it primarily to be found in hospitals? I believe most physicians would also welcome a machine that emits a warning signal if the organism is frequently detected and calls for rapid action (fig. 9.1).

Our system is more of a Volkswagen than a Porsche in the field of molecular diagnostics, but at least it is freely available. It consists of a sequencing machine and an assembly pipeline that helps us to structure the primary findings of the sequencing process; we then use in silico microarrays to look for the presence of predefined genes in the isolate. Multilocus sequence typing (MLST) additionally allows us to search for genetic variations such as point mutations. The best thing about it is that it‘s easy to change the microarray if your analysis shows that the pathogen in question is not *E. coli* but some other organism. All you need to do is click the mouse and a new test is performed in no time at all. This allows us to look at resistance genes, virulence genes and epidemiological markers. The drawback with this kind of analysis based on single nucleotide polymorphisms (SNPs), however, is that it is entirely possible that two samples from the same location may have different results. It is therefore sometimes preferable to focus solely on the epidemiological markers rather than analyse the whole genome.

Figure 9.2 shows an example that is already available online: you can enter the sequencing data of your sample directly into the programme. This supplies the MLST results together with a whole host of details, the most interesting of which from a clinical point of view is the sequence. Analysis of the same strain using the ResFinder programme provides, among other things, information on certain resistance genes and possible genetic mutations.

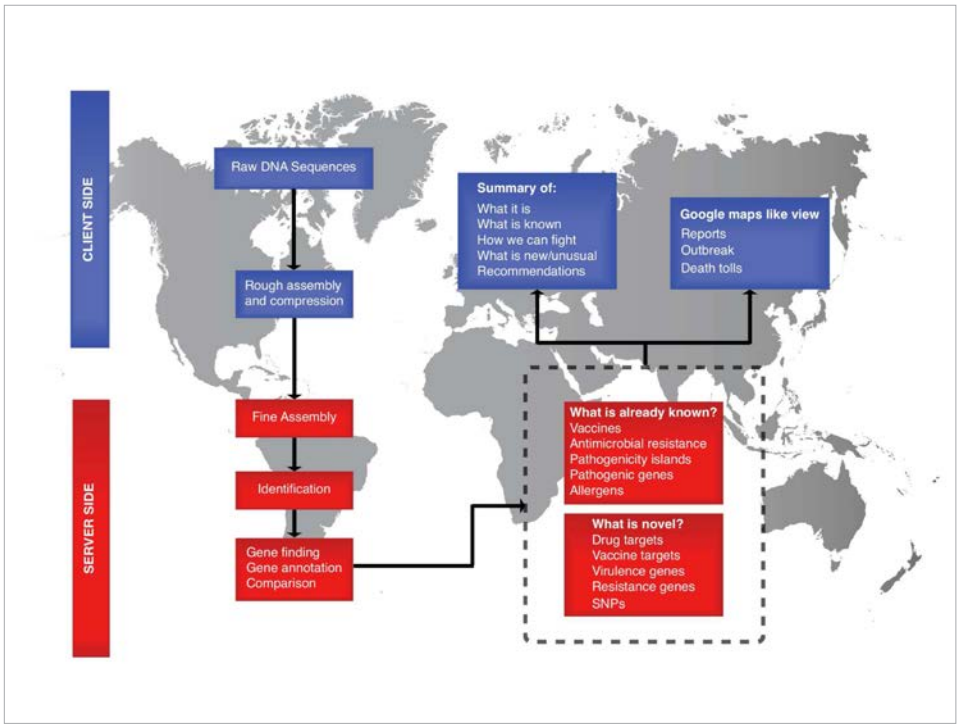
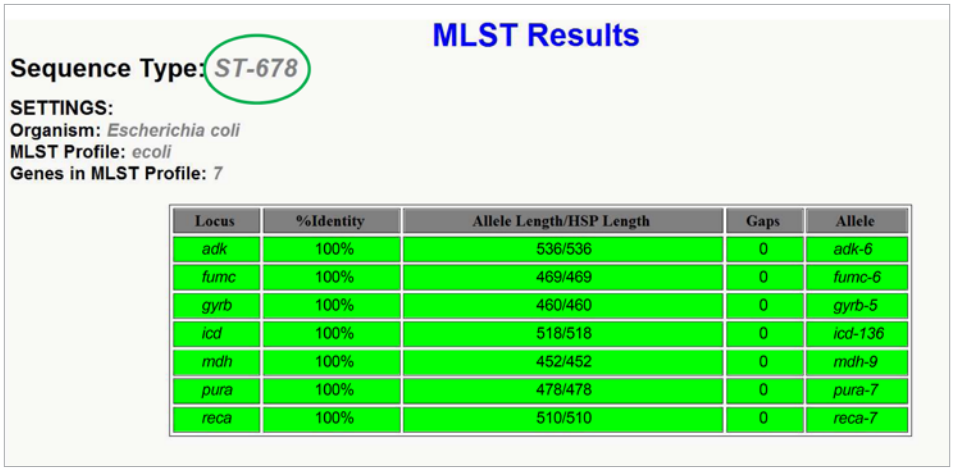


Fig. 9.1: Whole genome sequencing for the characterisation of pathogens in food outbreaks.

When will we reach the stage when whole genome sequencing can replace all other methods? I am not talking here about reference laboratories but about diagnostics in clinical laboratories. I believe it is a question of cost. Today, the cost of whole genome sequencing is in the region of 100 euros, and this price includes consumables, personnel costs and storage of isolates. It would certainly be possible to reduce the cost further to between 60 and 80 euros. So what about the cost of the other methods? Conventional identification costs ten euros, serotyping 25 euros, sensitivity tests 15–25 euros, pulsed field gel electrophoresis 50 euros, and traditional multilocus sequence typing about 250 euros. And then there are all kinds of additional molecular characterisations: a PCR analysis costs ten euros, but the total can quickly rise to 1,000 euros if a high number of tests are conducted. As you can see, therefore, whole genome sequencing is certainly competitive in terms of cost.



MLST Results

Sequence Type: *ST-678*

SETTINGS:
Organism: *Escherichia coli*
MLST Profile: *ecoli*
Genes in MLST Profile: 7

Locus	%Identity	Allele Length/HSP Length	Gaps	Allele
adk	100%	536/536	0	*adk-6*
fumc	100%	469/469	0	*fumc-6*
gyrb	100%	460/460	0	*gyrb-5*
icd	100%	518/518	0	*icd-136*
mdh	100%	452/452	0	*mdh-9*
pura	100%	478/478	0	*pura-7*
reca	100%	510/510	0	*reca-7*

Fig. 9.2: Identification of a bacterial strain after whole genome sequencing. Following comparison of the specified alleles, multilocus sequence typing shows that the entered sequence represents the *E.coli* strain ST-678.

So why is this technique not used routinely? Well, the devices are not yet available on the market and people still don‘t know what to do with the data. But there are already scientists

who are testing the use of this technique in real-time. Two articles were recently published on this topic in the British Medical Journal Open and the New England Journal of Medicine. The authors retrospectively compared the whole genome sequencing method with the traditional method for determination of outbreaks of an MRSA and a Clostridium strain. Interestingly, whole genome sequencing is far faster and better than the traditional techniques.

Can we roll out this technology on a global level? This would mean equipping all the experts on the front line with these systems and then entering the resulting data in a database in order to render trends and outbreaks visible. Is this at all conceivable? Most people would say it‘s far too complicated and resource-intensive. But it‘s technically possible. In purely arithmetic terms, we would need a computer with a total capacity of 23,000 cores and a memory of 60 petabytes in order to store an annual one billion DNA sequences worldwide. This would make it the thirtieth-largest computer in the world, slightly smaller than the one at Airbus in France.

From a scientific point of view, creating the necessary databases would be easy; it really isn‘t difficult. Things become more complicated, however, if we want to understand when an isolate is part of an outbreak. A great deal of research is still required to register and distinguish between clonal outbreaks, the long-term spread of sub-types or a change in the host specificities of a species. Bacterial phylogenetics is an extremely broad field for which we need standardised tests and outputs. The goal is also to determine how these data can be merged with epidemiological findings in real-time. It is possible that we will obtain too much information which will then have to be filtered – and for this we will increasingly need the services of epidemiologists and statisticians.

Can we win over partners around the world to this project? We have already held several meetings on this issue, both in Brussels and the USA, and the response to our idea was overwhelmingly positive. Europe is lagging behind somewhat, but we are already used to the Americans taking the lead on projects like these. Nevertheless, I believe Europe could have a major role to play in both technical and scientific terms.

There are a few challenges with regard to the metadata and some scientists who want to publish their data before they make sequences freely available. National authorities could be reluctant to pass on sequences of this kind to other countries. Various approaches are conceivable here and need to be discussed. Moreover, there could be liability problems if, for example, an outbreak in the USA is not registered by the FDA in timely manner. One of the things sequencing brought to light, for example, was that the cholera pathogen that caused the outbreak in Haiti in 2010 had been introduced into the country by UN peacekeeping troops from Nepal. The government in Haiti now intends to sue the United Nations, and Nepal may no longer wish to provide assistance during the next UN mission. In other words, there is still much to discuss and we believe that we have to broaden this discussion. One final important point: we need more specialised epidemiologists as well as statisticians and experts for data modelling, and our scientists should not be afraid of the new molecular biological techniques. Thank you very much.

Discussion

Moderator: I found it impressive that you as a natural scientist attach particular importance to rapid applicability. Are there any questions?

Question: I would first like to make a few comments and then ask my question. The sequencing of the overall genome of the EHEC O104:H4 strain showed that it wasn‘t a typical EHEC

strain but an entero-aggregative hemorrhagic *E. coli* strain, and one that didn‘t have an eae gene. And this is why initially we didn‘t assume it was an ETEC that led to illness. At least this is what the molecular biologists told me. That the outbreak wasn‘t detected for three weeks was also due to the fact that it took eight to nine days from consumption of the food to occurrence of the bloody diarrhoea.

Prof. Aarestrup: But that‘s exactly the point that ultimately supports our technology. If you had already characterised all isolates by this point in time, then you would have probably hit upon this unusual strain. And you would at least have been able to rule out the possibility that it is one of the typical EHEC strains.

Question: And that leads me to my question: this typing method will certainly result in the identification of more outbreaks. In other words, we are sure to see more frequent crises in future. Do you already perform this kind of typing in Denmark, and are you already reinforcing your preventive measures in the area of crisis management?

Prof. Aarestrup: Indeed, we will see more outbreaks, and we therefore also need more people with experience of risk management and risk communication, which will become more complicated in future. We will see a lot of things we haven‘t seen before and weren‘t able to see. But this doesn‘t mean we can ignore them. We need to take these findings on board and actively address them. We can‘t just sit here and wait until something happens or until other scientists render this technology useable. However, we in Denmark are not in a position to push ahead with this technology on a large scale. We have a few smaller projects where we‘re using it and a few where we are using traditional typing methods parallel to whole genome sequencing. There are also a few suspected VTEC cases that we‘re investigating. This is not a major topic, but we will be engaged in this pilot project for the next three months. We have also thought about implementing some of the projects in hospitals. The main aim is to determine whether we really can directly analyse clinical samples in real-time. And of course, we hope that there won‘t be any outbreaks, because we still don‘t know how to handle them.

Moderator: The next presentation will be held by Dr. Eric Poudelet. He is Director of the Safety of the Food Chain Department at the Directorate General of the European Commission for Health & Consumers. Yesterday during my introduction, I asked whether the cultures and structures in the EU Member States are so different that they present an obstacle to a uniform modus operandi. I‘m sure Dr. Poudelet will address this question and take a closer look at the role of the European institutions.

The Role of Member States and European Institutions in the Event of a Crisis

Dr. Eric Poudelet,

European Commission (DG SANCO), Brussels

Ladies and Gentlemen,

I have been asked to talk about the role of the Member States and the European institutions in the event of a crisis and would first like to look at a few legal issues. General food law is regulated by EC Regulation 178/2002, creating a legal basis for the deployment of EFSA and the introduction of a general plan for crisis management. EC Regulation 882/2004 on official controls requires the Member States to have contingency plans in place. These contingency plans are extremely well structured and organised in the field of animal health, because we have had several crises in the past – such as foot and mouth disease. The contingency plans were drawn up by the Member States and outline all necessary actions, because a rapid response is essential in such cases. The Member States need to be able to react immediately in the field of animal health to prevent the pathogens or the disease from spreading any further and also affecting other farms. This also entails measures such as the disinfection of cars or trucks as well as, where necessary, the culling of animals, the incineration of carcasses and so forth. It must be possible to initiate all these measures within the space of a few hours.

But the same applies to food – and will soon also apply to plants. Although these areas do not need to be addressed with the same degree of urgency, there is nevertheless a need for action in relation to the media and the political decision-makers. In 2004 the Commission adopted a decision based on the two aforementioned regulations; this decision lays down the statutory framework for intervention on EU level, in other words for the Commission and for the various agencies attached to it. But the procedure is unwieldy and has therefore never been initiated. We didn‘t even make use of it during the EHEC crisis in Germany. Nevertheless, we are prepared to respond to cases that have significant political impacts on EU level such as the dioxin crisis in Belgium in 1999.

In the event of a crisis, three elements are initiated at EU level: the first job is that of crisis assessment. We determine whether the outbreak affects humans, in particular in the event of problems in the food sector. Our primary point of contact is the European Food Safety Authority (EFSA).Then we may mobilise the European Centre for Disease Prevention and Control (ECDC). We also draw on the services of the Reference Laboratories in the EU. As you know, we have a network of 45 EU Reference Laboratories (EURLs), mainly in the field of animal health and the food sector. They are responsible for the development of analytical methods and the provision of support to the Commission in emergencies. The EURLs and EFSA have procedures in place that allow an extremely rapid response to inquiries or emer-

gencies. If we assign a mandate to EFSA, then it normally takes six to twelve months until the process is completed. But everything happens far faster in times of crisis: in such cases, the Reference Laboratories and EFSA issue their recommendations within two to three days. This network was mobilised during the EHEC crisis, for example. Where necessary, we can also draw on the services of the National Reference Laboratories in the individual countries (fig. 10.1). All these elements culminate in a risk assessment sent to the Directorate General SANCO, although it must be said that coordination between the two agencies and with the EU Reference Laboratories is a crucial point.

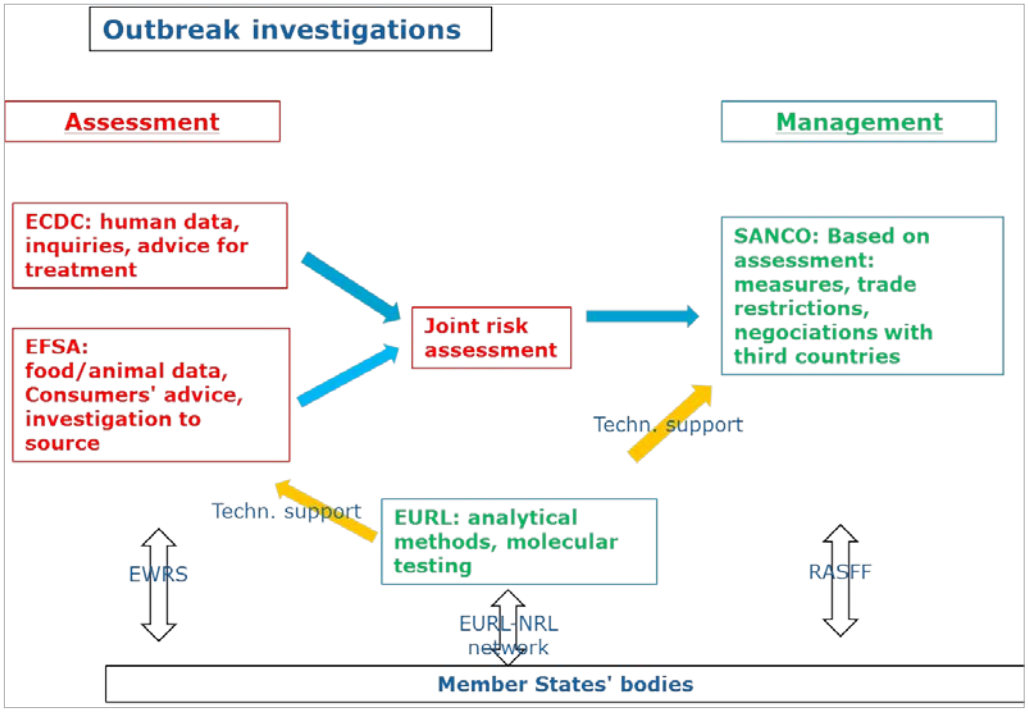


Fig. 10.1: Cooperation between European institutions in the field of crisis assessment and risk management.

What role do the European institutions play in these cases? Well, first of all we watch how the Member State in question reacts. As you will be aware, there is currently a problem in the Czech Republic with adulterated vodka, and this has resulted in some fatalities. This is a serious matter, and there are discrepancies between the fatalities reported in the press and those reported by the authorities. We also saw this difference between the official numbers and the figures reported in the media during the EHEC crisis. In these cases, we observe how the national authorities handle the crisis and we assess the measures they take. Where appropriate, we naturally also request the distribution of information via the Rapid Alert System for Food and Feed, a network operated by the Directorate General SANCO. We are in a position to ensure that all the information is passed on to all the contact points of the Member States within the space of one hour. There are around 3,000 alerts every year on major or less significant problems, both within the EU and for products imported from third countries.

We implement protective measures where necessary. There is the so-called „safeguard clause measure“ which allows the Commission to ban a product or an import from third countries or to shut down a company. We can implement measures of this kind within 24 hours and adopt new legislation relatively quickly. One important task is the provision of information to third countries, as the media report on every crisis, and third countries which read about a crisis are concerned about the import of products from the EU. This is why it‘s also our job to persuade third countries not to impose any general bans on EU products. But it isn‘t always easy.

In addition, we support the competent national authorities in their response to crisis situations, as smaller Member States have only a low level of scientific resources at their disposal. If necessary, we ask the ECDC or EFSA for assistance. We also publish recommendations to ensure uniform implementation of regulations in the different Member States. This is where our scientific bodies once again come into play. After the end of the crisis, we have to persuade all parties including the third countries to lift the measures they originally put in place. There are still a great many countries which operate an import ban on beef from the EU as a result of the BSE crisis back in the 1990s. It was just two days ago that Japan indicated that it will probably lift this import ban for some of the EU Member States. This example shows that we can also provide support to the national authorities in cases like these.

What lessons can we learn from crises and how do we respond to them? In the past, crises have often led to new regulations and legislation. It could be a reaction to public pressure, but we will certainly try to avoid this glut of legislation in future.

I would like to look at some concrete examples to illustrate the cooperation between the EU and its Member States: a few years ago, EC Regulation 178/2002 was adopted in response to the BSE crisis. EFSA was founded with the aim of creating an institution that can act independently. Prior to this, the EU Parliament had accused the EU Commission of manipulating the way in which scientific information was presented. They wanted EFSA in order to curtail the influence of the Commission in this area.

The second example is related to the EHEC outbreak in Germany, where all three of the elements described above were deployed: the Commission coordinated, supported and performed legal acts, audits and inspections. You probably all recall that first it was the Spanish cucumbers and then the Egyptian fenugreek seeds that were suspected as the source of the outbreak; our colleagues from the competent agency therefore travelled to Egypt to monitor how the organic seeds for the sprouts are produced and cultivated as well as to inspect the conditions under which they are harvested, stored, transported and exported to the EU. However, the most difficult part of the biological analysis process to determine the cause or sources of the outbreak is still within the remit of the individual Member State. Despite the fact that traceability of products is mandatory for companies in the food sector, it often poses problems in practical terms. This was also apparent during the dioxin incident in Germany.

