ON LINE INTERNATIONAL SYMPOSIUM

Credibility of scientific expertiseand decision-making

New challenges for health risk governance in a changing world

January & February 2021

ABSTRACTS BREAK OUT SESSIONS

Break out session - Tuesday 26th January

1. Risk assessment framework: a common vision?

(Atelier en anglais seulement)

Gérard Lasfargues (Anses), chairman, Thomas Burke (John Hopkins University), Richard Brown (WHO), Myriam Merad (CNRS/UNICE)

More than 10 years after the publication of the silver book, the reference framework for risk assessment has evolved, as well as the methods, to adapt to changes in the science of risk assessment and optimize its usefulness for public decision-making in different institutional contexts.

Nevertheless, faced with current major issues such as climate change or the emergence of important concepts for expertise (one health, global exposure, sustainability, etc.), what can be the capacity of this framework to address more systemic questions and influence the processes of decision-making?

What are the impacts of this frame of reference today in the practice of various public health organizations such as WHO or agencies responsible for safety and health? How have these institutions integrated the logic, content and forms of producing recommendations or advice for decision-makers?

Beyond the frame of reference itself, how can the forms, methods of expertise and the practices of groups of experts change the content, influence the results and strengthen the usefulness of scientific expertise? All these issues will be addressed by the speakers and discussed in this session dedicated to the risk assessment framework.

2. Computational and predictive methods for risk assessment: issues and promises

David Demortain (LISIS), , Frédéric Bois (CERTARA) , Kathryn Guyton (IARC) , Jean-Lou Dorne (EFSA) , Anax Oliveira (LHASA Limited)

Over the last ten years, risk assessment has witnessed a reorientation towards predictive methods. The National Research Council report on Toxicity Testing in the 21st Century thus marked the ambition to anticipate risks with greater accuracy, thanks to a combination of technological developments: the availability and volume of data afforded through the application of -omic techniques; progress in systems biology and mechanistic knowledge, as well as computing power, allowing to develop and simulate high-quality models; in recent recent years, the fast development of machine learning methods enabling to learn from vast amounts of data, in an unsupervised fashion. As the Toxicity Testing in the 21st Century report shows, these developments carried, and still carry great promises for risk assessment.

In hindsight, however, they also have pitfalls, and problems. Computational methods appear less transparent and accessible to reviewers of risk assessment than experimental methods. Relying on models and simulations, for instance, implies a trust in the quality of input data, in the quality of the biological knowledge put at the heart of the model, and so on. How well do these elements circulate? How open are they to review, evaluation and auditing? To what extent does computational expertise allow for the development of a counter-expertise? This session will be dedicated to the discussion of these developments and concrete applications in risk assessment, their risks and continuous promises. It will be the occasion to review and discussion more recent developments surrounding data and model-oriented risk assessment: is the current drive towards the development of new systems for data sharing a possible solution to limit the risks of depending on “black-boxes” for predicting risks? How are these risks and promises taken into consideration in the current drive towards the application of machine learning methods, also?

3. Le droit à l’épreuve de l’expertise scientifique : acteurs et pratiques en tension ?

(Breakout session in French only)

Christine Noiville (CNRS - ISJPS), modératrice, Elsa Supiot (ISJPS) , Didier Truchet (Paris 2) , Denis Zmirou-Navier (HCSP/CNDAPSE)

Longtemps angle mort de la réflexion juridique, l’expertise scientifique de agences sanitaires à des fins de décision de gestion des risques a fait l’objet ces deux dernières décennies d’un encadrement touffu. Règles de prévention des conflits d’intérêts, de composition des comités d’experts, ou d’organisation des travaux de ces derniers ont visé à « soumettre à l’État de droit » l’activité d’expertise dont les enjeux collectifs (protection de l’environnement, de la santé, etc.) ne sont plus à démontrer. Au cours de cette session, qui commencera par une brève description du cadre juridique ainsi mis en place, trois points critiques seront plus particulièrement abordés :

- La mise en œuvre des règles de droit. Il s’agira, à partir d’un état des lieux des normes et pratiques développées par les instances d’expertise en France, de pointer les avancées et limites, notamment en termes d’indépendance, de transparence, de contradictoire de l’expertise et de prévention des conflits d’intérêts.
- Le juge face à l’expertise. On évoquera ici une « vieille » question profondément renouvelée ces dernières années, celle de savoir quels sont les outils et le rôle du juge lorsqu’il est confronté à des affaires mettant en jeu des questions d’expertise complexes. Se fait-il, comme on l’entend parfois dénoncer, expert à la place des experts ?
- La mise à l’épreuve de l’expertise par les lanceurs d’alerte. Il sera ici question de l’évolution récente de la réglementation sur les lanceurs d’alerte, lesquels sont souvent considérés comme des aiguillons essentiels en termes de transparence et de contradictoire de l’expertise.