The most difficult task, however, is ensuring effective communication in coordination with the regional and national authorities as well as the Commission. This is an area in which we have meanwhile downgraded our expectations, as experience during the crisis showed that we were seldom successful in persuading the press to report on our recommendations and arguments. But there are exceptions: during the BSE crisis there was a case of BSE in a goat in France, and we were worried that this finding might raise concerns about milk products, particularly goats‘ cheese. However, the excellent cooperation between AFSSA (the French agency), EFSA, the French authorities and the Commission ensured a coherent information policy and therefore prevented scaremongering by the media. The key point is that diverging messages in the area of crisis communication produce reactions in the media that we are powerless to stop. Thank you very much.

Moderator: Thank you, Dr. Poudelet. Gerd Billen is not only a social scientist, but also a nutritional scientist and Director of the Federation of German Consumer Protection Organisations. Mr. Billen, what are the biggest shortcomings in the management and prevention of crises, and what needs to be improved?

Government Crisis Prevention from a Consumer Organisation's Point of View

Gerd Billen,

Federation of German Consumer Organisations (vzbv), Berlin

Ladies and Gentlemen,

I'm very grateful for this opportunity to contribute some ideas from a consumer viewpoint. I'd like to start by pointing out that consumers face a variety of crises on a daily basis. We're currently in the midst of a euro crisis, and a lot of people are coming into our advice centres to find out whether their private pensions are still safe. This week, we held an event on the subject of patient safety, looking at ways of preventing the approximately 17,000 unnecessary deaths that occur in German hospitals each year due to treatment errors. As you can see, crises occur in many different areas of life. Consumers don't see them in terms of science, or how much harm a particular substance does or doesn't cause. They see them more in terms of relationships: whether they can trust a particular institution's assessment of a product's potential risks, and whether they can trust the media. So from a consumer perspective, crises aren't just about health.

I understand that there needs to be a clear, objective basis for food regulation. But there are lots of other issues for consumers, like whether they're being told the truth. I'll explain this with an example. If you go shopping in a supermarket, you could be excused for thinking that vitamin C or calcium deficiency is the main cause of death in Germany. You'll find an incredibly large number of products enriched with these two substances, and this message creates a crisis of confidence not just in specific institutions, but in people themselves: they wonder whether they can trust themselves to make decisions that are right for them.

In the future, people involved in crisis management and risk assessment will have a new issue to contend with: where is the right place to go for good, clear advice on things like diet and food additives? We can no longer take for granted that consumers themselves know what's good for them.

In the past, we've spent a great deal of time analysing the way consumer health protection is organised in Germany, including the crises we discussed yesterday and today. I think there are several lessons we can learn from this. The first concerns food regulation. The Federal Audit Office review made it very clear that crisis management, prevention and communication needed to be improved. Last year, during the dioxin crisis, each of the sixteen state consumer affairs ministers published separate messages on their websites. If people wanted to know which eggs were safe to eat, they had to wade their way through the information on sixteen sites. In a country like Germany, communication is a national responsibility that must be properly coordinated, and we can't put out different or conflicting messages.

Our criticism is of the regulatory process itself. In common with some other European countries, Germany has a federal structure. The food regulation system is a relict of the 20th century, and in many cases no longer provides an adequate response to problems, so we're calling for the federal government to be given greater responsibility for regulation. This means inspecting large volumes of goods entering Germany through its ports and international airports, and regulating multinational companies. It's no longer about inspecting three-packs of pizzas on supermarket shelves: it's about the whole quality management process, and it's a job for specialists.

So we have a very clear expectation that the state should have a constitutional responsibility for food safety, and find ways of improving the food regulation system in Germany. I don't intend to discuss this in any more detail here, but we've found from a consumer point of view that there was better and clearer communication during the EHEC crisis than during the dioxin crisis. It was more consistent, we didn't get federal and state government spokespeople contradicting one another, and most people involved appeared to be singing from the same song sheet. As a result, the public ultimately believed what government bodies were telling them. We have no intention of preventing the media from investigating these issues, because that's their job, but it's crucial that the government's credibility is not damaged.

I'd also like to commend the BfR, the Federal Institute for Risk Assessment, for being such a pillar of strength amid a barrage of scientific, unscientific and pseudoscientific opinions. I'm pleased that we have an institution capable of taking a long hard look at the situation, ignoring the political pressure, and achieving results. This independence is essential, and it must be strengthened.

It's clear that we need to adopt a much more European and global approach to crisis prevention and communication. Regulation and risk assessment must take account of the globalised food market, which could include globalising the European rapid alert system and expanding the food warnings website in Germany.

My next point is particularly important from a consumer point of view: the food safety sector must accept that today's consumers get their information from different sources than they did ten or twenty years ago. The internet provides us with many new information opportunities. We want to know about the quality of products, and we want to know not just what we're buying, but who we're buying it from and what their background is. It's vital to have legal instruments, such as laws on the freedom of information and consumer information, to assess suppliers' reputations and credibility.

In Germany, we're currently debating whether food inspectors' reports on things like restaurants and bakeries should be made available locally to consumers. The discussion is still ongoing, but I'm fairly confident that a transparent monitoring system like this would significantly boost consumer confidence and help to drive the black sheep out of the market. The big retailers are doing a lot to improve their reputations and quality control, but this is not always the case with restaurants. More and more people are eating out, and microbiological contamination can be a serious threat to food safety, so we also need to place more of a spotlight on the people who process the food and identify any breaches of the rules. There's also an increasing need for consumer research in Germany to answer a variety of questions: how consumers respond to particular trends, what causes crises, and why government bodies and service providers are not always trusted. The BfR is already working on this, and I believe there's a need for a great deal more research, because consumers' food-buying decisions and attitudes to eating are often anything but rational. We still believe that we do what we want, but instead we want what we do, and there are over 100 factors that affect our dietary behaviour.

Another important issue for the future is evaluating new technology. People are very interested in all aspects of food and health, so it's important to adopt a proactive approach to assessing the possible advantages, disadvantages, risks, benefits and opportunities of technology. It seems to me that the debate on genetic technology has very quickly degenerated into a war of attrition, and this should be avoided in other new areas of science, such as nanotechnology. To give another example: three years ago, consumers suddenly discovered that the fresh milk they'd been buying was lasting for four weeks. Producers had assumed that everyone would be delighted with extra-shelf-life milk, but many consumers were simply confused because of the lack of good, clear, proactive communication. This is something else that needs to be explored in consumer research.

Consumers need lighthouses to help them navigate their way through the complexities of everyday life. Credibility is crucial for bodies like the BfR, the state, government bodies and companies, and standardised, easily understandable messages help to build a basis of trust. The other question we need to answer is whether there has been sufficient Europeanisation in the area of crisis prevention. Thank you very much.

Discussion

Question: What's your view, as the Federation of German Consumer Organisations, of public attitudes to the issues of dioxins and EHEC? EHEC is undoubtedly a crisis, with a number of deaths and serious injuries, but dioxins were more of a perceived crisis than a real one. Do you think the large-scale media coverage caused as much public uncertainty?

Gerd Billen: The media needs there to be good guys and bad guys, and it wasn't immediately clear who the bad guys were in the case of EHEC. People obviously expected fast solutions, but a large proportion of consumers accepted that further tests had to be carried out and the authorities would do everything humanly possible. The crisis unit's communication was more consistent and appropriate. The review found other things that didn't work so well, but I don't want to go into them now.

The dioxin issue didn't get interesting until it became a political hot potato. Personally, I didn't take the whole issue seriously at all, because the figures showed that the dioxin levels weren't a serious risk to human health. But people are always interested in bad news, and the key question for a lot of people was whether the consumer affairs minister would have to resign. That was why the public debate sparked so much attention. In that respect, various institutions shared responsibility for the media crisis, which is why they should work together to assess the situation and communicate in a joined-up way. As a consumer, you've got no way of knowing whether dioxins will affect you differently than EHEC. Consumers are completely dependent on the views of institutions they feel they can trust. It's not just the objective finding that matters, it's the relationship between consumers and institutions.

Moderator: In the dioxin story, the message simply didn't get across: we've found dioxins in eggs, but there's no health risk. Was that your experience too?

Gerd Billen: No. I think it has something to do with the way consumers perceive risk. When there's a plane crash, people are more afraid that there will be another one, even though statistically it may actually be less likely. The more remote the risk, the easier it is to ignore. For example if you don't have a private pension, there's a relatively high risk that your retirement income will be low. Yet people will spend a hundred times longer buying a new outfit than thinking about a private pension.

The message about dioxin in eggs wasn't sufficiently nuanced, and it wasn't tailored to consumers' information needs. All they said was there's no acute health risk to consumers, but everyone knows that dioxins are bad for your health.

Question: It's almost like consumers enjoyed the crisis because there was a scapegoat. You even get that impression reading your script. You say "the system of penalties is not a sufficient deterrent, and nor is the frequency of inspections. Public prosecutors and judges are fighting shy of implementing either." Does that mean the public opinion needs somebody they can blame?

Gerd Billen: No. You're talking about the results of the analysis of the dioxin crisis. There are almost no specialist public prosecutors' offices in Germany, and those that exist don't have the human resources to deal with bad businesses. As far as I know, there hasn't been a single case against anyone who deliberately contaminated chicken feed in Lower Saxony. The association of food inspectors is clearly saying that inspections depend on how much money is available, and when things are going badly for the country, they make cutbacks. Responsibility for food inspections lies partly with local authorities and partly with state councillors who obviously want to keep on the right side of companies within their jurisdiction. These are facts: they're not about people enjoying crises, and you can read about them in the report of the Federal Audit Office. Our role is also to point out the weaknesses in the system.

Question: Do you think that the states' federal status is causing problems with communication? You talked about the need for joined-up communication. How do you see the problem in federal states such as Germany, Italy, Spain, with strong states or regions?

Gerd Billen: We published a joint statement with the German Federation for Food Law and Food Science, retailers' and farmers' federations. It was partly aimed at politicians, and said that the existing system of food monitoring in Germany is no longer adequate. This applies both to communication and crisis management. There isn't even a formal requirement that the federal government has the central role in crisis management. Institutions such as the BfR, which are doing a lot of good work in this area, theoretically operate with no legal basis. That's why I criticise the federal states for delaying and obstructing all these improvements, and the German food and agriculture industries, and many companies, agree with me. I hope that we'll soon have an intensive debate that takes us forward without arguing about responsibilities and trying to score political points.

Moderator: Thank you very much indeed. We now come to the next speaker, Professor Chris Gaskell, of the London School of Economics and Political Science. I think it's very important that we should also hear from the social sciences. Professor Gaskell, how much trust do you think the European public has in food safety?

Trust in Food Safety in Europe and Elsewhere

Professor George Gaskell,

London School of Economics and Political Science, London

Ladies and Gentlemen,

In this presentation I would like to explain some of the social scientific background to the understanding of the phenomenon of trust. I will also make some references to some of the projects we have conducted jointly with the European Food Safety Authority.

The German sociologist Niklaus Luhmann introduced a helpful distinction between trust, familiarity and confidence

Familiarity
With familiarity the future is a generalised extension of the past. It is taken for granted that life will go on as normal. Everyday routines are so well established that we are hardly aware of them. Generally speaking, interactions with family members, acquaintances and expert systems progress without a concern that expectations based on past experience will not be fulfilled. Trust and/or confidence are simply not an issue.

Trust
In an increasingly complex world people cannot be experts or even reasonably well informed about every new situation or decision they confront. As such, people may actively decide to rely on others and in so doing they act on trust. To trust is to transfer or delegate responsibility for the future to an 'other'. However, the actor is aware that there is a risk of disappointment, as the 'other' may or may not act in the interests of the person. Trust acts to reduce the uncertainty of the future, and eliminating the perceived risk provides a basis for action. Crucially, with trust the actor recognises that he or she has a choice in the matter, to trust or not to trust. Frequently, but not exclusively, it involves personal relations between the actor and the other.

Confidence
People's lives are inevitably affected by social institutions, technical systems and the actions of unknown others. While the dangers inherent of relying on such 'others' could be entertained, normally they are not. It is assumed that the engineers checking trains and planes, food producers and public servants for example, know what to do and are doing it properly. In such situations people have confidence that their implicit expectations will be met. Disappointment is not normally contemplated, in part, because the actor has no choice in the matter; there is no realistic alternative. When expectations are disappointed it leads to feelings of

threat or danger (as opposed to risk), because there is no feasible way out. Decisions based on confidence frequently, but not exclusively, involve relations with systems or experts.

What are the conditions that need to be satisfied for us to trust another? Bernard Barber, an American sociologist, outlined three expectations underlying trust that can be framed as questions: (i) are the values of the other compatible with our own?; (ii) is the other competent, does s/he have the necessary knowledge and experience to make a good right decision?, and (iii) what are the other's motives; will s/he act in the public interest or are their personal interests the prime motivation?

As an example of these expectations let us consider the role of the national and international banks in the recent global financial crisis. Arguably, most people still think that banks have a role in society (value compatibility), but whether hedge funds and other speculative financial instruments meet with public approval is an open question. The significant financial losses incurred by the banks calls in question their basic competence to use investors deposits carefully. Having lost billions of euros and having been bailed out by tax payers these highly paid bankers often awarded themselves bonuses, all pointing to personal rather than public interests as the motivator – an absence of fiduciary responsibility.

What happens when people's expectations about others are not fulfilled? In his organisational sociology, Albert Hirschmann describes three possible responses to organisational change: people can remain loyal in spite of everything, they can express a critical opinion (voice) or they can get out of the situation (exit). In Luhmann's trust situation there is an opportunity for the exit choice. If we place our trust in someone who does not fulfil our expectations, we can transfer our mandate to someone else who, we hope, will serve us better. However, in everyday life we find ourselves in confidence situations where there is no possibility of exit – voice is the only option. Yet will voicing objections have an effect? We may write to our Member of Parliament, or the local mayor, or the public utility company. But, I suspect that most people don't bother as they assume that their protest will merely end up in a waste paper basket. This is a systemic problem in contemporary societies. Without public accountability, poor institutional performance leads to public frustration and declining support for such institutions.

There is another important issue connected with trust: the question of attribution. Many experts believe that if the public does not trust a particular organisation it is somehow due to a deficit, a fault, in the public. One sees this with scientists who often argue that lack of support for science based innovation stems from public ignorance of the 'facts'. This leads to the public relations approach designed either to persuade the public to have more faith in scientists or to instruct them about scientific issues. This is a PR approach based on false attribution. Trust cannot be demand and it is not built by working on or manipulating the other. Trust is cultivated by working on oneself, whether as an individual or an organisation. People have to show by their own actions that they are trustworthy.

How is this achieved? By articulating their values and priorities; by demonstrating that they are competent, and by being seen to be working in the interests of the other and not their own. Those of you who work with EFSA know that they have been criticised in some circles on account of conflicts of interest among the members of expert panels. When such conflicts appear the claim is that EFSA is in the hands of industry. Of course declared 'interests' are not necessarily conflicts of interest. Both individuals in and organisations themselves need to vigilant as, so often, it is the perception of conflicts that drives media coverage.

In 2010, EFSA commissioned a Eurobarometer on Food Risks which I helped to design and analyse. Among other things, we asked a representative sample of Europeans about their

concern about food risks. It turned out that chemicals, pesticides and toxic substances are the greatest cause of concern. We also asked about trust in those involved in the food chain, the regulatory authorities, informers and scientists (fig. 11.1 & 11.2).

Scientists, National Competent Authorities and European institutions are generally highly trusted to give accurate information about serious food risk. Health professionals, family and friends, consumer and environmental protection organisations are trusted too. Trust in information found on the internet is very low across Europe. Within the food chain, only farmers are trusted; not manufacturers or supermarkets. The message here is that the independence of an institution is of decisive importance to the general public. The consumer protection organisations have very high trust ratings, as have the food safety authorities.

	Trust in food chain	Trust in regulators	Trust in informers	Trust in scientists
United Kingdom	53%	56%	64%	71%
EU	**45%**	**64%**	**71%**	**79%**
France	38%	55%	67%	78%
Germany	31%	52%	74%	66%
Italy	48%	59%	65%	70%
Latvia	38%	48%	65%	80%

Fig. 11.1: Who do consumers trust in a food crisis? The highest trust ratings were achieved by the scientists (values highlighted in green).

	Trust in food chain			Trust in regulators		
Country	Farmers	Food manufacturers	Supermarkets	National government	European institutions	(E)FSA
United Kingdom	67%	43%	48%	52%	48%	68%
EU	**61%**	**38%**	**35%**	**52%**	**65%**	**73%**
France	62%	26%	27%	39%	56%	69%
Germany	43%	23%	27%	47%	51%	58%
Italy	58%	41%	47%	46%	64%	67%
Latvia	62%	26%	25%	23%	62%	60%

	Trust in informers				
Country	physician, doctors, health professionals	friends and family	information found on the internet	consumer organisations	environmental protection organisations
United Kingdom	90%	79%	35%	70%	61%
EU Mean	**87%**	**85%**	**42%**	**74%**	**70%**
France	92%	79%	29%	85%	76%
Germany	75%	82%	45%	81%	79%
Italy	75%	81%	44%	71%	69%
Latvia	76%	94%	38%	51%	57%

Fig. 11.2: In contrast, the trust of consumers in manufacturers, traders and online information is relatively low (values highlighted in red).

From a range of questions in the Eurobarometer Survey, we segmented (grouped) European consumers into four groups. These groups are described below and their estimated percentages in some countries shown.

Cluster 1: "Moderates" (EU: 39 %; NL: 19 %; UK: 35 %; D: 25 %; DK: 35 %; F: 34 %)
Moderate levels of worry about food risks, perceive food as a source of stress somewhat more than a source of pleasure, believe they have agency, and have moderate levels of confidence in public authorities and trust in the food chain.

Cluster 2: "Uninterested and trusting" (EU: 16 %; NL: 31 %; UK: 30 %; D: 40 %; DK: 19 %; F: 11 %)
Low levels of worry about food risks and very low generalised risk sensitivity, relatively little engaged with food. For the 'uninterested and trusting' food is as much a source of pleasure as it is a source of stress. They have high levels of confidence in authorities and trust in the food chain.

Cluster 3: "Relaxed enjoyers" (EU: 23 %; NL: 39 %; UK: 25 %; D: 7 %; DK: 32 %; F: 28 %)
Low levels of worry about food risks and relatively low generalised risk sensitivity. Food is first and foremost a source of pleasure, not a stressor. Medium levels of trust in the food chain and authorities, medium levels of perceived personal agency.

Cluster 4: "Worried fatalists" (EU: 28 %; NL: 10 %; UK: 10 %; D: 28 %; DK: 14 %; F: 27 %)
General very risk sensitive, very engaged with food and highly worried about food risks. Little trust in the food chain, low confidence in public authorities doing enough to protect them from these risks, and low perceived personal agency.

When it comes to managing food-related risks, the majority of Europeans believe that they can do things to protect themselves from a range of risks (personal agency) and also believe that public authorities are doing enough to protect them. The segmentation analysis above shows that almost one third of Europeans are 'fatalists', i.e. lacking both personal agency and trust in public authorities doing enough to protect them. This seems a worrying finding as Europe faces the problems of obesity and related diseases. As is clear from the segmentation analysis above, people in each of the member states are rather heterogeneous. In parallel, we find striking differences between the publics across the Member States. These are evidence in an analysis of the unprompted comments to an open ended question regarding problems connected with food and nutrition. For example, the main concerns in Germany include contamination and adulteration of food, with a healthy diet playing a relatively minor role. This contrasts with France where health and nutrition and the origin of foods are of far greater importance.

Our analyses show that people with a low level of trust in the food safety authorities tend to perceive food risks as more severe. By contrast, those who believe that food has become safer in the last ten years and that they have the situation under control tend to place their trust in the authorities. With a cross-sectional design we cannot establish causal relations but, converging lines of analysis point to the important role of trust. It is also interesting to note that of all the food risk concerns of the public, health and nutrition have a high priority.

Discussion

Moderator: I found some of the data amusing. The proportion of relaxed connoisseurs in the EU is 23 %, but it is only 7 % in Germany. I would have bet money on that. That the French place the highest value on the quality of their food doesn't surprise me either, but it's good to see the scientific evidence.

Question: Many thanks for the interesting presentation. What important factors does an institution have to be trustworthy?

Prof. Gaskell: As I said, values, competence and a sense of responsibility for public well-being in conjunction with the independence of authorities from trade and industry are very important in this regard. All of the indications we found here show that scientists and institutional science enjoy a very high level of trust throughout Europe. That is why EFSA is absolutely right to rely upon and promote science based regulation. Of course science cannot solve all of the problems, especially those of an ethical and moral nature. I am thinking here about the debate on cloned animals and the question as to whether people even want to eat these animals.

Science plays a decisive role in risk assessment, but where risk management is concerned we have to accept that there are also other legitimate factors which have to be considered within the scope of WHO terminology.

Question: Many thanks for this brilliant presentation. I have learnt from all of the facts and figures that despite all of the crises and concerns, Germans still look for cheap food. Why is that? The Italians spend 30 % of their money on food, the Germans less than 20 %. What can you say about this?

Prof. Gaskell: Yes, many thanks. My co-worker in this research project is Katrin Hohl from Munich who recently took her PhD in London and who now has an academic position. She is always perplexed where her own country is concerned in these studies. She says exactly the same thing, namely that her compatriots don't spend a lot of money on food and that the contrast to London is almost dramatic. What this means is that I don't know the answer to your question either. The fact is that Europeans are different from one country to another.

Moderator: We are coming now to the presentation by Klaus Jürgen Henning, who heads the specialised unit at the BfR with responsibility for legal issues and the German EFSA focal point. It is difficult for a layman to keep track of all the various laws and procedures in the different countries and in the federal states of Germany and I fear this may also apply to the odd expert. Please give us a helping hand, Mr. Henning.

Outline Legal Conditions in Times of Crisis

Klaus Jürgen Henning,

Federal Institute for Risk Assessment (BfR), Berlin

Ladies and Gentlemen,

By way of introduction to the outline legal conditions of crisis management, let us deal initially with the question of which protected assets can be threatened in a product crisis. These include the free movement of goods, which is protected on a national level by the constitution in Germany, on a European level by the EU treaty and globally by the agreements of the World Trade Organization WTO. This is balanced off by the health and self-determination of consumers, which are also legally protected. The state has protection obligations which may require sovereign intervention. Government bans, warnings and recommendations must be set on a legal foundation. Official warnings meet with a lot of legal criticism, especially from commercial businesses. This is countered by the authorities who argue that the necessary warnings and recalls should actually be issued directly by the affected companies without any intervention by the authorities. The European rapid alert system RASFF often has to be used to alert authorities throughout the EU to prevent situations such as a ship with a cargo that was rejected in Hamburg for food safety reasons from moving on to Rotterdam to attempt to unload the non-marketable goods there.

We often encounter a public dispute among experts in times of crisis. Companies, authorities and consumers must also be able to deal with this in terms of both the facts and the legal aspects. We work in multi-level systems where legal regulations are issued on a national, regional, local and above all EU level. On top of this, the press have a right of information and the public can demand freedom of information from the authorities within the existing legal framework. Cases usually only end up in court when the crisis is over and damage claims and criminal proceedings have to be negotiated.

Few legal provisions that already apply today relate specifically to a crisis. In principle, the same legal rules apply during a crisis as in „peacetime“: food must be safe, product claims must not be misleading, products must be traceable and the rapid alert system for food and feed (RASFF) has to function properly. The question of responsibility does, however, become vitally important in times of crisis and the search for someone to blame is fast and furious. Public attention explodes and response times are drastically reduced, while fear and self-interest increase. Many different parties bear responsibility in food crises, from producers and traders through national and European authorities to the individual employee (fig. 12.1). The first general rule of consumer protection is that initial responsibility rests with the manufacturer. What also applies is that responsibility for state intervention lies mainly with the administrations of the communities and federal states in Germany. This is the main battlefield in

times of crisis. National authorities, such as the BfR, ANSES and DTU lie “above” this level, followed by the European authorities and ultimately the World Trade Organization and World Health Organization on a global level.

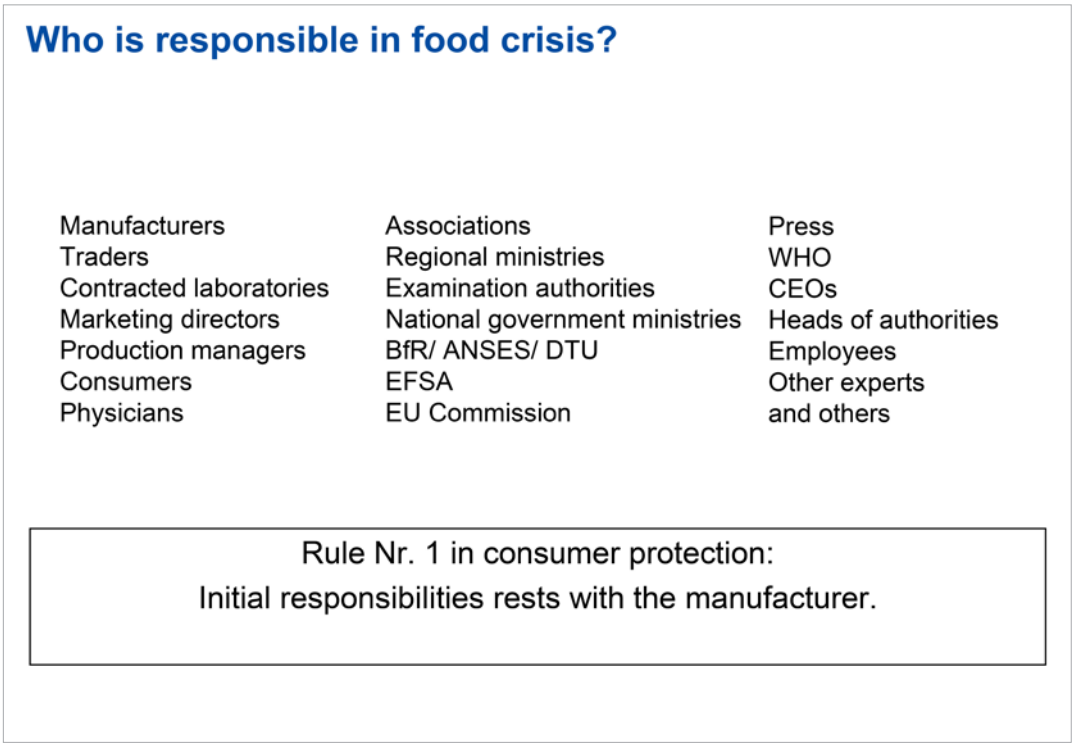


Fig. 12.1: Who is responsible in food crises?

One of the most important processes in a crisis is the exchange of information. A crisis that breaks out in Germany is often a European crisis. As the BfR is the „EFSA Focal Point“ for Germany, it regularly exchanges information with EFSA and other Member States and is experienced in the handling of scientific divergence. In times of crisis, such as during the dioxin crisis in early 2011, the BfR had three main communication levels: the German institutions, the other EU Member States and EFSA. The dioxin crisis led to a ban on German foods in some foreign markets. The BfR gave a first-hand risk assessment and written update of the current situation to the other member states and EFSA a total of 18 times during the EHEC crisis so that the authorities of the other countries could explain the situation to their citizens and keep them up to date with developments.

The practical legal questions which can occur during a product crisis are shown in figure 12.2. They relate to damage claims from consumers or producers, the question of whether official liability proceedings can or should be initiated and aspects concerning personal injury. The federal states are responsible for issuing official warnings in Germany, but this is not always easily understood by the responsible persons elsewhere in Europe. Another consideration in a crisis concerns the question of whether and when the press must be informed. The answer is that the authorities must enable consumers in Europe to make their own decisions on product selection in times of crisis so that they can minimise their own risks if they so desire.

In addition to this, claims for information and questions of protection of secrets have to be clarified. During the dioxin crisis in 2011, an official press spokesman announced that a suspected producer of industrial fat had been found and that this industrial fat had probably been mixed with animal feed thereby causing the high dioxin values. The same afternoon, the public prosecutor’s office visited the company named by the press spokesman, but they

did not find any documents upon their arrival. The public prosecutor's office then initiated investigation proceedings against the press spokesman due to breach of secrecy. In addition to this, there are frequent claims of bribery and corruption in times of crisis, or it is demanded that the authorities release files. What generally applies therefore, amid all the legal wrangling is that there should be clear legal responsibilities which should also be observed. Networks that are too complicated can water down responsibilities.

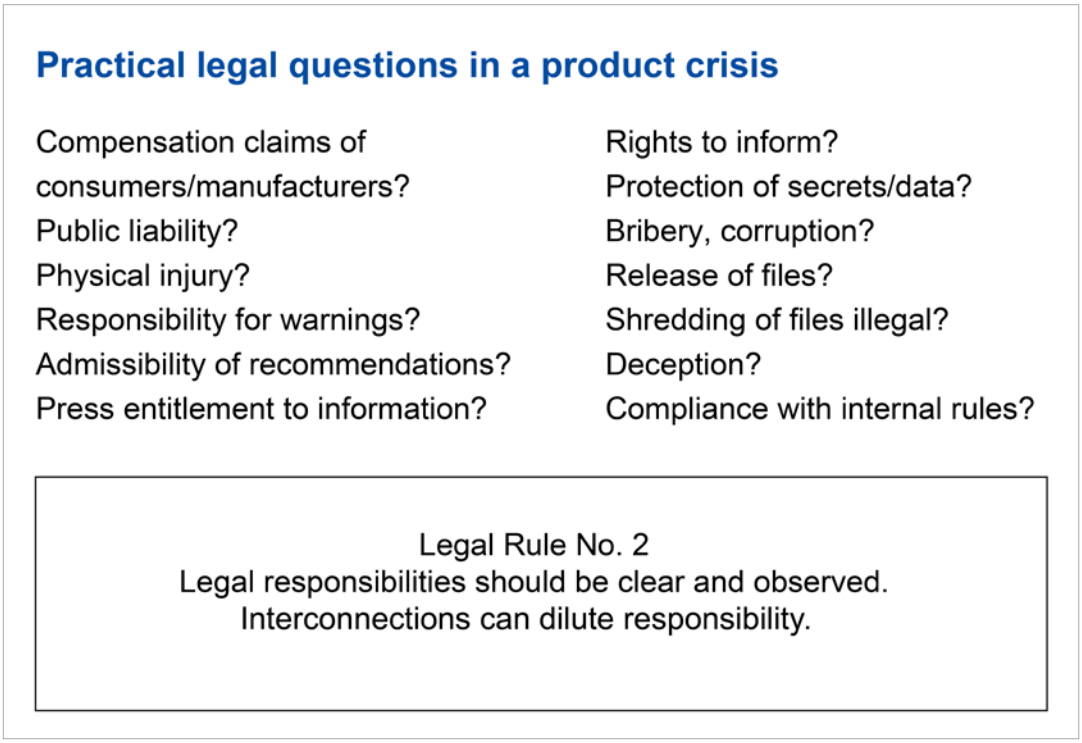


Fig. 12.2: Practical legal questions in a product crisis.

Among the tools that contribute towards upholding the law in product crises are prosecution under criminal law by the public prosecutor's office and damage claims under civil law, as well as bans, product approval decisions, warnings and business closures under public law. The leather spray case from the 1980s is a typical sample case in this context which began with patients complaining to their doctors about lung problems. Lung oedemas then started to crop up for which no cause could be found initially. The Federal Health Office then initiated investigations and identified a shoe spray with a new composition as the cause of the lung damage. The spray was taken from the market, but while conducting a search of the manufacturer's premises, the public prosecutor's office found that warnings and reports from customers about the dangers of the spray had long since been received by the company. The court sentenced the managing director to several years in prison (Federal Court of Justice, NJW 1990, 2560 ff.).

The second leading case in German product law involved „contaminated" pasta (Higher Regional Court of Stuttgart, NJW 1990, 2690 ff.). A supervisory authority had informed the press that the pasta of a certain company was contaminated, but this claim did not stand up in court and eventually led to a compensation payment of ten million deutsche marks by the responsible federal state. The third typical case concerned the antifreeze agent diethylene glycol in Austrian wines. When consumers could no longer keep track of which wines were banned and which ones were not, the responsible federal ministry published a list of prohibited wines. This triggered a 15-year legal dispute at the end of which the legality of the disputed information was confirmed (Federal Constitutional Court, NJW 2002, 2621 ff.).

Where product law is concerned, we have learnt from this on the one hand that the managing directors of manufacturing companies can be sent to prison for causing personal injury if they do not react in time, that official information can lead to damage claims if it cannot be substantiated and that the authorities may name banned products if the consumer requires this information for orientation.

The cases show that in addition to the known provisions of food law, other regulations are applied in food crises, i.e. the Criminal Code, the Civil Code, the Press Act, the Freedom of Information Act, the Consumer Information Act, the Data Privacy Act and the Civil Service Act, as well as internal rules applicable within the authorities and companies, etc. The state often faces a dilemma in times of crisis. If it overreacts, as in the pasta case, there is damage to trade and industry. If it hesitates and thus damages or misleads the consumer, mistrust among consumers results. We are still suffering today from the BSE crisis and the suspicion that followed in its wake.

We should therefore be well prepared for crises, e.g. by means of good internal documentation within authorities and companies and through quality assurance systems. Legal provisions and responsibilities must be known and this requires knowledge of the structures of each sector and authority, as well as of the scientific disciplines involved and their specialised terminology. This requires a professional approach to helplessness, fear and panic which has to be practiced. Everyone has to know their rights and obligations, especially in times of crisis. This means that companies require precise knowledge of their tracing systems, authorities should know the limits of their responsibilities and that employees should be aware of their decision-making authority and right to protest. Employees should also have the courage to contradict their supervisors if it appears that something illegal is threatening to happen within their companies or authorities. Employees have information obligations and must comply with internally prescribed rules and procedures. Organisational units take action in times of crisis, which means that representation systems must function properly. Preparation also includes practiced guidelines for risk assessment. 1,000 scientific expert reports from the member states are stored on the EFSA internet exchange platform of the EFSA virtually waiting to be used in the event of a crisis. In addition to this, crisis exercises can uncover critical points and events like this symposium can improve awareness of proper action in a crisis.

Let me now come to a third important legal rule: crises do not come as a surprise. If you do not evaluate previous crises, you increase your risk of error and liability the next time. My favourite provision in German administrative law is: “Administrative procedures must be implemented simply, appropriately and in a timely manner (Art.10 Administrative Procedures Act).“

Synopsis: No special laws apply in crises. Legal risks grow if responsibilities and representation systems are not known. Liability risk is reduced if regular processes are aligned in such a way that they can be made crisis-resistant with little conversion effort. Appropriate solutions demand interdisciplinary approaches. Crises do not stop at national borders (fig. 12.3). Many thanks for your attention.

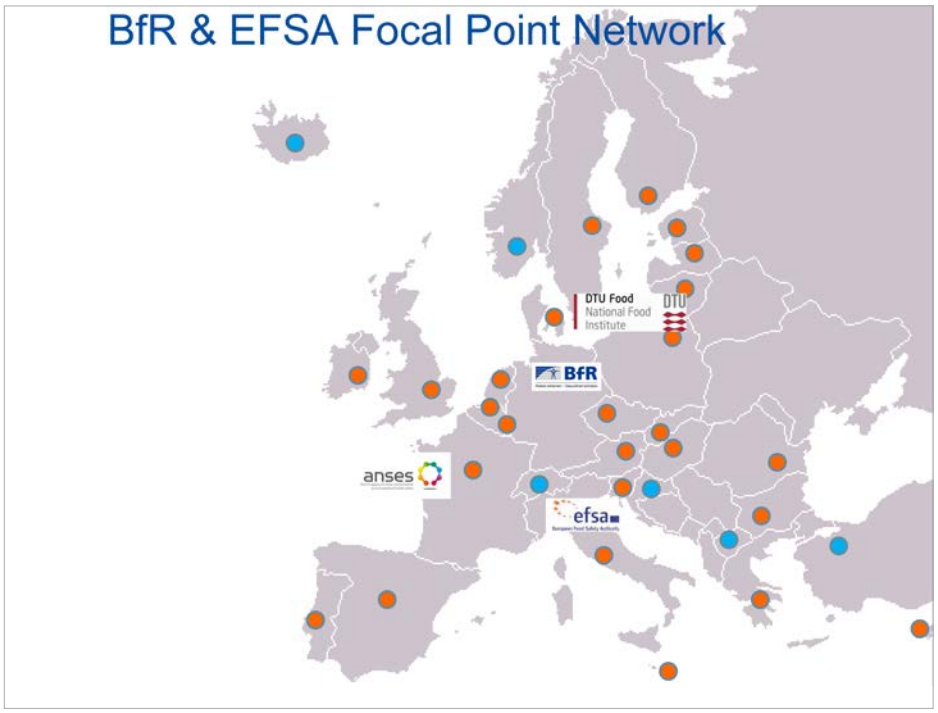


Fig. 12.3: BfR and EFSA Focal Point Network.

Discussion

Moderator: Thank you. I have a question on the Freedom of Information Act. Journalist associations and trade unions complain in unison that authorities make up reasons why the public cannot be informed via journalists, and that authorities sometimes try to demand excessive fees for information. How long will it take before the FIA really does sink into the heads of all of the responsible public authority employees?

Klaus Jürgen Henning: I think we are a good bit further ahead with this now in Germany than we were ten years ago when the law was passed. In complete contrast to Germany or France, information rights of this kind have been established in the Scandinavian and Anglo-American countries for centuries. This new information culture still has to grow on the European continent, and it is growing.

Question: Have you received any requests from NGOs or manufacturers demanding access to documents after a crisis to check that everything was disclosed?

Klaus Jürgen Henning: Not so much from NGOs, but commercial companies often approach us. It is not untypical that the lawyers of various companies want to know what the authorities knew and when. This is not necessarily aimed at the authorities, by the way. The companies sometimes want to find out amongst themselves who was responsible for what and who can claim damages from whom.

Moderator: Thank you. We have heard several times over the last two days that crisis exercises are indispensable if we are to learn from the past and be prepared for the future. Christoph Unger is the president of the Federal Office of Civil Protection and Disaster Assistance which supports the LÜKEX exercise series. What happens here and can it be used in some way to simulate a food crisis too?