A longstanding blind spot in legal thinking, the scientific expertise implemented by health agencies for making risk management decisions has over the last two decades been subject to ever more complex supervision. Rules on the prevention of conflicts of interest, the composition of expert committees or the organisation of their work have sought to submit the expertise activity – whose collective stakes (environmental and health protection, etc.) are now self-evident – to "the rule of law". During this session, which will begin with a brief description of the legal framework in place, three critical points in particular will be addressed:

- Implementation of the rule of law. Based on a review of the standards and practices developed by expert bodies in France, this will involve identifying the advances and limitations, mainly in terms of the independence, transparency and adversarial nature of expertise, and the prevention of conflicts of interest.
- The judge versus expertise. An "old" question that has been entirely reshaped in recent years is what is the role of the judge and the tools that can be used when faced with cases involving complex issues requiring expert appraisal. Does the judge become the expert instead of consulting a panel of experts, as is sometimes claimed?
- Expertise put to the test by whistleblowers. This will discuss recent developments in regulations on whistleblowers, who are often seen as essential drivers of transparency and adversarial expertise.

Break out session – Tuesday 2nd February

4. Risk communication in the digital and fake news age?

Brice Laurent (CSI), chairman , Lynn Frewer (Newcastle University) , Dominique Cardon (médialab/SciencesPo) , Jocelyn Raude (EHESP)

The dynamics of public controversies has recently been affected by the increasing role of social media and other digital tools. These devices facilitate the circulation of information to ever wider groups of publics. In this context, public bodies have identified new challenges related to the trustworthiness of risk communication.

This session considers this situation as an impetus to explore the mechanisms through which the credibility of risk communication is manufactured, online and offline. It discusses case studies related to particular domains (vaccines, food products), types of use of digital tools, and theoretical approaches to risk communication. These case studies will provide elements to examine the following questions: how are digital media used to communicate risks? How are risks defined in the digital world?

Do new social movements, and possibly new risk-related concerns, emerge through the use of digital media? More generally, these questions will lead us to discuss the contemporary challenges of public trust, and the need to redefine the ways and means of public expertise.

5. Biotechnologies: Risk assessment, technology assessment and responsible research and innovation

Pierre-Benoît Joly (Inrae), chairman , Claire Marris (The University of Edimburgh), Stephen Hilgartner (Cornell University) , Ben Hurlbut (Arizona State University)

In recent decades, developments in biotechnology have produced a cascade of new risk management and regulatory questions, often surrounded by controversy. Novel methods of genome editing using CRISPR are

recent a case in point, as are the long-standing debates over genetically modified (GM) food and crops. Risk management in this domain not only involves addressing technical issues and dealing with uncertainty and ignorance, but also finding ways to incorporate citizens' concerns into research agendas, decision making, and responsible research and innovation.

The combination of controversial knowledge claims, contested goals, and different modes of public reasoning challenge efforts to maintain the credibility of expertise and the legitimacy of risk management policy. Restrictions on access to information, such as proprietary data, and the politics of information transfer across organizational boundaries can complicate these challenges. This session will use biotechnologies, such as genome editing and GMOs, to explore these issues and their broader implications.

6. (Re)Framing circular economy: What place for a systemic understanding?

Louis Laurent (INRS), chairman , Charles Bodar (RIVM) , Clark Miller (University of Arizona) , Walter Stahel (Product Life Institute) , Michel Héry (INRS)

Circular economy is often considered the solution to address the scarcity of planetary resources. It implies waste recycling, eco-design, possibly reduced consumption. It is often associated to bio-economy – which integrates environment as an integral part of the loop. More generally, circular economy is a priori based on a systemic approach; however, it has not been completely implemented so far. It implies to take into account:

- Economic issues. In a neoliberal system, circular economy can be developed only if it is competitive, even if external cost can be taken into account through public regulation. The economic aspects may also influence the flows of materials between the states, depending of local labour costs.
- Environmental issues. The positive outcome from recycling in terms of resources consumption can be reduced by energy consumption and transport. Besides, recycling can pollute.
- User behaviour. These depend on various factors, such as costs, ease of use and disposal, representations of risks, etc.
- Health risks. Recycling materials has a positive effect but it can induce recycling of chemicals or biological contaminants. This can induce new risks for consumers as for the workers. Hazards can also arise from illegal use of waste. Furthermore, regulation at various level of public action can be conflicting.