Emergency preparedness in Germany: the LÜKEX exercises

Christoph Unger,

Federal Office of Civil Protection and Disaster (BBK), Bonn

Ladies and Gentlemen,

I'd like to start with a brief introduction to my organisation. It was re-established in 2004, but its roots go back much further: it was set up as the Federal Office of Civil Protection in 1958, during the cold war, to protect the public if war should break out. The organisation largely shut down in 2000, but the terrorist attacks of September 11, 2001, and the floods on the river Elbe in 2002, led to its being reopened with a wider remit. A review of these major events found that state governments were not working well with one another or with the federal government. I was the head of a ministerial office in Lower Saxony at the time, and we simply weren't aware of what was going on in other states like Saxony, Saxony-Anhalt and Brandenburg. A number of new resources were set up, including the Federal Office of Civil Protection and Disaster Assistance (BBK), and we agreed to start carrying out more joint exercises.

Major national disasters require close cooperation among all the parties involved as part of a federal security architecture, including civil defence institutions, the army and the police. We want these bodies' responsibilities to remain unchanged, but we also want them to be fully prepared and experienced at working together effectively in a crisis. Also, the state alone is no longer able to protect the public, and we need additional resources from the private sector. This is particularly important because private companies now operate critical infrastructure such as hospitals and postal and telecommunications services.

We've already discussed the issue of federal structures. Civil defence in Germany is based on a complex, highly decentralised system of 16 states, some 420 local disaster protection organisations, 12,000 local authorities, five large private aid organisations, local fire brigades, and 1.7 to 1.8 million volunteers. Disaster relief may also involve the civil defence organisation Technisches Hilfswerk, the federal police, and the army (fig.13.1).

Despite the existing constitutional and budgetary constraints, we're trying to adapt this system to the nature and magnitude of the events involved, so responsibility for everyday events involving the rescue services, fire brigade or technical assistance lies with local authorities. The BBK concentrates its skills and services on major events of national importance.

The structure of crisis management in Germany reflects this complex situation, and requires cooperation both within and between state and federal governments. Over the last few years, we've been working with the federal interior ministry on improving the structure: for example after the Elbe floods, the interministerial coordination group was revived as an interface between central and state governments and the various other bodies involved. Cooperation

within the crisis unit has also improved, but the problem of federal structures remains, and exercises are a way of improving the system.

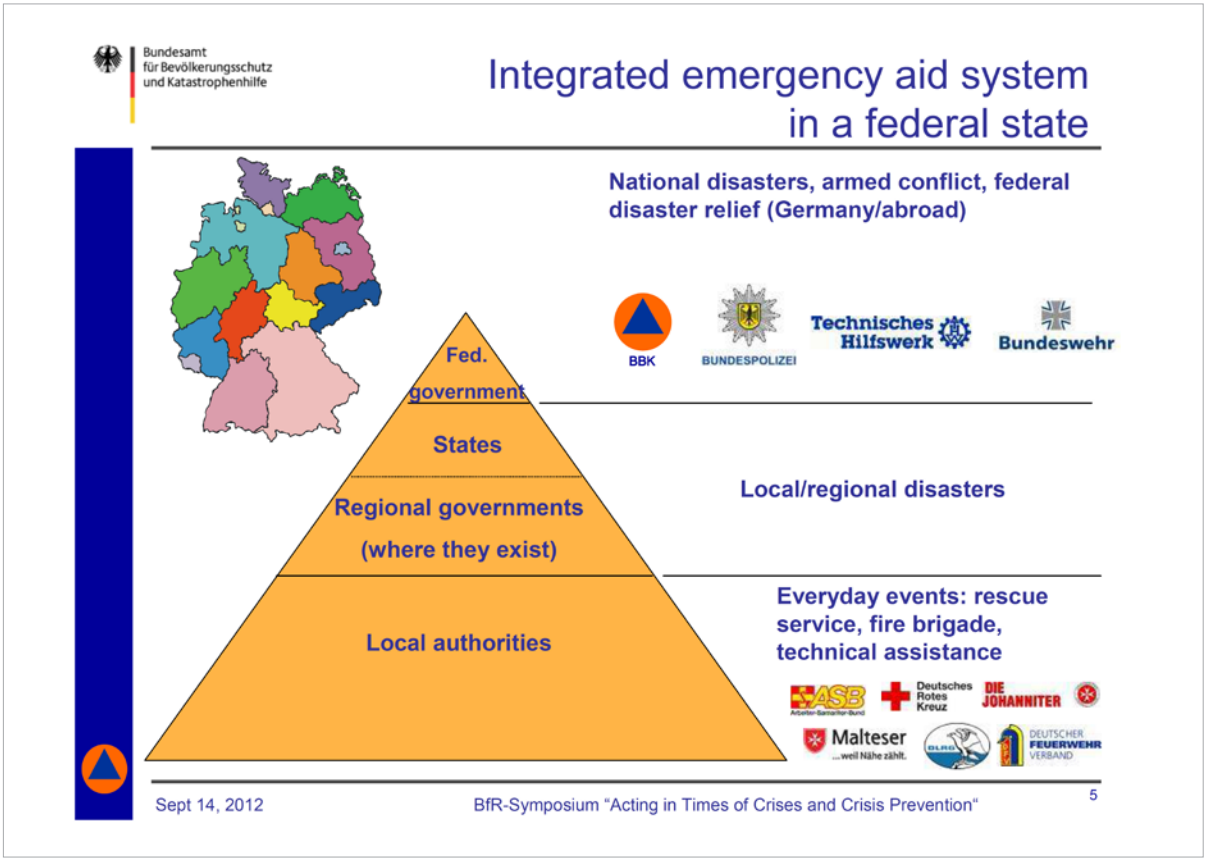


Fig. 13.1: Integrated emergency aid system in a federal state.

The BBK's civil defence responsibilities also include maintaining an early warning system. This is currently being improved for use in peacetime disasters, allowing us to inform the public in a matter of seconds. We're also providing support to federal, state and local governments in the form of emergency preparedness training at our academy, and exercises and technology. Yesterday, for example, there was a suspected chemical attack on a consulate in Berlin, and a specially equipped analytical task force was deployed by the BBK and the Berlin authorities. Another important crisis resource is the joint reporting and situation centre, which is staffed around the clock and manages domestic and international information flows. We're also involved in psychosocial care for affected people and their relatives: for example the BBK has a unit that looks after Germans returning home after being involved in accidents, assaults or kidnappings abroad.

One of my organisation's primary responsibilities since 2004 has been carrying out strategic crisis management exercises under the name LÜKEX. These use a wide variety of scenarios to improve the entire state crisis management system. The people involved work from their own desks within their organisations rather than a special exercise centre, and participation is voluntary. Exercises last two days, the whole exercise cycle lasts two years, and we carry out a large amount of groundwork to enable people to take part in preparation for a possible real crisis in the future. As well as intensive preparation for exercises, we now also have an accompanying research programme.

These exercises focus on issues which have been repeatedly mentioned during the symposium, such as risk and crisis communication, psychosocial issues, and the involvement of companies that own critical infrastructure.

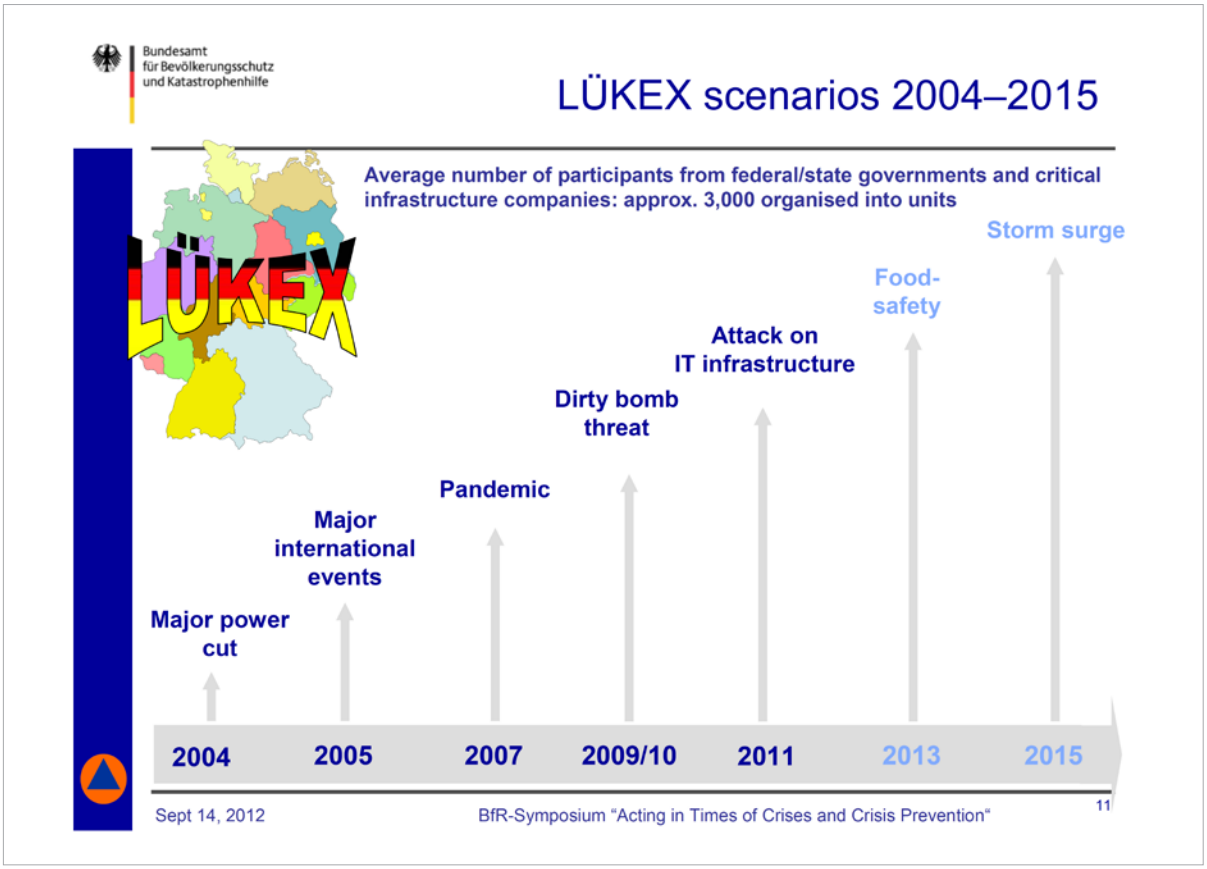


Fig. 13.2: LÜKEX scenarios 2004 – 2015.

We've dealt with a wide range of situations since the start of LÜKEX. People laughed at us when we carried out power-failure exercises after large-scale outages in North America and Italy, but there have since been real instances in Germany, for example during windstorm Kyrill in the Münsterland region, and another caused by a ship transiting the River Ems. Both of these caused large-scale power cuts which until then had been considered impossible. Eighteen months after our pandemic exercise in 2007, there was an epidemic of swine flu. In 2011, LÜKEX focused on possible hacker attacks on IT infrastructure, food safety is on the agenda in 2013, and the theme in 2015 will be storm surges (fig. 13.2). When we hold our food safety exercise, it will be very important to involve not only health and food safety bodies, but also the security authorities. It will therefore simulate a threatened deliberate release of toxins or biological agents that presents a risk to food safety, public health and internal security.

The exercise involves a nationwide crisis, so the state authorities will be required to work together, and will involve both the public sector and a major food supplier. One of our partner companies in recent years has been the Tengelmann retail chain, and we've also worked with other critical infrastructure operators such as Deutsche Telekom whose staff receive training at our academy before taking part in an exercise.

The crisis management structure is complex, and so is the process of preparing for exercises. The LÜKEX project group consists of my authority, the Federal Office of Consumer Protection and Food Safety, the Federal Institute for Risk Assessment, the Robert Koch Institute, and other federal authorities. We also work closely with critical infrastructure companies, aid organisations, trade federations and expert advisory bodies, and a similar organisational structure operates at state level.

After we agree the overall scenario, we begin the detailed planning process. We write a script that includes media inserts such as messages from the police and the public, press and TV reports, and ticker text. All of these are incorporated into the exercise documents for participants. Exercises last two days, and are followed by an evaluation and report summarising the lessons learned, which we hope will be put into practice. The ultimate decision lies with the state governments and other parties involved, each within its own area of responsibility.

The exercises involve a large number of people and a great deal of organisation, but both have been drastically reduced by changing the exercise cycle. The cost to the federal government, including human resources, is around 2 million euros per cycle, but I believe that LÜKEX has a major part to play in improved crisis management. So far, our exercises have always been deliberately focused on national emergency structures, but we're looking to involve our European partners in the food safety exercise. Thank you very much.

Panel discussion: Crises – Opportunity or Disruptive Factor for Food Safety

Participants:

Gerd Billen, Executive Director of the Federation of German Consumer Organisations

Dr. Marcus Girnau, Director of the German Federation for Food Law and Food Science (BLL)

Prof. Gérard Lasfargues, Scientific Director of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES)

Dr. Tobin Robinson, Head of Unit Emerging Risks, European Food Safety Authority (EFSA)

Dr. Jørgen Schlundt, Director of the National Food Institute at the Technical University of Denmark (DTU)

Dr. Michael Winter, Federal Ministry of Food, Agriculture and Consumer Protection, Germany (BMEVL)

Professor Reiner Wittkowski, Vice-President of the Federal Institute for Risk Assessment (BfR)

Moderation: Justin Westhoff, Medical and Scientific Journalist

Moderator: It‘s probably no surprise that, as a resume of the conference, I have chosen to give the title of “Cooperation and Communication” to our panel discussion. I believe that two papers from which I would like to outline a few points supply an excellent basis for our discussion. The abstract of the competent French ministry on this conference calls for improved coordination of networks in Europe together with new guidelines. It also sees a need for more effective coordination of communication within the EU. The second text is the opinion of Germany‘s Federal

Audit Office which has already been mentioned several times during the conference. The suggestions for improvements it proposes include more efficient monitoring of producers, improved financial and personnel resources for the food monitoring authorities, standardised quality management, cross-border performance comparisons and, where necessary, and I am quoting, "the upward transfer of responsibilities to federal level in the event of crises". It also looks as though there could be a national crisis team and/or a taskforce. We will soon know more about this. Moreover, the BLL and the Federation of German Consumer Organisations have published a joint declaration calling for bundling of national decision-making powers and improved crisis management and communication. That's all I'd like to say by way of introduction. Dr. Winter, you are responsible for the Federal Institute for Risk Assessment (the BfR) at the German Ministry of Food, Agriculture and Consumer Protection. After the EHEC crisis, there were calls for the harmonisation of government statements and the founding of a federal task force for food. What has become of these demands and what is your opinion on these issues?

Dr. Winter: A lot of demands were raised in the wake of the EHEC crisis. You have mentioned the most important ones that I believe are necessary to consolidate the excellent range of tools and this taskforce that we created during the crisis. We have held lengthy talks with the regional states, and I am in the fortunate position to be able to tell you about the decisions of the conference of Germany's regional consumer protection ministers. There will be a taskforce, and a corresponding agreement will be signed by the federal government and the regional states.

However, it won't get to the stage where decision-making powers are transferred to the federal government. The outcome of political deliberations is that even this crisis should not call into question the fundamental division of power between the federal government and the regional state governments. The aim of this taskforce agreement is to create a structure that will also prove efficient in future crises. Should it be necessary in future, we will be able to mobilise this taskforce. As concerns communication, this is an extremely sensitive issue, as has become clear in many of the statements today and yesterday. Our taskforce agreement therefore stipulates that certain basic principles be laid down for handling communication processes. This means that the BfR and, where necessary, our other scientific institutions, in other words the RKI or the BVL, will communicate scientific findings to the consumer. As during the EHEC crisis, for example, the BfR will publish recommendations on the consumption of food products. In addition, the federal government and the regional states have agreed that the government will report on the situation in Germany through daily press conferences or statements and that the regional states can add information that is of importance for their own activities.

Moderator: You say that this taskforce should not be a centralised entity. Is this a reflection of the unfavourable side of the federalism coin or even of regional egoisms?

Dr. Winter: My answer is a clear and categorical "no". The regional states have certainly recognised the benefits of this taskforce. But we can't have one law in the crisis and another in non-crisis times. That's why we don't want to try to change Germany's Basic Law in this area but to rely on the experience gained in past crises and agree on a process that will ensure more effective cooperation in future. This is one of the items on the agenda of the taskforce negotiations.

Moderator: Thank you. Dr. Marcus Girnau is Director of the German Federation for Food Law and Food Science, the BLL. Mr. Girnau, your organisation is particularly dependent on the trust of the consumer and on this trust not being eroded or eroded any further. So what are you doing to address this issue?

Dr. Girnau: The food industry has no interest in food crises either. That's why it places a lot of emphasis on avoiding crises by means of preventive measures. The three-level monitoring process was set up for this purpose: first of all, there are wide-ranging on-site quality assurance measures taken by the companies themselves; then there are private external checks to verify these measures and on the third level official food monitoring which controls the control system. I believe this is a good and efficient system. It goes without saying that even the most sophisticated regulatory measures cannot totally prevent the activities of a few black sheep. But what we can do is increase the pressure of law enforcement on these people so that they have to discontinue their business activities. Like I said, this is in the inherent interests of the food industry

Moderator: Mr. Billen, where do you see the biggest flaws or even negligence in the inspection system from the point of view of the consumer?

Gerd Billen: I don't want to use the word "negligence" in this connection. The talks I hold with the various involved parties don't always have the same outcome. Take the producers: we find relatively few problems in the area of quality assurance in all those companies that are part of larger structures or who use recognised quality assurance systems like QS. These are the people who supply the market and whose reputation is under pressure from retailers, who naturally want to purchase quality goods. The situation is more difficult in atomised markets, however, markets of the kind that exist in the hotel and restaurant sector, for example. And this is why this sector is one of the focal points of our activities.

Moderator: What about the "rotten meat" scandal? It wasn't just the small kebap outlets that were involved but also the suppliers.

Gerd Billen: This does happen, but my impression is that it is not of central relevance to the overall situation. What's more important is the question of the structural changes necessary to avoid these kinds of problems. I talked about food monitoring earlier. This is a process that can't depend on how much money is available. It must be independent; it can't be the remit of the municipality or the district and it has to have access to the resources it needs to do the job properly. This also includes support from institutions like the BfR. We need an independent, publicly funded inspection process in order to achieve good results.

I believe it should be possible to amend Germany's Basic Law in this area. A debate on the division of labour between federal and regional level is inevitable during the next legislative term on the issue of education, so why shouldn't we also have a debate about food monitoring? It's not about criticising shortcomings and apportioning blame but about organising the system in such a way that the various levels can bring their strengths into play. Five years ago, the Federal Audit Office published a report on the situation of the internal intelligence agencies in Germany. The current debate on the far-right terrorist cell shows that its criticisms at the time were justified. I understand that the regional states are not particularly keen on conducting this debate, but we need a frank and open review to determine who can best perform the tasks that need to be performed. I'm not yet familiar with all of the details of what the consumer protection ministers have decided today, but we will analyse them and then make an assessment.

Moderator: I think consumer protection organisations are incredibly important, and I'm happy they exist. People expect them to be critical and sceptical about everything the authorities say. But how do you handle enquiries from hysterical people, outsiders or crazies?

Gerd Billen: All kinds of people contact us with questions; there's not really anything we can do about it. One thing we do try to ensure is that our in-house activities are also driven by

quality. In other words, there is a clearly defined process that takes place in network groups before we publish any advisory statement on a specific issue. We have the advantage of being publicly funded and are therefore not dependent on private donors or companies – and this is why everything works more or less as it should. If we don‘t possess the necessary level of expertise to handle questions addressed to us, we cooperate with reliable, independent and well-equipped institutions that we can trust. And this is also how we provide even troublemakers with the most factual information at our disposal.

Moderator: Thank you. Dr. Jørgen Schlundt is from the Food Institute at the Technical University of Denmark, in your presentation yesterday, you put across two central messages. The first one was: forget crises, what we need to do is change the system. The second message was that it would have been possible to predict most crises, including the EHEC crisis. Your second message is not undisputed; but if you‘re right, then what do we need to change at European level?

Dr. Schlundt: Improvement measures on European level are not enough; they need to be implemented globally. The EHEC crisis is a case in point, where the original contamination took place outside Europe. We need clearly defined rules and guidelines on the use of animal dung, animal waste and excrement in agriculture. If everything had been done properly in Egypt and other contamination incidents had been avoided, then the crisis wouldn‘t have happened. That was one of the problems. Sprout producers use non-sterile plant material which germinates in water at temperatures of between 20-30 °C; these conditions not only favour the growth of the sprouts but also, unfortunately, of the bacteria. That‘s why we need suitable seed tests to ensure that there is no contamination with *E. coli*. Systems like these are already available. These two measures alone would go a long way to preventing outbreaks of this kind in the future. This of course does not mean that there will not be any more outbreaks. I think most people understand this.

Moderator: Denmark may be a small country, but it is a leader on questions like these. What can the other Europeans learn from the Danes?

Dr. Schlundt: In Denmark, we have created an integrated system that merges health data with food and animal data. This kind of system exists in several countries in the meantime. What‘s interesting is that the original idea was best formulated in the Clinton plan “From farm to table” in 1997. We were so impressed that we began to implement the concept right away. In the USA, on the other hand, they only talked about it, but didn‘t actually do anything.

Moderator: Professor Gérard Lasfargues is Deputy Director General of ANSES, where he is responsible for scientific activities. Is France satisfied with the measures taken by other European countries in response to the recent food crises?

Prof. Lasfargues: Thank you for your question. We‘re not fully satisfied. The system may be efficient in times of crisis because we have highly effective tools like RASFF and RAPEX, but I – along with public opinion in France – believe that there is still room to optimise the system. We think there should be a three-step approach: the provision of prevalence data, the monitoring of pathogens and risk assessment to support the risk managers and to form a basis for prioritisation of risks. There is still major potential for optimisation. Even in crisis-free times, the basic data supplied by the member states is extremely heterogeneous and hardly allows any comparative analysis. We must work with the European authorities, the relevant institutions and EFSA to create a fast and effective system for the collection of data.

Moderator: And you have also drawn your own conclusions from past food crises. Do you have any advice for other countries?

Prof. Lasfargues: Outbreaks can multiply, as we can see from the listeria outbreaks in the USA, Germany and France. This means we need a targeting monitoring system and microbiological criteria that are recognised worldwide. At the same time, we need an international approach to imports, as imports are always connected with food safety issues; and that is why the Member States of the European Union must cooperate with the WHO, the FAO and other relevant bodies.

Moderator: Thank you very much. Dr. Robinson, you work at EFSA, the European Food Safety Authority. Do you sometimes despair of the Member States, the long decision-making processes and the bureaucratic obstacles?

Dr. Robinson: I am not surprised by this question. We operate in a highly complex environment and often interact with other authorities and the Member States. If we are to be successful, we also have to take account of the situation in the different national contexts. This is something we have to live with. An effective network is all-important. We make use of scientifically based networks on a daily basis, and this allows us to identify the partners we want to cooperate with. We already heard this morning that it‘s about trust. It‘s important that the exchange of data becomes a routine process in crisis-free times. This then also has a positive effect on cooperation during a crisis. It‘s worth mentioning that we cooperate not only with our partners in the Member States but also with stakeholders in industry and NGOs. Here again, it‘s all about building trust, so that we can trust the information we receive and that the people that provide this information can trust us to treat their data in a responsible manner.

Moderator: Thank you very much. Dr. Robinson, you work at EFSA, the European Food Safety Authority. Do you sometimes despair of the Member States, the long decision-making processes and the bureaucratic obstacles?

Dr. Robinson: We are an independent authority but we work together closely with the risk managers and that‘s the way it should be. The majority of our work involves handling requests from the EU Commission. In general, we are consulted in advance before receiving each mandate through official channels. This gives us the opportunity to ensure that the right question is being asked, in order to provide answers that are meaningful from a scientific point of view and useful to the risk manager. In other words, we have to do a large amount of coordination and consultation behind the scenes.

Moderator: Mr. Billen, how much of this is wishful thinking, and how great are your hopes that we may still see some movement in this area?

Gerd Billen: To be honest, I‘m not all that pessimistic. Despite all the criticism, the key factor is that the institutions are able and willing to learn. And that‘s exactly what I‘m seeing from the municipal level up to national and even European level. Significant changes are only made after scandals; that‘s an empirical fact. The next food crisis is bound to come. So we should start to think now about the possible shape and form of improvement measures in the processes of the affected authorities or companies. My faith in the dependability of the systems has also increased in this regard. It depends to a high degree on how, above all, the state institutions and the companies react in crisis situations. Are they authentic and open? Do they try to ensure transparency? Do they admit it if there‘s something they don‘t yet know? Consumers greatly value and reward honesty. If our actions are based on these principles, then we will be able to achieve a great deal. Furthermore, I can only support Mr. Schlundt‘s call for global measures. This is an area in which we have a lot of ground to make up.

Moderator: Thank you. My next question is for Professor Wittkowski from the BfR. Following the reforms, the BfR can devote all its energy to scientific risk assessment and advising the

political decision-makers. Are you happy about that? And, in your opinion, how unwieldy are the national and international decision-making paths?

Prof. Wittkowski: The first thing I would like to say is that the statutory remit of the BfR – the scientific assessment and communication of risks and advising of political decision-makers – is not in question. I would like to emphasise in particular that progress has been made in crisis management. It was already pointed out yesterday that, in times of crisis, daily situation reports are compiled based on the knowledge available at the time and that these reports form the basis for communication by all the responsible parties. It‘s really only logical that this should result in coordinated risk and crisis communication. I also believe that if we are to be ready to deal with the next crisis, changes of a structural or personnel nature can only be introduced when there are no crises. Trying out measures of this kind in the middle of a crisis is without doubt the worst strategy.

Our discussions so far have focused mainly on organisation. Ultimately, however, the primary goal is of course to ensure that the statements we make are prepared in a scientific manner. The acquisition, scientific processing and analysis of data, as well as the resultant assessment and communication of risks, fall within the remit of the BfR and ultimately form the basis for crisis management as well as crisis communication. I would like to give you a few figures here: at the BfR, roughly ten employees normally work in the Reference Laboratory for *E.coli* and on the investigation of food-induced outbreaks of infections and intoxications. During the EHEC crisis, 120 BfR employees were directly involved in dealing with the crisis as it unfolded. Fortunately, we have a lot of young people at the institute working on research projects who we were able to call on for assistance at extremely short notice. What I mean to say by this is that we must have the necessary resources. The Reference Laboratories must be strengthened, all the more so, if we want to use the self-assessment data of trade and industry in the event of a crisis. This is without doubt a good objective, but it also means the necessary infrastructure has to be in place. It is not enough to simply collect these data; it must also be possible to use them for the purpose of risk assessment and for other measures. This in turn means that the Reference Laboratories need to be authorised to compare the data in advance with those of the industrial laboratories. We need to have this resource debate, because it is not only the Reference Laboratories in Germany that are chronically understaffed. Just imagine that a crisis like last year‘s EHEC crisis with all its complications had occurred in smaller Member States of the European Union. In everything we do, we need to also think about expanding the necessary networks so that we can make use of skills and expertise to prevent crises not only in the European Union but globally too.

Moderator: Thank you. I would now like to come back to Dr. Robinson. How does EFSA ensure that it is independent vis-à-vis all the various interest groups?

Dr. Robinson: As you know, this is currently an extremely important issue for us, as we have repeatedly come under attack regarding the independence of some of our experts. We were set up as an independent institution, and it is our duty to ensure the independence of our scientific output. This is essential to the credibility of the work we do. In the meantime, we have created what is probably the most stringent system of any European institution. This is no trivial matter, as we are reliant on voluntary participation. The stricter the guidelines on independence, the lower the number of scientists who are available. In recent years, there has been a strong trend towards industry-funded research at public institutions in most of the Member States. Naturally, this complicates the perception of the independence of our experts. If our work is to be impartial, independent and of a high scientific calibre, we therefore need ways and means that allow us to recruit competent experts whilst ensuring that our scientific outputs are seen to be independent.

Moderator: Professor Wittkowski, if we want to gain and maintain the trust of the public, then the independence of experts is a key issue. How is this independence ensured in Germany?

Prof. Wittkowski: Well, as we just heard in Professor Gaskell's presentation, trust isn't something you can dictate, it has to be earned. This is a lengthy process, and one we at the BfR are also involved in. In doing so, we have identified three trust-building pillars: independence – both financially and on the basis of civil service law covering aspects such as impartiality – adherence to scientific principles and transparency, which means that we publish everything we do. Even the reports and opinions we send to the government ministries are freely available to everyone on our website. We don't just tell people what we do, we also explain how we arrive at an assessment, how we conduct risk assessments and how we handle uncertainty. I believe this concept is a successful one.

Moderator: I would like to ask a third and final question on the issue of "trust". Mr. Winter, there has always been a certain tension between the highest federal authorities in Germany – the scientific advisory institutions on the one side and, on the other, the supervising ministries and ministers who occasionally issue statements that leave the scientists shaking their heads. What happens if the BfR confronts your ministry with a clear-cut scientific finding? Is this information passed up unchanged to the top level?

Dr. Winter: Of course the scientific assessments reach the top level of our ministry; and it is not seldom the case that the findings from the BfR confront us with the problem of how to respond in terms of risk management. We have to take account not only of scientific risk assessments but also of other legitimate factors. This necessarily leads to discussions with the BfR management, but that doesn't mean we exert any pressure on the BfR to publish an expert opinion that is more favourable from our point of view. Legal regulations are in place, that stipulate the independence of the BfR precisely in order to avoid that kind of situation. Initially, it wasn't always easy for the ministry officials to accept this independence, but an effective communication culture has meanwhile been established between the ministry and the BfR. We did ourselves a big favour when we made the BfR independent, because its scientific statements also carry weight among the public at large.

Moderator: What happens when the ministry decides that other aspects are more important than purely scientific ones? Does the ministry render this discrepancy transparent in the public sphere?

Dr. Winter: I'm not aware of any case like this, but the transparency rules require that any discrepancy is also communicated. We would explain that, for certain reasons, we had to act in a way that was different to that indicated by the scientific risk assessment.

Moderator: Thank you. Dr. Schlundt, the media play a central role in the communication process. What's the situation in Denmark? How much faith do journalists place in the findings you present them with?

Dr. Schlundt: I believe the journalists have a great deal of faith in us, particularly as we are now attached to a university and therefore independent. But I'm not quite as sure that the media only pick up on negative reports. We issue 40 – 50 press releases a year, and experience shows that positive reports are also well received by the press. On the European level, I think EFSA was not really successful in this regard. I'd like to give you an example: We have achieved a clear reduction in cases of salmonellosis in recent years by taking suitable preventive measures. This success is confirmed by the data, but the European authorities did not communicate the figures to the media. I don't know why we always wait for a crisis before we start communicating. We should focus more on proactively spreading positive news.

Moderator: I share your feeling that proactive communication is not pursued to an adequate degree, either on European level or in the member states. Dr. Robinson, is this because the media are only interested in bad news, or are there other reasons?

Dr. Robinson: I'd certainly say the press are more interested in dramatic events than in reporting on good news. Of course, there are also success stories in the field of food safety; we have tried to communicate them and we will continue to do so. You're right, though, we should attach greater importance to this aspect. But I would categorically refute the accusation that we have done nothing in this direction.

Moderator: Professor Lasfargues, what kind of relationship do you have with the media in France?

Prof. Lasfargues: Eric Poudelet has already pointed out that we need to be very modest when it comes to communication. I would agree with him. Trust isn't something you can dictate, it has to be earned anew every day: through expertise, impartiality, method transparency and scientific quality. I think George Gaskell is right when he says that trust is an active decision which is not about delegating responsibility but accepting this responsibility jointly and sharing it. Risk assessors, scientists and risk managers all have to take on responsibility in their respective spheres, in particular on the level of national and European early warning systems. This means we must listen and we must correctly interpret the early warning signals from the databases, microbiological vigilance networks and other systems. It is of paramount importance that we share our knowledge – not only with scientists but also with other agencies and stakeholders. This process must be formalised so that we have a forum for discussion that we can shape on a continuous basis with the stakeholders. This is an absolutely key precondition for the meaningful communication of validated statements.

Moderator: Thank you very much.

Closing Remarks

Professor Reiner Wittkowski,

Vice-President of the Federal Institute for Risk Assessment (BfR), Berlin

Ladies and Gentlemen,

The last two days have shown us different perspectives – from politics, trade and industry, administration and science – and conveyed to us in a credible way that the will to learn from crises exists. We have discussed many different ways and means of optimising processes, establishing responsibilities, enlarging networks and providing better tools to prevent and overcome crises, thus averting potential damage from consumers and the economy.

Even with the best preparation, however, we can still be sure that the next crisis will come. I don't believe there is an ideal way to overcome a crisis, because each one is different. Even if there is a functioning crisis management system, scientifically outstanding evaluation and measuring practices and fixed rules for crisis communication, we should not deny that many impulses in a crisis come from the outside, which means that we must first make them visible and controllable. To be equipped for this, what we need most of all are personnel resources – people to collect and evaluate the scientific data upon which crisis management and crisis communication are built. My wish would be that we use the crisis-free times to give some thought in Germany and elsewhere to how to prepare sufficiently for the next crisis. I'm not only thinking about increasing personnel and technical resources but also about the continuous expansion of a network of mutual support in times of crisis.

I wouldn't like to envisage what would happen if a crisis of the magnitude of the EHEC outbreak were to occur in one or more smaller member states of the European Union. That would pose us with great challenges. That is why Dr. Schlundt was completely right to remark in his presentation on crisis prevention and zoonosis control that we must keep focused on the global aspect at all costs, and it's also why I'd like to make a suggestion to the European Commission here. We heard during yesterday's event about the idea of setting up a global genome sequence database with the help of which pathogens could be typed very quickly all over the world. This would not only produce time savings in overcoming the crisis, it would also bring great benefits to crisis prevention. The establishment of a database of this kind would require the investment of several hundred million euros and sums of this kind are quick to meet with rejection in the European Union. On the other hand though, the compensation payments to vegetable farmers in the European Union to cover the economic losses incurred by the EHEC crisis amount to around 227 million euros plus a further 17 million for advertising to restore consumer confidence in fruit and vegetables. The sums spent on the preventive measures described above would therefore pay themselves off fairly quickly.

Crisis control and prevention, consumer protection and economic protection all require strategic thinking in larger dimensions and longer time frames and this is only possible in crisis-free times.

We all know how important risk and crisis communication are. The discussions within the scope of this event have shown that we not only have to communicate coherently but that we also have to create trust with our communication, ideally right from the beginning. The health threat in the dioxin incident in early 2011, which the public perceived subjectively, would presumably have been less severe if people had taken this realisation to heart. Timely, transparent and open communication which includes the explicit communication of scientific uncertainty has to be our objective. Communication of this kind cannot merely be credible, it must also be able to alter the way in which the risk is perceived by the general public, thereby contributing to the objectivity of discussions and debates. In addition to this, we should start to think about when and in what form knowledge-based risk communication transforms into knowledge-based crisis communication. This is all still unclear and we may need instruments to help with the transition. The decision of the responsible bodies to create a uniform information basis for everyone by means of daily status reports was an important one which is certain to reduce the divergence in communication.

In these last two days of the symposium, we have exchanged a lot of information and received plenty of food for thought. In theory, we all actually know pretty well what has to be done to overcome and prevent a crisis, but in what form this theory will be put into practice remains to be seen. I personally would like to see a bit more visionary power in the work on topics and structures, and I believe that my colleagues from France and Denmark think exactly the same.

To finish up, I would like to express my thanks to our cooperation partners ANSES and the National Food Institute at the Technical University of Denmark for the good working relations we enjoyed and for the joint preparation of this symposium. A special word of thanks is due to all of the speakers, the moderator, Justin Westhoff, and everyone who was involved in the organisation of this symposium.

Appendix – Materials

European Legal Basis in the Area of Food Law

Regulation (EC) No. 178/2002 (European Food Law Base Regulation) contains, in articles 55 to 57, regulations on the crisis management of the European Commission:

> **SECTION 3 – Crisis Management**
> **Article 55 General Plan for crisis management**
>
> (1) The Commission shall draw up, in close cooperation with the Authority and the Member States, a general plan for crisis management in the field of the safety of food and feed (hereinafter referred to as 'the general plan').
>
> (2) The general plan shall specify the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54.
>
> The general plan shall also specify the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy.
>
> **Article 56 Crisis unit**
>
> (1) Without prejudice to its role of ensuring the application of Community law, where the Commission identifies a situation involving a serious direct or indirect risk to human health deriving from food and feed, and the risk cannot be prevented, eliminated or reduced by existing provisions or cannot adequately be managed solely by way of the application of Articles 53 and 54, it shall immediately notify the Member States and the Authority.
>
> (2) The Commission shall set up a crisis unit immediately, in which the Authority shall participate, and provide scientific and technical assistance if necessary.
>
> **Article 57 Tasks of the crisis unit**
>
> (1) The crisis unit shall be responsible for collecting and evaluating all relevant information and identifying the options available to prevent, eliminate or reduce to an acceptable level the risk to human health as effectively and rapidly as possible.
>
> (2) The crisis unit may request the assistance of any public or private person whose expertise it deems necessary to manage the crisis effectively.
>
> (3) The crisis unit shall keep the public informed of the risks involved and the measures taken.

The general plan was drawn up in accordance with Article 55 of Regulation (EC) No. 178/2002 following the resolution by the Commission from 29 April 2004 (2004/478/EC). The general plan,

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0478R(01):EN:HTML,

defines the crisis situation, lays down the crisis management procedures and the applicable

transparency principles, and prescribes the communication strategy principles, thereby implementing the specifications given in Article 55, Section 2 of Regulation (EC) No. 178/2002.

Regulation (EC) No. 882/2004 (control regulation) constitutes, in terms of union law, another important legal act in the area of consumer health protection. Article 13 of this regulation requires member states to draw up operational contingency plans which serve the purpose of implementing the general plan for the crisis management of the European Commission (Art. 55 of Regulation [EC] No. 178/2002). At the same time, Article 13 specifies the content of the operational contingency plans:

Chapter IV – Crisis Management

Article 13 Contingency plans for feed and food

(1) For the implementation of the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002, Member States shall draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment.

(2) These contingency plans shall specify:

a) the administrative authorities to be engaged;

b) their powers and responsibilities;

c) channels and procedures for sharing information between the relevant parties.

(3) Member States shall review these contingency plans as appropriate, particularly in the light of changes in the organisation of the competent authority and of experience, including experience gained from simulation exercises.

(4) Where necessary, implementing measures may be adopted in accordance with the procedure referred to in Article 62(3). Such measures shall establish harmonised rules for contingency plans to the extent necessary to ensure that such plans are compatible with the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002. They shall also indicate the role of stakeholders in the establishment and operation of contingency plans.