In particular, the health agencies are facing these challenges. They should adapt risk assessment and prevention methods, by deeply integrating the systemic dimension of circular economy, encompassing environmental, public and occupational health, as well as economic aspects.

Break out session - Monday 8th February

7. Que mesure l'évaluation de l'intégrité scientifique ? (in french)

(Breakout session in French only)

Mathias Girel (ENS), chairman, Olivier Le Gall (OFIS) , Stéphanie Ruphy (ENS), Gilles Salvat (Anses)

L'intégrité scientifique est une valeur, elle-même reliée dans les textes cadres à ces autres valeurs que sont la fiabilité, l'honnêteté, le respect et la responsabilité. Sans intégrité scientifique, la qualité de la science

produite par les communautés de recherche est entamée, de même que la confiance qui peut être accordée à cette même recherche. Les codes de conduite existants donnent de nombreux outils pour instruire les pratiques les plus inacceptables, la fabrication, la falsification et le plagiat. Mais d'autres questions tout aussi importantes, et parfois moins objectivées, peuvent atteindre à la qualité et aux finalités de la science produite: des intérêts, des agendas de recherche qui laissent en friche de la science « non faite » (undone science) qui serait pourtant précieuse pour les agences réglementaires et sanitaires et l'expertise scientifique dont elles ont la charge.

Le Code de conduite européen pour l'intégrité de la recherche relève ainsi par exemple que « s'abstenir de publier les résultats de la recherche » ou tolérer des « biais » induits par les donateurs et sponsors sont également des manquements inacceptables. Ne faut-il pas aussi questionner les changements à l'œuvre dans le paysage de la recherche et de la production de connaissances dont témoignent de tels manquements ? Que mesure, et que doit mesurer, l'évaluation de l'intégrité scientifique? Comment les outils dont nous disposons permettent-ils de penser ces pratiques inacceptables, en dehors des cas bien balisés de la fabrication, de la falsification et du plagiat? Où s'arrête l'évaluation de l'intégrité scientifique ? Dans le contexte de la pandémie, une attention particulière sera accordée à la pression temporelle exercée par la crise sanitaire.

Scientific integrity is a value, which is itself linked to other values such as reliability, honesty,r espect and accountability in the framework texts. Without scientific integrity, the quality of the science produced by research communities is diminished, as is the trust that can be placed in that research. Current codes of conduct provide numerous tools setting out the most unacceptable practices: fabrication, forgery and plagiarism. But there are other equally important and sometimes less objective issues that can affect the quality and purpose of the science produced: interests, research agendas that neglect «undone science» of potential value to regulatory and health agencies and to the scientific expert appraisals they are responsible for.

For example, the European Code of Conduct for Research Integrity states that «withholding research results» or tolerating «bias» induced by funders and sponsors are also unacceptable violations. Should we also therefore question the changes taking place in the research and knowledge production landscape that are reflected by such violations? What does – and should – the assessment of scientific integrity measure? How can the available tools help us consider these unacceptable practices, besides the well-defined cases of fabrication, falsification and plagiarism? Where does the assessment of scientific integrity end? In the context of the pandemic, particular attention will be paid to the time pressure exerted by the health crisis.

8. Social mobilisation, science and expertise: between participation and contestation? (in french)

(Breakout session in French only)

Alain Kaufmann (Université de Lausanne), modérateur, Marcel Calvez (Université Rennes 2), Philippe Chamaret (Institut Ecocitoyen), Johanna Lees (LASSA)

Au cours de la dernière décennie, on a vu s'intensifier les interactions, voire les collaborations, entre les acteurs classiques de l'évaluation et de la gestion des risques, et un multitudes d'acteurs sociaux. Citoyens, riverains et associations sont de plus en plus associés à des processus d'expertise, que ce soit dans le

contexte d'accidents industriels, de surveillance et de veille, ou de processus de dialogue au long cours au sein des agences de l'État en charge des questions sanitaires et environnementales. Parfois qualifiée de « sciences citoyennes », cette inclusion croissante de parties-prenantes et de non-experts oblige à repenser et élargir tant les processus d'expertise au sens strict, que les normes et les pratiques de production des connaissances sur les risques pour la santé et l'environnement.