Risk Reduction and Emergency Preparedness
WHO Six-Year Strategy for the Health Sector and Community Capacity Development

World Health Organization (WHO)

http://www.who.int/hac/techguidance/preparedness/emergency_preparedness_eng.pdf

Major emergencies, disasters and other crises are no respecters of national borders and never occur at convenient times. The magnitude of human suffering caused by these events is huge, and many aspects of people's lives are affected – health, security, housing, access to food, water and other life commodities, to name just a few. That is why it is vital to have emergency plans in place, so that the effects of disasters on people and their assets can be mitigated, and a coordinated response may be launched as effectively and efficiently as possible when disasters or other crises strike. The aim is to save lives and reduce suffering.

Although many emergencies are often unpredictable, much can be done to prevent and mitigate their effects as well as to strengthen the response capacity of communities at risk. The World Health Organization is the lead agency for addressing the health aspects of emergency preparedness and response. In 2005, its World Health Assembly (WHA) passed a resolution calling on the Organization to provide technical guidance and support to countries building their emergency response capacities, stressing a multisectoral and comprehensive approach. The following year, another resolution called on Member States to further strengthen and integrate their response programmes, especially at the community level, and emphasised interagency cooperation at the international level. WHO Regional Committees have also passed resolutions in support of emergency preparedness.

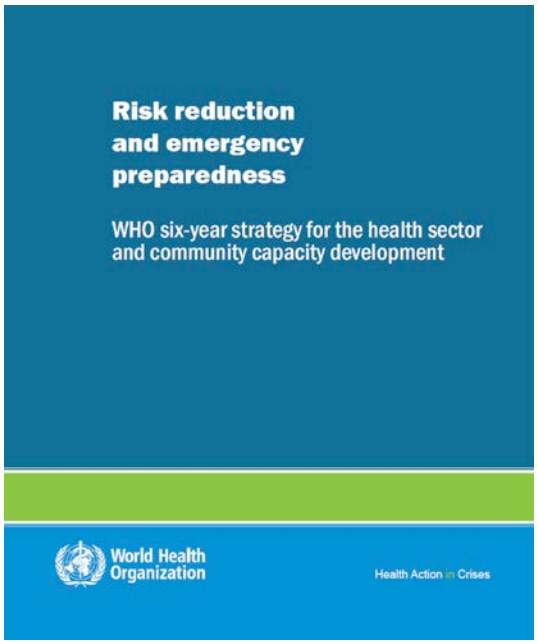
In 2005, the Humanitarian Response Review, commissioned by the Emergency Relief Coordinator, concluded that major improvements were needed in humanitarian response. The Inter-Agency Standing Committee (IASC), the United Nations Economic and Social Council and the UN General Assembly therefore recommended the implementation of a set of four humanitarian reforms in order to improve the capacity, predictability, timeliness, effectiveness and accountability of international humanitarian action including: the strengthening of the Humanitarian Coordinators System, the establishment of a Central Emergency Response Fund and other financial reforms, enhanced partnership between UN and non-UN humanitarian agencies, and the cluster approach. WHO is the designated lead of the health cluster, the role of which is to build global capacity for humanitarian health action by developing global guidance, standards, tools and resources to inform, enhance and facilitate the implementation of the Cluster Approach at the country level as well as to improve surge capacity, access to trained technical expertise and material stockpiles to improve response operations. A key to achieving the desired impact of these reforms, and specifically of the cluster approach, is the strengthening of the preparedness capacity of countries and communities particularly at risk before emergency strikes.

The World Conference on Disaster Reduction, held in January 2005 in Kobe, Japan, adopted the Framework for Action 2005–2015: Building Resilience of Nations and Communities to Disasters and provided and promoted a strategic and systematic approach to reducing vulnerabilities and risks to hazards. WHO will partner the United Nations International Strategy for Disaster Reduction (ISDR) and other UN and non-UN agencies in the 2008–2009 Safe Hospitals Initiative, which aims at building the resilience of hospitals and other health facilities to disasters, both structural and functional, so that they would still be functional under emergency situations.

Under the aegis of international policies, including WHA resolutions, and as part of its mandate as the international health lead agency and the IASC global health cluster leader, WHO intensified its work during 2006 in the field of emergency preparedness and response. Beginning with the definition of its global strategy and moving gradually into the implementation of the main directions highlighted in the strategy.

This strategy is based on the recommendations of a global consultation held by WHO in February 2006 that brought together experts in emergency preparedness and response from around the world. The consultation was followed by several important activities to discuss the various components of the strategy and to reach consensus on the objectives and key strategic directions.

With the finalization of the strategy, work to bring it into practice had already been started by WHO and its partners. Indeed several new initiatives took place in 2006 while the Strategy was under finalization. The main ones were the development and the implementation of a global survey on country emergency preparedness, a global consultation on mass casualty management in emergency settings, a consultation on the role of nursing and midwifery in emergencies, and another on non-communicable disease management in emergencies. Other initiatives are planned for 2007.



Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on strengthening coordination on generic preparedness planning for public health emergencies at EU level (COM [2005]) 605 final)

European Commission

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0605:FIN:EN:PDF

The overall goal is to assist Member States in developing their plans and factoring in the EU dimension, with its body of laws in various sectors with a bearing on public health emergency plans. The Communication together with the technical guidance document,

http://ec.europa.eu/health/preparedness_response/docs/gpp_technical_guidance_document_april2011_en.pdf,

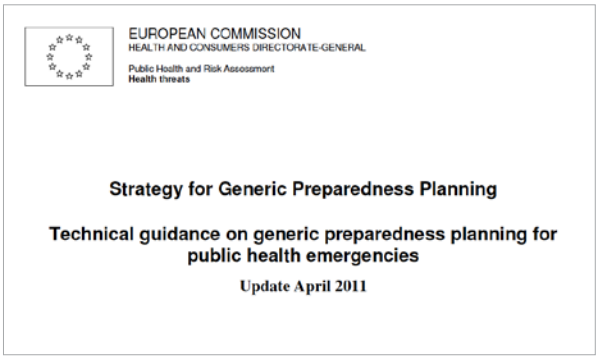
form the matrix for the development of the general or specific plans of individual states and describe the core elements that must be taken into account in preparedness planning in relation to health crises. With a view to drawing up national operational contingency plans in the health care system, the Commission describes, for each one of the following areas, measures which must be included or considered in the plans: information management, communications, scientific consultation, liaison, management and control structures, preparedness planning in the health sector and preparedness planning across different sectors.


COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28.11.2005
COM(2005) 605 final

COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

on strengthening coordination on generic preparedness planning for public health emergencies at EU level


EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Public Health and Risk Assessment
Health threats

Strategy for Generic Preparedness Planning

Technical guidance on generic preparedness planning for public health emergencies

Update April 2011

EFSA Procedures for Responding to Urgent Advice Needs

European Food Safety Authority (EFSA)

http://www.efsa.europa.eu/en/supporting/pub/279e.htm

This document provides guidance on the practical arrangements necessary to ensure responsiveness of the European Food Safety Authority (EFSA) to the need for urgent advice on food and feed safety. The document is separate to the EFSA Business Continuity Plan (BCP).

A situation requiring urgent advice of EFSA typically arises where the potential risk resulting from food and feed has caused or is likely to cause widespread concern to consumers, farmers or other stakeholders with a direct interest in the production, supply or use of food, and where the exact nature of the risk is not immediately apparent or the impact is potentially large.

Within the mandate of EFSA, this document sets guidance on the identification of urgent situations, introduces two internal response levels, explains how the urgent advice structures are activated, which steps must be followed, who the actors are, and their tasks. The document describes Operational Facilities and other arrangements relevant for dealing with requests for urgent advice.

In order to prepare EFSA staff for handling situations requiring urgent advice following the procedures outlined in this document, regular training events are arranged both internally and together with Member States (MS) and other stakeholders. The training consists of workshops, table-top as well as command post simulation exercises, focussing on the various aspects of handling food/feed crises.

To ensure EFSA's ability to respond to requests for urgent advice, even in times of unusual disruption of business, the processes of the EFSA BCP have been established. These also assist in managing disruption caused by high demands on EFSA resources, including staff, during prolonged food/feed crises.

A successful framework for action leading to the production of urgent advice by EFSA should be characterized by flexibility and the capacity to adjust to the unique circumstances on a case-by-case basis within the framework outlined in this document and taking into account the accumulated experience of dealing with similar situations in the past. This document is therefore a living document to be reviewed and updated regularly in the light of experience.

efsa
European Food Safety Authority
Supporting Publications 2012:EN-279

TECHNICAL REPORT

EFSA procedures for responding to urgent advice needs[1]

03 May 2012

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This document provides guidance on the practical arrangements necessary to ensure responsiveness of the European Food Safety Authority (EFSA) to the need for urgent advice on food and feed safety. It sets guidance on the identification of urgent situations, introduces two internal response levels, explains how the urgent advice structures are activated, which steps must be followed, who the actors are, and their tasks. The document describes Operational Facilities and other resources for dealing with requests for urgent advice.

KEY WORDS

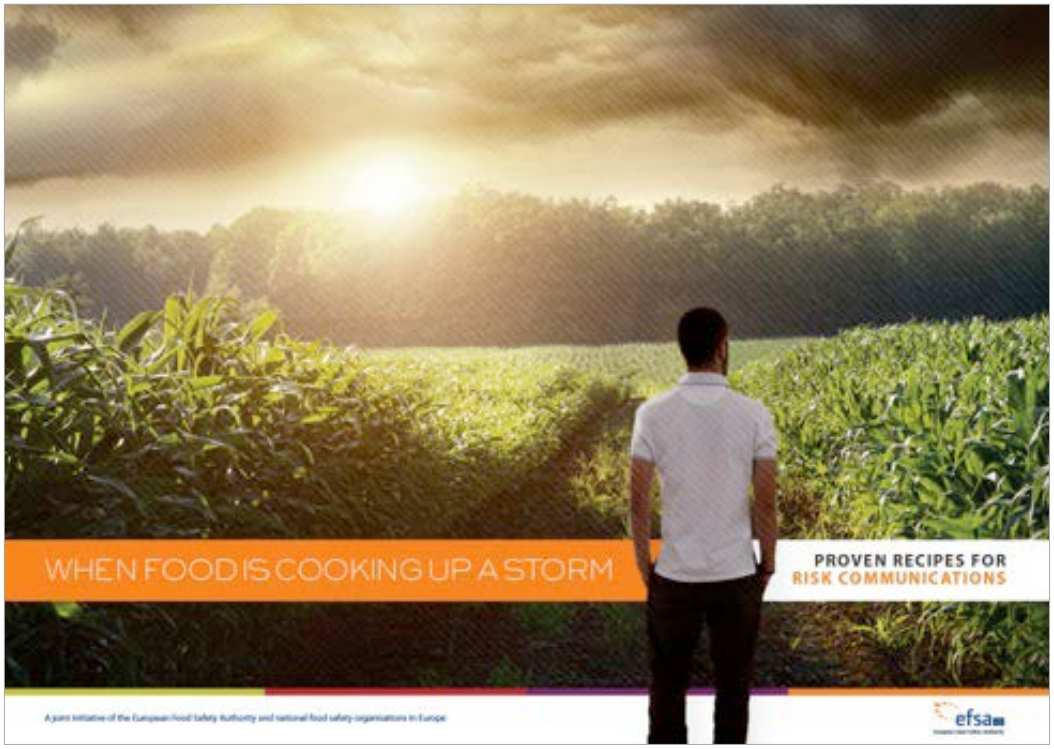
Crisis preparedness, urgent advice.

When Food Is Cooking Up a Storm – Proven Recipes for Risk Communications – Risk Communication Guidelines

European Food Safety Authority (EFSA)

http://www.efsa.europa.eu/en/corporate/pub/riskcommguidelines.htm

The objective of these guidelines – a joint initiative of the European Food Safety Authority and national food safety organisations in Europe – is to provide a framework to assist decision-making about appropriate communications approaches in a wide variety of situations that can occur when assessing and communicating on risks related to food safety in Europe. The aim is to provide a common framework applicable for developing communications approaches on risk across public health authorities in different countries.



Krisenkommunikation (Leitfaden für Behörden und Unternehmen)

Bundesministerium des Innern (BMI)

http://www.bevoelkerungsschutzpotal.de/SharedDocs/Downloads/BVS/DE/Krisenkommunikaton/Krisenkommunikation.pdf;jsessionid=241FB4BB6E28F35F862E21C41B63E61C.1_cid295?__blob=publicationFile

Im komplexen politischen und staatlichen System Deutschlands mit seiner föderalen Struktur sind die Bundesländer nach dem Grundgesetz im Rahmen der Bewältigung von Katastrophen und Krisen originär zuständig.

Auf der anderen Seite werden aber existenzielle Fragen der Krisenbewältigung unmittelbar an die Bundesregierung beziehungsweise die Ressortverantwortlichen gestellt, insbesondere dann, wenn dem Ereignis oder der Krise eine übergreifende geografische, politische und gesellschaftliche Bedeutung zugemessen wird.

In Krisen ist es erforderlich, bei allen Verantwortlichen den gleichen Informations- und Wissensstand sicherzustellen sowie Medien und Bevölkerung möglichst umfassend, aktuell, widerspruchsfrei und wahrheitsgemäß zu informieren.

Dazu ist bereits im Vorfeld die Festlegung der Abstimmungsprozesse von öffentlich wirksamen Informationen zwischen den Behörden unabdingbar; im Ereignisfall fehlt erfahrungsgemäß die Zeit, neue Verfahren einzuführen oder bestehende Verfahren und Prozesse kurzfristig zu optimieren.

Krisenkommunikation ist daher ein wichtiger Bestandteil des Krisenmanagements. Sie verlangt, genauso wie das Krisenmanagement selbst, klare Strukturen und vorbereitete Strategien. Krisenkommunikation muss regelmäßig auf Aktualität überprüft werden und bedarf anlassbezogen und in begründeten Fällen, insbesondere auf der Grundlage neu gewonnener Erkenntnisse („lessons learned“), der Überarbeitung und Aktualisierung.

Dieser Leitfaden soll den für die Krisenkommunikation verantwortlichen Mitarbeiterinnen und Mitarbeitern in Behörden bei der Erhebung, Analyse und Optimierung der externen und internen Krisenkommunikation und ihrer Strukturen eine Orientierungshilfe sein, Akzeptanz für die besonderen Maßnahmen des Krisenmanagements innerhalb der Behörde schaffen und damit auch einen Beitrag zur Stärkung des Bewusstseins für Krisenkommunikation auf allen Ebenen liefern. Er eignet sich gleichermaßen für Unternehmen und Organisationen der freien Wirtschaft.

Für die Behörden ist er eine Ergänzung zu der im Ressortkreis Krisenmanagement abgestimmten Auskunftsunterlage der Ressorts der Bundesregierung. Er enthält neben allgemeinen Ausführungen, Definitionen und Erläuterungen auch

- Handlungsempfehlungen,
- Hinweise zur Analyse vorhandener Krisenkommunikationsstrukturen und
- ein Muster zur Erstellung eines organisations- beziehungsweise ressortspezifischen Krisenkommunikationsplans.

Im Leitfaden wird der Begriff der Krisenkommunikation bewusst weit gefasst. Damit die Kommunikation im System Staat – Bürger – Medien funktionieren kann, muss im Hintergrund die

Kommunikation und Abstimmung innerhalb der und zwischen den zahlreichen Behörden des Staates möglichst reibungslos ablaufen.

Krisenkommunikation ist ein unabdingbarer Bestandteil auch des staatlichen Krisenmanagements. An erster Stelle steht dabei die externe Krisenkommunikation mit der Presse, den Medien und der Bevölkerung. Voraussetzung für das Gelingen der externen Krisenkommunikation ist das Funktionieren der Krisenkommunikation im eigenen Haus sowie zwischen den Ressorts, den Geschäftsbereichsbehörden, den Organisationen und Institutionen.

Dieser Leitfaden wird sich daher auch mit der Gestaltung der Kommunikation innerhalb der eigenen Behörde sowie der Kommunikation zwischen den beteiligten Behörden und Unternehmen beschäftigen und Möglichkeiten zur Optimierung aufzeigen.

Standard Operation Procedure for Crisis Management

Federal Institute for Risk Assessment (BfR))

BfR-SOP-180
Standard Operation Procedure for Crisis Management

SOP owner	President
Target group/customer	Federal Institute for Risk Assessment (BfR)
Area of application	Federal Institute for Risk Assessment (BfR)

	Name	Datum
Written / revised		
Checked AL'in 1		26/05/2011
Checked AL'in 1		26/05/2011
Released Pres		26/05/2011

PLEASE NOTE: The current and binding version of this document as well as the history of amendments that have been made to it are posted on the intranet and are to be found only there. Anyone who uses a printed version of this document will need to make sure that the copy they are using is current. Working with outdated versions would constitute a violation of our due diligence requirement.

1 Aim

The aim of this standard operation procedure (SOP) is to standardize the responsibilities distributed and the procedures to be followed when incidents and crises occur, with a view to avoiding uncertainties with regard to the course of action to be taken as well as to guarantee rapid processing while following official procedures.

2 Description

This SOP specifies responsibilities at BfR for the handling of an incident or crisis and determines the extent to which procedural workflows are to be adapted to needs resulting from in-creased time pressures.

3 Definitions

Incident (as defined in this SOP)	An incident occurs when a situation has a high potential for turning into a crisis and it is deemed that it could develop into a crisis within a given amount of time. An incident as defined in this procedural guide requires an explicit written declaration by the president of BfR or his representative in office (vice president). An incident can be declared a crisis or can be ended by means of a written declaration issued by the president.

Crisis (as defined in this SOP)	A crisis occurs when it appears that risk to human health attributable to food, feed, consumer goods, or chemicals cannot be prevented, eliminated, or reduced to an acceptable level. A crisis as defined in this procedural guide requires an explicit written declaration by a federal ministry with oversight responsibility in this area (BMELV, BMU, BMVBS) or by the president of BfR or his representative in office (vice president). Each crisis is ended by means of a written declaration issued by the office in question.