On observe notamment la nécessité d'articuler des formes émergentes « d'épidémiologie populaire », fondées sur des enquêtes de proximité en relation avec des « clusters » de cancer ou d'autres nuisances, réalisées par ou en collaboration avec des riverains, avec les méthodes épidémiologiques standard reposant sur de larges échantillons, des statistiques robustes et des temps longs. Ces situations confrontent les agences à des difficultés majeures liées aux limitations de l'approche standard du type « une substance, une cause, un effet » dans des contextes où de nombreux facteurs inconnus sont susceptibles d'intervenir : modes de vie, expositions différentiées, effets cocktails, perception et ressenti des risques, conflits politiques et d'aménagement sous-jacents, etc. On ne peut pas bien entendu réduire ces conflits méthodologiques et politiques à de simples problèmes de « communication ».

Nous aborderons dans cet atelier diverses situations concrètes dont la complexité et le caractère souvent conflictuel nécessitent l'inclusion d'une multitude d'acteurs jusqu'ici exclus du processus d'expertise et d'évaluation des risques.

The last decade has seen greater interaction, and even collaboration, between the traditional players in risk assessment and risk management, and a multitude of social players. Citizens, local residents and voluntary associations are increasingly taking part in expertise processes, whether in the context of industrial accidents, surveillance and monitoring, or long-term dialogue processes within government agencies dealing with health and environmental issues. Sometimes referred to as «citizen science», this growing participation of stakeholders and non-experts requires us to reassess and broaden both the expertise processes in the strict sense, and the standards and practices used to generate knowledge about health and environmental risks. In particular, there is a need to articulate the emerging forms of «popular epidemiology», based on local surveys relating to clusters of cancer or other hazards and conducted by or in partnership with local residents, using standard epidemiological methods based on large samples, robust statistics and long periods of time.

These situations confront agencies with major difficulties due to the limitations of the standard «one substance, one cause, one effect» approach in contexts potentially involving many unknown factors: lifestyles, differentiated exposures, cocktail effects, perception and feeling of risks, underlying political and land planning conflicts, etc. Obviously, these methodological and political conflicts cannot just be reduced to simple «communication» problems. In this workshop, we will address various specific situations whose complexity and often conflicting nature require the involvement of a multitude of players who were hitherto excluded from the expertise and risk assessment process.

Break out session - Tuesday 9th February

9. Endocrine disruptors: Did EDCs disrupt conventional risk assessment and management?

Robert Barouki (Inserm), chairman , Angel Nadal (Miguel Hernàndez University) , Stéphane Horel (Le Monde) , Ann Crabbé (University of Antwerp)

The discovery of Endocrine Disruptive Compounds (EDCs) by the end of the last century has undoubtedly led scientists and policy makers to revisit some established paradigms in the environment and health field.

Low dose and long term effects, chemical mixtures and emerging substances are now at the top of the agenda of research institutes and safety agencies. Furthermore the fact that these compounds are primarily identified by their mechanisms of action rather than their toxicity endpoint is also likely to lead to a significant change in chemical risk assessment, paving the way for additional mechanisms-based categories of chemicals.

All these changes were accompanied by numerous controversies involving scientists, agencies, political players and obviously citizens, with more to come in the future. The session will address some of the major issues related to the EDC revolution including :

- the role of scientists in influencing public decision and their interaction with policy makers (Angel Nadal),
- the role of investigative journalism in uncovering the intricacies of public decision making (Stéphane Horel).
- the contribution and expectations of stakeholders (Ann Crabbé).

10. Pesticides regulation and health and the environement challenges: Strengths and weaknesses of regulatory sciences facing uncomfortable knowledge and societal demand

Jean-Noël Jouzel (CNRS - CSO), chairman , Laura Beane Freeman (NCI/NIH) ,François Dedieu (LISIS), Evangelia Ntzani (Brown School of Public Health)

Because they are toxic by design, pesticides have long been regulated so as to control their dangers. Yet, over the past decades, scientific data coming mostly from the field of epidemiology have shown that some populations, particularly the agricultural workforce, is statistically at risk of having chronic diseases such as Parkinson's disease or blood cancers because of their exposure to pesticides. The integration of these data in the regulatory framework of risk assessment and premarket authorization for pesticides appears to raise particularly strong challenges, both in terms of articulating science and policy, and in terms of communication about risks related to occupational and environmental exposure to pesticides. The aim of this panel is to cast a light on these challenges and on the way they can be faced both by science and by public authorities.

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