4 Offices and Responsibilities

Offices	Responsibilities
President	• to issue a written declaration instructing that a situation be responded to as an incident or a crisis, to the extent that this has not already been done by a federal ministry with oversight responsibility in this area. • to represent BfR on the crisis task force at BMELV • to determine the lead organizational unit (OU) at BfR • if necessary, to determine a coordinating OU for the crisis • to issue a written declaration ending the incident or crisis, to the extent that this has not already been done by a federal ministry with oversight responsibility in this area • to order an after-the-fact analysis of the situation as well as the formulation of an internal assessment after the end of a crisis
Responsible organizational unit (OU)	• assume responsibility for proper handling of mandated duties in a crisis • if necessary, see to the creation of a crisis task force • pass on information to the coordinating OU, to the extent that one has been established, as well as to EG 23 • check RASFF reports received for completeness • systematic monitoring of compliance with the requirement that an interdisciplinary approach be taken in work carried out • if necessary, appoint a documentarian to keep a record of the work done • if necessary, submit an application for overtime and for additional work on the part of OU management • to pass on information to the president of BfR at regular intervals
Coordinating OU	• to provide support, e.g. in obtaining scientific opinions from other institutions and bodies (national and international) or from expert networks, e.g. the BfR committees, in close coordination with the lead OU, in obtaining missing information, and in maintaining contact with other organizations during a crisis • to pass on information to the lead OU and EG 23
Mail room	• on finding documents that recognizably require immediate attention, to send them to the document registration desk right away or to send an advance copy directly to 21 after an accompanying telephone call and from there a cc to the document registration desk
Registration of documents	to register documents immediately and pass them on to 21 with an accompanying telephone call
Management office	• after mail room working hours (after 4:00 pm): to monitor incoming mail for crisis-relevant e-mails that need to be dealt with immediately • to maintain, update, and distribute a list of emergency telephone numbers
Section 11	to order overtime and additional work at the request of the lead department head (DH)
EG 21	• to pass on advance copies of relevant crisis-related documents arriving at BfR both to the lead OU as well as to DH 2 and EG 23 • to clarify responsibility with the relevant department head
EG 23	• to pass on relevant information from press and public relations work to the lead OU and the coordinating OU • to announce the beginning of a crisis as well as the end thereof on the BfR intranet

Offices	Responsibilities
EG 35	to immediately equip the crisis rooms with the requisite technology
All OUs at BfR	• to support the lead OU • to pass on crisis-related documents and supporting information to the lead OU immediately for purposes of assessing and addressing the crisis and only after that to follow normal administrative procedures

5 Legal basis and related documents

BfR Standard Operation Procedure	The standard operation procedure serve as a basis for shaping a uniform, efficient, and clearly structured administrative workflow. These rules are intended to make it possible to complete the tasks faced in a manner that does justice to the persons involved, is rapid, effective, and clearly structured.
VwVfG Section10	Administrative Procedures Act, Section10: “Administrative procedures are not tied to specific forms as long as there are no special provisions of law regarding the form of a procedure. They are to be carried out simply, expediently, and rapidly.“
Guide, crisis management, food safety, BMELV	Guide to organizational structures and responsibilities at BMELV in crisis situations, last updated in May 2007 (see BfR Intranet).
Organization of crisis management, BVL	Outline description of procedures at BVL in the area of crisis management, last updated in November 2006 (see BfR intranet).
Guide, crisis communication, BMI	BMI crisis communication guide for administrative authorities and companies, last updated in July 2008 (see BfR Intranet).
Reg (EC) No. 178/2002, Art. 55-57	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

6 Performance and quality features

The position statements BfR needs to put out as well as the internal and external communication it needs to engage in when dealing with a crisis are to be effected as quickly and as objectively as possible, making use of available expertise both inside and outside the organization.

7 Procedural structures

7.1 BfR‘s role in a crisis

It is the function of BfR and its staff to detect early on situations in the fields of consumer pro-tection and public health that could potentially result in a crisis and to issue position statements in which assessments are given of the potential threat involved and the measures that may have to be taken.
In accordance with its legally defined mission, BfR provides crisis management assistance in situations involving food and feed safety as well as product and chemicals safety. Its role in a crisis situation is to formulate and present health-related assessments, to supply a series of advisory papers, as well as to inform the public.

7.2 Declaration of a crisis

If BfR is informed by BMELV that a specific situation is to be viewed as a crisis, in the very

first crisis document issued the president of BfR will define the organizational unit (OU) at BfR that will assume leadership responsibility in providing crisis management assistance.
Even if BMELV has not yet defined the situation in question as a crisis, the president of BfR can declare the situation to be a crisis internally at BfR by issuing a written instruction to that effect.

7.3 Declaration and handling of an incident

The president of BfR can declare the situation to be an incident by issuing a written instruction to that effect. In a case of this kind, the Procedural Guide for Crisis Management, or individual elements of it, CAN then be used by BfR.
In the course of events an incident may be declared a crisis by BMELV or by the president of BfR.

7.4 Distribution of tasks and responsibilities

When the first crisis-relevant document arrives 21 will call the lead department head (DH) to clarify which organizational unit (OU) will assume the lead role. The result will be confirmed by 21 in a written message to the lead department head.
In addition to choosing the lead OU on the basis of the kind of expertise required, the president of BfR can also choose a coordinating OU for the crisis. The coordinating OU will act in a supporting role, for instance obtaining scientific opinions from other institutions and bodies (national and international) or from expert networks (e.g. BfR committees) in close coordination with the lead OU, obtaining missing information and maintaining contact with other organizations.
All of BfR‘s other OUs will provide priority, rapid, and effective support to the lead OU in the process of completing the tasks at hand during the crisis. They will supply crisis-related documents and supporting information needed for assessment and crisis management expeditiously and of their own accord. They will provide these documents and information to the lead OU immediately and will then follow prescribed administrative procedures after the fact.
The lead OU can choose a documentarian among its own staff or in the coordinating OU to keep a written record of workflows and everything that happens during the crisis.

7.5 Modification of standard procedures

The standard procedures established shall apply. However, in addition to this everyone involved shall be able to inform each other by the fastest possible means, e.g. by telephone, e-mail, fax, or from hand to hand, as much as is necessary. Advance copies are to be sent by e-mail or fax to the lead OU immediately, accompanied by a telephone call, to let them know what is coming.
The mail room may send an urgent document from a federal ministry with oversight responsibility in this matter directly to the document registration desk or, in a crisis situation, it may send all crisis-relevant documents immediately to the document registration desk with accompanying telephone calls. The document registration desk would register the document and then immediately send it on to EG 21, accompanied by a telephone call.
IIf the document registration desk cannot be reached, the mail room would send the document in the form of an advance copy to EG 21 with an accompanying telephone call and a cc to the document registration desk.
EG 21 would immediately send an advance copy to the lead OU with an accompanying tele-phone call. On the arrival of the first document EG 21 would agree with the lead department head, whether crisis-relevant advance copies are to be sent to the lead OU by e-mail or by fax.
After 4:00 pm (when the mail room closes) the management office will take over the above-described mail room tasks and send urgent e-mails with an accompanying telephone call to EG 21. If it is not possible to reach anyone there the management office will immediately call the general management.

7.6 Interdisciplinarity

The lead OU will systematically check at the beginning of the crisis and then at regular intervals thereafter to make sure that there is compliance with the requirement that an interdisciplinary approach be taken in all work carried out, for instance through the early involvement of BfR OUs that have special expertise in the fields of epidemiology or consumer rights.

With the approval of the general management the lead department head can form a crisis task force. The members of a crisis task force should be the lead OU, its department head, the gen-eral management, OUs that are to be involved on the basis of their areas of expertise, if neces-sary the coordinating OU, EG 23, EG 21, and a documentarian. The task force could also have further members.

7.7 Internal communication and information management

EG 23 will announce the crisis on the BfR intranet, describe it briefly, and indicate the OUs that will likely be involved in the crisis management effort. It will also announce the end of the crisis on the intranet.
The lead OU can create a directory in GroupWise where all incoming documents will be stored. The owner of the directory can grant access to it to all BfR staff members who are involved in the crisis management effort.
The lead and coordinating OUs, on the one hand, and EG 23, on the other, will regularly and rapidly exchange information that can be used for crisis communication as well as for specialist analysis.

Incoming documents that are relevant to crisis communication will be sent on by EG 21 to DH 2 and EG 23 as an advance copies.
In order to keep everyone involved updated and to agree on a uniform narrative when commu-nicating with the outside world, briefing sessions can be held in person or by telephone conference. These briefings should be attended by the lead OU, the general management, EG 23, as well as other OUs as needed.
The lead OU is to keep the president of BfR abreast of developments at all times.

7.8 Public communication

Procedures to be followed with regard to public communication can be taken from the PG on providing information to the press and the general public.

7.9 Dienstzeiten und Erreichbarkeiten

Section 11 will order overtime and additional work at the request of the lead department.

The head of the lead department will decide the extent to which availability by telephone must be ensured.

The OUs involved will make sure that their telephones and faxes are manned or that the call forwarding function is on when they move their work to the crisis rooms.

An emergency phone list with the business mobile phone numbers of the president, the vice president, and all the department heads will be kept by the management office, checked at regularly intervals, and made available in the current version to the above-named management staff, as well as EG 21, EG 23, and the doormen.

7.10 Crisis rooms and infrastructures

The crisis rooms will be chosen by the lead OU, the OUs to be involved, as well as by the general management.
The following crisis rooms have been named:

- Marienfelde, …
- Alt-Marienfelde, …
- Jungfernheide, …

In a crisis situation EG 35 will see to it that the crisis rooms are rapidly equipped with a printer, a fax, a video conference system and/or telephone conference system, additional laptops if needed, including a connection to the BfR network, as well as mobile phones.

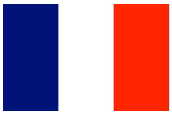
7.11 Ending a crisis and after-the-fact analysis

A federal ministry with oversight responsibility or the president of BfR will issue a written decla-ration ending the crisis. The president will order an after-the-fact situation analysis on the part of all the OUs that were involved in the crisis management effort within two weeks of the end of the crisis and an internal written assessment of crisis management performance at BfR within six months.

The EU yearbook “Food Safety” by the BfR provides an overview of the competent authorities and the structures of food and feed safety in the European Union and the member states. The focus is on risk assessment. The overview of the organizational structures and collaboration within the European Union facilitates – especially in times of crisis – the search for European partners.

http://www.bfr.bund.de/cm/364/eu-food-safety-almanac.pdf

Adapting the EU Framework for the Prevention and Management of Foodborne Public Health Crises



French interministerial memorandum

In the opinion of the French authorities, the recent enterohemorraghic *Escherichia coli* (E. *coli*) outbreaks, which claimed a large number of victims in Europe (including the fenugreek seed crisis that sickened 4,000 people and led to 46 deaths, mostly in Germany), not to mention the crises caused by dioxin contaminations and the Fukushima nuclear disaster, warrant detailed feedback and adaptation of Europe's public health framework. This would more effectively guarantee the high standard of food safety expected by our fellow citizens for foodstuffs produced and sold in the European Union.

Greater attention should be paid to hygiene during the growing phase, early warning handling, crisis communications, controls on imported foodstuffs and the monitoring of emergent risks. This is consistent with the focus on the fundamentals of food safety in Europe based on the management of risks at each stage of production, starting with primary production, right through from farm to fork.

The recent public health crises that have struck plant production in Europe, considered in relation to those observed in Japan during 1996 probably caused by consumption of radish sprouts (9,500 cases, 12 deaths) or in the United States during 2006 caused by consumption of fresh spinach (205 cases, 3 deaths), demonstrate that no farming sector is immune to the risk of a food safety crisis and can afford to do without HACCP analysis.

Accordingly, the French authorities are informing the European Commission and its European partners of several action proposals outlined in this document based around five ways of improving the prevention and management of foodborne public health crises.

1. Review early warning and public health crisis management organisations to achieve greater consistency, transparency, responsiveness and effectiveness.

The E. coli outbreaks in Germany and France during June and July 2011 provided a perfect illustration of the importance of having a multi-disciplinary European network to handle health alerts. Nonetheless, improvements need to be made to the organisation and operation of this network.

The coordination of the European human health (EWRS) and food and feed safety (RASFF) networks needs to be strengthened and better defined to improve its efficiency. This measure also needs to cover coordination with the counterpart international networks (INFOSAN, RSI) and be part of the global strategy of risk management promoted by the WHO (World Health Organization), the FAO and the OIE (World Organisation for Animal Health) under the "One Health" initiative.

In accordance with the principle of subsidiarity, improvement of the European framework should also lead to the definition of new guidelines ensuring that each Member State endows itself with an operational organisation present at every level (national, deconcentrated and/or decentralised) systematically providing centralised, effective and coordinated management of early warnings.

Moreover, the RASFF and EWRS guidelines need to be revised through the drafting of a

joint protocol for the management of major CAFI (Community-acquired foodborne illness) incidents. This operational protocol will need to identify the various human health and food safety agents, their role and the chronological order of the various possible measures. Special attention will have to be paid to arrangements for the sharing of information between the various agents, use of outside experts, investigation and survey capabilities, the regulations and protective measures (SCFCAH [Standing Committee on the Food Chain and Animal Health]) and best communication practices (see point 2). Feedback loops need to be systematically incorporated in the framework as a means of achieving continuous improvement in the networks.

Member States should be informed (oral presentation in the SCFCAH, for example) how early warnings are handled in each other Member State, in line with the guidelines referred to above. This organisation is covered in a specific chapter of the multi-annual national control plan (MANCP).

2. Strengthen public health controls on primary plant production.

The recent crisis justifies consolidation of the Hygiene package's European regulatory corpus for which there is no implementing regulation to date for EC Regulation no. 852/2004 specific to the hygiene of plant-based foodstuffs (as is the case for foodstuffs of animal origin and for animal feed). For these sectors of activity, this implementing regulation for Regulation no. 852/2004 should lay down the shared rules geared to introducing public health risk control plans, traceability measures and self-controls, etc. It should also outline the control resources that need to be implemented for the various inputs (irrigation water, fertilisers, etc.). Commission Regulation (EC) no. 2073/2005 on microbiological criteria for foodstuffs should also be extended with arrangements for certain plant-based foodstuff/microorganism combinations.

The quality of water used to irrigate primary productions and to pretreat plants should at the very least be covered by common guidelines at EU level. The concept of clean water needs to be clarified based on EFSA's scientific advice to safeguard a consistent public health standard for the water used in various food-related processes (irrigation and sprayed water, rinsing water, washing water, etc.). This is especially crucial because water represents one of the principal vectors of biological (microorganisms) and physical/chemical (chemical contaminants) contamination.

Furthermore, the EU regulations should explicitly provide for the introduction across the board of guides to good hygiene practices for all sectors of activity, and especially for all crops. These guides to good hygiene practices represent highly valuable tools that industry organisations should be encouraged to draft to facilitate the task and give helpful day-to-day points of reference to farmers. These guides should be submitted for the EFSA's opinion prior to their adoption.

Lastly, it is crucial to acquire better knowledge of the sources of contamination of plant-based foodstuffs at European level with a view to harmonising and tightening up official controls. France is proposing two areas for further work, covering sprouted seeds as a matter of priority:

- Defining harmonised sampling methods
- Preparing risk analysis prior to the definition of control and monitoring plans

3. Tighten up public health controls on imports.

For several years, France has been calling for the public health standards and controls on imports to be tightened up, especially in the plant sector. In a memo sent to the Commission on 15 February 2011, in response to its report dated 21 December 2010 on the effectiveness and consistency of import controls, the French authorities underlined the imperative of pursuing greater harmonisation, creating more scope for risk analysis and also adopting the same high standards for imported farm and food products as third-party countries impose on European products (principle of reciprocity).

It is obvious that certain trade partners do not shy away from conducting a growing number of audits in Member States, even extending as far as insisting on approving orchards or nurseries on an individual basis every year. Our proposal has two aims: the primary goal is to protect public health, animal health and plant health, and the second is economic, since it would prevent competition from being skewed and reinforce the reciprocity rules.

France believes that it is crucial for the EU to seize the opportunity provided by the review of Regulation (EC) no. 882/2004 on official controls currently in progress to adopt a number of major new principles:

- Subject third-party countries exporting plant-based foodstuffs to tighter controls on their overall public health risk management framework based on a risk analysis (based on dispatch area or type of product), mirroring those adopted in the animal sector and incorporating the hygiene of primary production, inputs, the health of plants/harmful organisms, monitoring and control plans, official control and certification systems, self-controls, traceability arrangements, etc. These controls would be carried out by the FVO (Food and Veterinary Office, document-based study of the monitoring plans, for example, and on-site inspections, where appropriate). This preventative approach should pave the way for effective implementation of restrictive measures (protective clauses) if any recommendations drafted by the FVO go unheeded.
- Arrange for notification upon import into the EU of any batch of farm or food products carrying particular risks, with the information being entered in a European system dedicated to public health and plant health controls (which could naturally be the TRACES system). Firstly, this system makes it possible to adapt controls at the level of the risk identified by public health and plant health monitoring (RASFF and EUROPHYT systems, etc.) and, secondly, ensure the traceability of the batches in the event that a public health issue emerges subsequently.

4. Reinforce the prevention of emerging public health risks.

France is proposing consolidating the arrangements for the prevention of public health risks by reinforcing the monitoring of emergent risks. The phenomena of emergence and re-emergence are usually associated with changes in the man/environment interface or new modes of consumption, production or travel. Effective monitoring systems at national, European and international level should help to detect any significantly unusual signals.

Assessment of the risk associated with the emergence of a pathogen in the food chain entails cross-referencing the non-human monitoring data with human monitoring data, which itself requires close cooperation between the bodies in charge of monitoring, evaluating and managing risk, and also with operators.

At European level, the EFSA holds centrally the monitoring data for the major zoonoses

(in accordance with EC Directive no. 2003/99). This data is reconciled with the human monitoring data gathered by the ECDC (European Centre for Disease Prevention and Control). The OAV reports may help the EFSA to assess the completeness of the epidemiological monitoring of known and identified pathogens. France is proposing that this framework should be extended with a review of passive emergence monitoring and mapping of emergence probabilities. To this end, the EFSA may issue recommendations to Member States on emergences to be monitored, including the implementation of “flash” monitoring plans to establish whether a supposed risk actually exists (H5N1, for example).

It is therefore desirable to expand the databases on food chain contaminations to all pathogens of interest under the combined oversight of the EFSA and the ECDC. Inspiration could be drawn from the arrangements put in place in March 2011 on Listeria monocytogenes by the EU’s reference laboratory.

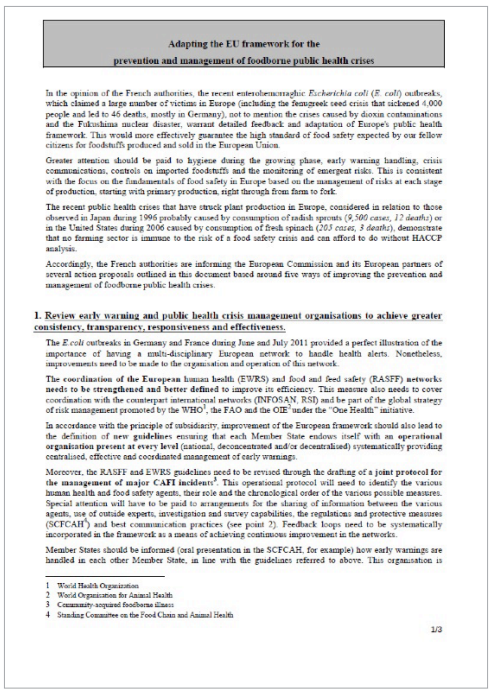
5. Handle communications more effectively in crisis situations in order to deliver precise, validated and useful information.

Crisis communications represent a major priority that is extremely sensitive and challenging in terms of avoiding disproportionate reactions.

There are two goals: firstly, to protect consumers by providing them with useful information as swiftly as possible and, secondly, to avoid triggering unfounded disruption of economic sectors of activity as a result of inappropriate media coverage.

The handling of any early warning or large-scale health crisis therefore requires expertise in two areas: communicating with the general public and providing information to the relevant professionals. It cannot overlook the emphasis on transparency required for public actions, but needs to incorporate the scientific and technical backing of authoritative and representative bodies more effectively into its time planning.

In these circumstances, the rules of communication need to be coordinated to a greater extent at European level and in Member States to ensure their overall consistency.



Adapting the EU framework for the prevention and management of foodborne public health crises

In the opinion of the French authorities, the recent enterohemorrhagic *Escherichia coli* (*E. coli*) outbreaks, which claimed a large number of victims in Europe (including the fenugreek seed crisis that sickened 4,000 people and led to 46 deaths, mostly in Germany), not to mention the crises caused by dioxin contaminations and the Fukushima nucleus disaster, warrant detailed feedback and adaptation of Europe's public health framework. This would more effectively guarantee the high standard of food safety expected by our fellow citizens for foodstuffs produced and sold in the European Union.

Greater attention should be paid to hygiene during the growing phase, early warning handling, crisis communications, controls on imported foodstuffs and the monitoring of emergent risks. This is consistent with the focus on the fundamentals of food safety in Europe based on the management of risks at each stage of production, starting with primary production, right through from farm to fork.

The recent public health crises that have struck plant production in Europe, considered in relation to those observed in Japan during 1996 probably caused by consumption of radish sprouts (*9,500 cases, 12 deaths*) or in the United States during 2006 caused by consumption of fresh spinach (*203 cases, 3 deaths*), demonstrate that no farming sector is immune to the risk of a food safety crisis and can afford to do without HACCP analysis.

Accordingly, the French authorities are informing the European Commission and its European partners of several action proposals outlined in this document based around five ways of improving the prevention and management of foodborne public health crises.

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The coordination of the European human health (EWRS) and food and feed safety (RASFF) **networks needs to be strengthened and better defined** to improve its efficiency. This measure also needs to cover coordination with the counterpart international networks (INFOSAN, ISS) and be part of the global strategy of risk management promoted by the WHO[1], the FAO and the OIE[2] under the "One Health" initiative.

In accordance with the principle of subsidiarity, improvement of the European framework should also lead to the definition of new **guidelines** ensuring that each Member State endows itself with an **operational organisation present at every level** (national, deconcentrated and/or decentralised) systematically providing centralised, effective and coordinated management of early warnings.

Moreover, the RASFF and EWRS guidelines need to be revised through the drafting of a **joint protocol for the management of major CAFI incidents**[3]. This operational protocol will need to identify the various human health and food safety agents, their role and the chronological order of the various possible measures. Special attention will have to be paid to arrangements for the sharing of information between the various agents, use of outside experts, investigation and survey capabilities, the regulations and protective measures (SCFCAH[4]) and best communication practices (see point 2). Feedback loops need to be systematically incorporated in the framework as a means of achieving continuous improvement in the networks.

Member States should be informed (oral presentation in the SCFCAH, for example) how early warnings are handled in each other Member State, in line with the guidelines referred to above. This organisation is

1 World Health Organization
2 World Organization for Animal Health
3 Community-acquired foodborne illness
4 Standing Committee on the Food Chain and Animal Health

1/3

Guidelines – Administrative Contingency Plan

Norwegian Food Safety Authority

Scope

The Administrative Contingency Plan forms part of the Norwegian Food Safety Authority‘s (NFSA) compliance with the following requirements pursuant to the EEA Agreement:

- Regulation 882/2004 Article 13
- Other EU regulations that require contingency plans

Administrative Contingency Plan

The NFSA‘s administrative contingency plan consists of the following documents:

Instructions for Alert and Notification Systems

The Instructions for Alert and Notification Systems apply to everyone in the NFSA who learns about a serious incident or suspicion thereof. They also apply to staff members performing staff tasks and the officer on duty. They are intended to ensure that the organisation, our advisory institutions and affected parties are informed about incidents, and that we fulfil our international notification obligations. The instructions will also ensure that we establish contacts necessary to manage serious incidents.

Instructions for National Emergency Duty

The instructions apply to:

- Emergency preparedness to ensure the tasks of the Norwegian Food Safety Authority (NFSA) are addressed outside normal office hours, ref. the special agreement concerning compensation for this duty
- Employees in the NFSA who are appointed duty officers
- The duty officer in the emergency duty in the NFSA

In these instructions a duty officer is defined as an appointed employee in the NFSA who at any given time is on duty. The instructions are intended to ensure that the Norwegian Food Safety Authority (NFSA) maintains proper emergency preparedness outside office hours with a special emphasis on animal health and animal welfare.

Instructions for Managing Incidents

These instructions apply to all employees in the NFSA when managing incidents. Incidents should if possible be managed within the ordinary line organisation. When the available resources are insufficient, the line organisation can be reinforced, a managing regional office can assume responsibility or Staff is set up. Staff is set up to ensure the efficient and appropriate coordination and management of the extra resources provided. The management’s goal is to return to the line organisation as soon as possible and Staff is disbanded.

Template for instructions – allocation of management responsibilities in the event of incidents – document template

This is a template that is used if one, or more, regional offices are assigned management responsibilities in the event of an incident.

Produced by hehaa	Approved by KABRY	Document owner Director General	Reference to the regulation Articles 13 and 42 2. j)	Reference to Control Plan chapter <no.>
Document ID 2007/106859-7	Version 07	Guidelines for the Norwegian Food Safety Authority Administrative Contingency Plan	Valid from 21.12.2007	Page 1 of 4

Instructions for Staff

These instructions apply when the Norwegian Food Safety Authority (NFSA) is setting up Staff, either via the Director of Controls or via a Chief Regional Officer. Incidents should if possible be managed within the ordinary line organisation. When the resources available are insufficient, the line organisation can be reinforced or Staff set up. Staff is set up to ensure the efficient and appropriate coordination and management of the extra resources provided. The management's goal is to return to the line organisation as soon as possible and Staff is disbanded. Measures cards have been drawn up for the Staff functions at head office and regional offices, incident commanders and field managers at the district office, as well as directors, chief regional officers and chief district officers.

Instructions for Communications

These instructions come into force when Staff is set up at a regional office and/or head office and apply to the H5/R5 staff function. They shall ensure the appropriate staffing of H5/R5 and efficient and consistent communications internally and externally in a contingency situation.

Instructions for Log

The Instructions for Log must be used when managing incidents and by the NFSA's officer on duty, the ICT officer on duty and the officer on duty for media. They are intended to ensure that inquiries to the officer on duty and incidents are logged appropriately.

Administrative assistance and cooperation on the area of feed and food – guidelines

These guidelines deal with the obligations of the Director of Controls or the person he/she authorises (hereafter the Director of Controls). The guidelines fulfil the control regulation's requirement to establish organisational arrangements that address the obligations concerning notification and the coordination of assistance when this is needed across national borders between the official feed and food authorities in the EEA region.

Specialist contingency plans structure – guidelines

The structure covers the NFSA's plans of measures for managing and/or combating risks that threaten fish, animals and plant health, safe food and market access, referred to as the specialist contingency plans (SCP). The purpose of the specialist contingency plans and underlying procedures for feed, plants, terrestrial animals, aquatic organisms, food and market access is to provide an overview of the specialist, management and administrative framework that provides the basis for preventing and managing incidents within the NFSA's

administrative areas. If the management requires Staff organisation, the service rules within the Administrative Contingency Plan must be used.

Specialist contingency plans – document template

This template must be used as the starting point for preparing specialist contingency plans.

Exercises and training
Training

Employees, who are going to fulfil different roles when the NFSA sets up Staff at different levels are pre-appointed, see personnel list on the contingency website. Training/information measures must be carried out each year for this group. Briefing on the NFSA‘s contingency plans forms part of the „Information for New employees of the Norwegian Food Safety Authority“.

Evaluation reports for incidents and exercises are published on the internet.

Some EU legislative acts contain special requirements concerning the training of its own employees and external actors that must be followed:

- Dir 2003/85 (FMD)
- Dir 2001/89 (CSF)
- Dir 2005/94 (AI)
- Dir 2006/88 (aquatic animals)

Exercises

The NFSA is required to carry out contingency exercises every year. The regions must cooperate and use each other‘s scenarios.

Some EU legislative acts contain special requirements concerning exercises that must be complied with:

- Dir 2003/85 (FMD)
- Dir 2001/89 (CSF)

Cooperating contingency agencies

Descriptions of the routines for cooperation with other agencies are available on the intranet/ contingency.

- The civilian emergency planning system – Directorate for Civil Protection and Emergency Planning (DSB)
- Nuclear preparedness – Norwegian Radiation Protection Authority
- Infection preparedness – National Health Service
- Preparedness for acute pollution – Norwegian Coastal Administration
- Marine stocks – Directorate of Fisheries
- Grazing crises for reindeer – Norwegian Reindeer Husbandry Administration

Agreements

Agreement with the Norwegian Veterinary Association concerning compensation, etc., for veterinarians when they are ordered to work pursuant to section 2 of the Act relating to Veterinarians and Other Animal Health Personnel – overview

The agreement applies to the whole of the NFSA and covers compensation, etc., for veterinarians in private practice when they are ordered to work in contingency situations pursuant to authorisation in section 27 of the Act relating to Veterinarians and Other Animal Health Personnel. The agreement must be followed when they are ordered to work pursuant to the Act relating to Veterinarians and Other Animal Health Personnel.

Updating and maintenance

Preparedness is part of the control process and the Director of Controls is the document owner of plan documents.

Approval of the plan documents is allocated as follows:

Plan document	Approved by
Administrative Contingency Plan	Director General
Instructions for Managing Incidents	Director Department of Control
Instructions for Staff	Director Department of Control
Template for instructions – assigning of management responsibility in the event of incidents	Director Department of Control
Instructions for Log	Director Department of Control
Instructions for Alert and Notification Systems	Director Department of Control
Instructions for National Emergency Duty	Director Department of Control
Instructions for Communications	Director of Communications Staff
Administrative help and cooperation on the area of feed and food (EEA) – guidelines	Director Department of Control
Agreement with the Norwegian Veterinary Association concerning compensation, etc., for veterinarians when they are ordered to work pursuant to section 2 of the Act relating to Veterinarians and Other Animal Health Personnel	Director General
Specialist contingency plans structure – guidelines	Director of Controls
Specialist contingency plans – document template	Director of Controls
Specialist contingency plans land animal health	Head of Section for Land Animals and Animal Health Personnel
Specialist contingency plans fish health	Head of Section for Fish and Seafood
Specialist contingency plans plant health	Head of Section for Plants and Vegetables
Specialist contingency plans food	Heads of sections Animal-based food (infectious matter)/Sales to Consumers (foreign substances)
Specialist contingency plans substances in feed for production animals	Heads of sections for fish and seafood (fish feed)/ land animals and animal health personnel (land animal feed)
Specialist contingency plans drinking water	Head of Section for Sales to Consumers (being worked on)
Specialist contingency plans radioactivity	Director of Controls
Specialist contingency plans market access	Head of Section for Import and Export

The process owner is responsible for ensuring the documents are reviewed and revised annually if required in light of evaluations of exercises and incidents. The alert and notification lists are continuously updated.

Instructions for developing and maintaining governing documents for KIM must be complied with when updating the contingency plans.

Updated contingency plans are always available via the NFSA‘s quality system (KIM).

Changes

Version	Approved	Approved by	Produced by	Changes
01	21.12.2007	Jolys	hehaa	1st version of document approved
02	22.01.2008	Jolys	hehaa	Chief regional officer given authority to approved on-site documents for RO and DO
03	01.02.2009	Jolys	hehaa	Managing RO incorporated
04	25.03.2009	Jolys	hehaa	Agreement with DnV concerning payment upon ordering on duty incorporated with Director General as owner
05	18.12.2009	Jolys	hehaa	Management of incidents in the line organisation, Communications and conformity with other revised instructions
06	15.07.2010	Jolys	hehaa	Use of public helpline and Log in MATS
07	19.01.2011	Kabry	hehaa	Lists services rules and agreements that apply for the management of incidents in the NFSA. Earlier text moved to the instructions

Guidelines
Administrative Contingency Plan

Mattilsynet

Scope
The Administrative Contingency Plan forms part of the Norwegian Food Safety Authority's (NFSA) compliance with the following requirements pursuant to the EEA Agreement:

- Regulation 882/2004 Article 13
- Other EU regulations that require contingency plans

Administrative Contingency Plan
The NFSA's administrative contingency plan consists of the following documents:

Instructions for Alert and Notification Systems
The Instructions for Alert and Notification Systems apply to everyone in the NFSA who learns about a serious incident or suspicion thereof. They also apply to staff members performing staff tasks and the officer on duty. They are intended to ensure that the organisation, our advisory institutions and affected parties are informed about incidents, and that we fulfil our international notification obligations. The instructions will also ensure that we establish contacts necessary to manage serious incidents.

Instructions for National Emergency Duty
The instructions apply to:

- Emergency preparedness to ensure the tasks of the Norwegian Food Safety Authority (NFSA) are addressed outside normal office hours, ref. the special agreement concerning compensation for this duty
- Employees in the NFSA who are appointed duty officers
- The duty officer in the emergency duty in the NFSA.

In these instructions a duty officer is defined as an appointed employee in the NFSA who at any given time is on duty. The instructions are intended to ensure that the Norwegian Food Safety Authority (NFSA) maintains proper emergency preparedness outside office hours with a special emphasis on animal health and animal welfare.

Instructions for Managing Incidents
These instructions apply to all employees in the NFSA when managing incidents. Incidents should if possible be managed within the ordinary line organisation. When the available resources are insufficient, the line organisation can be reinforced, a managing regional office can assume responsibility or Staff is set up. Staff is set up to ensure the efficient and appropriate coordination and management of the extra resources provided. The management's goal is to return to the line organisation as soon as possible and Staff is disbanded.

Template for instructions - allocation of management responsibilities in the event of incidents - document template
This is a template that is used if one, or more, regional offices are assigned management responsibilities in the event of an incident.

Incident Response Protocol (Revised May 2011)

Food Standards Agency (FSA)

http://tna.europarchive.org/20120530191353/; http://www.food.gov.uk/multimedia/pdfs/incidentresponseprotocol.pdf

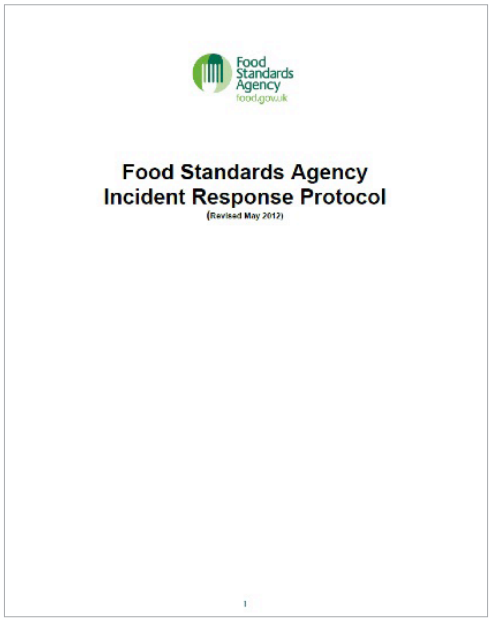
Investigating and managing incidents to ensure that food safety is protected has been, and will continue to be, a key part of the Food Standards Agency's work.

Since the FSA was set up in April 2000, it has investigated approximately 9,000 incidents and acted to protect consumer interests and public health.

The Incident Response Protocol provides FSA staff with a user-friendly guide to the procedures that should be followed when managing an incident. The protocol includes details of notification procedures, roles and responsibilities during incidents and arrangements regarding closure and review.

All parts of the FSA adhere to the principles laid out in the protocol. Where there are minor variations in roles and responsibilities, these are reflected within this document (under localised variations).

Any member of staff can potentially be called up at any time to help respond to an incident or emergency, even if they do not routinely get involved with incidents. Consequently, it is vital that all staff are aware of the importance of dealing with incidents in line with the protocol and have a clear understanding of procedures. By following the protocol, all FSA staff can play their part in ensuring that incidents are dealt with in a consistent and efficient manner. Feedback on the protocol is always welcome and comments will contribute to regular reviews, to ensure this document is fit for purpose.



Annual Report of Incidents 2011

Food Standards Agency (FSA)

http://www.food.gov.uk/multimedia/pdfs/annual-report-of-incidents.pdf

In 2011, we were notified of and investigated 1,714 food and environmental contamination incidents in the UK. This was 209 more than the number of incidents investigated in 2010. Where appropriate, action was taken to ensure consumers' interests in relation to food safety were protected.

Notification of an incident can be received from a variety of sources, including government departments, organisations and a wide range of businesses. The top three reporters of incidents to us in 2011 were border inspection posts (426), local authorities (297) and fire services (246).

In addition to the incidents that get reported to us, we will also from time to time receive food complaints from consumers who may have suffered food poisoning, or found food on sale past its useby date. Investigation of isolated complaints of this kind is the responsibility of local authority food enforcement officials and as such we will promptly forward the complaint on to the relevant local authority to investigate. In contrast, where a foodborne illness outbreak has occurred, we will be involved, working with key stakeholders to isolate the source of the outbreak and ensure that contaminated food is seized and promptly taken out of the food supply chain.

The three largest contributors to the total number of recorded incidents in 2011 were:

- Environmental – 21 %
- Natural chemical contamination – 17 %
- Microbiological contamination – 16 %

In 2011 we investigated seven 'high' level incidents. We define high level incidents as severe, complex, widespread and likely to generate a high level of concern in public and media perception of the issue. Further details regarding two of these high level incidents, the Fukushima nuclear emergency and the E. coli O104 outbreak in Germany and France linked to fenugreek seeds from Egypt, are contained in case studies 1 and 3 respectively. A full list of the high level incidents in 2011 is included within the Statistics section (Appendix 1).

Risk assessment, management and communication lie at the heart of the Agency's incident response protocol. The Agency works in partnership with enforcement authorities, food business operators and other key stakeholders in order to manage incidents proportionately. Our decisions are science and evidence-based, putting the consumer first.

Action taken by us to protect consumers in relation to food safety included issuing 59 alerts and 47 information notices to local authorities. All our alerts and information notices are published on our website. We also sent 507 notifications to the European Commission, via the Rapid Alert System for Food and Feed (RASFF). The RASFF portal is an effective tool to exchange information about measures taken when responding to food and feed incidents.

In addition to the upturn we have seen in incident reporting, we have also experienced a marked increase in the amount of food fraud intelligence supplied to us by local authorities and others. In 2011 our Food Fraud Team entered approximately 1,400 records on the Food

Fraud Database, up 50% on the previous year. This intelligence is fed into our computer system and helps us to build up a coherent picture of fraudulent activity across the UK, which is then fed back to food enforcers to assist them with their ongoing investigations.
To test our incident procedures in conjunction with other similar arrangements, we routinely participate in cross-government emergency exercises, such as Exercises Nightshade and Larkspur in 2011. Outputs from our incident/exercise reviews may result in revisions to our incident procedures, in order to deliver a more efficient and consistent approach.

In the run up to the London Olympics, in 2012 we will be taking part in a number of Olympics related emergency exercises to test our levels of preparedness, including our communications networks with LOCOG, food businesses, local authorities and other government departments to ensure that we are all ready for the unique food safety challenge that the Games represent.

During 2011, our systems for the detection of potential new and re-emerging risks to food safety were finalised and are now operational. These systems will build our knowledge of the strengths and weaknesses within the complex web of global food chains that exist today, thereby enabling us to make predictions about potential future food safety risks that we may face. By targeting our research and surveillance activities at these weaknesses, we will develop a better understanding of when, why and how incidents occur. This in turn will support our policy making and enforcement activities whilst helping us to identify more effective ways of preventing future food safety issues.

We are always looking to improve our incident response capability. Planned developments to our incident response systems in 2012 include improvements to our online incident report form to make it easier for stakeholders to report incidents to us. In 2012 we will also be completing our IT project, designed to link our incidents database with the emerging risks and food fraud databases, to create an ‚intelligence network'. This will improve our capability to store, manage and search information and intelligence. In addition, we will continue to analyse our incidents' data to help us identify new and re-emerging risks.

List of illustrations