

# Health Risks, Precaution and Innovation

*Summarized proceedings*

**24**  
**JUNE 2015**

Chapsal Amphitheater  
27, rue Saint Guillaume - 75007 Paris

# Health Risks, Precaution and Innovation

8h30      *Registration & welcome*

9h00      **OPENING SESSION**

Laurence TUBIANA, Director of the Sustainable Development Center at Sciences Po Paris, Special Representative of the French Minister of Foreign Affairs for the 2015 Paris Climate Conference

and Marc MORTUREUX, Director General of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES)

9h15      **KEYNOTE SPEECH**

*The many-faceted nature of the precautionary principle: science, technology, social justice and accountability*

Pr Nicholas A. ASHFORD - Professor of Technology and Policy - Massachusetts Institute of Technology

**SESSION 1: ORIGIN, SCOPE AND EVOLUTION OF THE PRECAUTIONARY PRINCIPLE**

*Moderator: Sébastien TREYER - Director of Programmes at the Institute for Sustainable Development and International Relations (IDDRI)*

10h15      **Legal implications of the precautionary principle**

François-Guy TRÉBULLE - Professor - University Paris I Panthéon Sorbonne

10h35      **Precaution and the myth of over regulation**

Steffen FOSS HANSEN - Senior researcher - Technical University of Denmark

10h55      **The precautionary principle in international law and related trade issues**

Nicolas DE SADELEER - Professor of law - Jean Monnet Chair Holder - Saint Louis University - Bruxelles

11h15      *Coffee break*

11h45      **Discussion - Session 1**

## SESSION 2: MANAGING HEALTH RISK IN A SITUATION OF UNCERTAINTY

*Moderator: Marie-Françoise CHEVALLIER-LE GUYADER - Director of The Institute for advanced Studies in Science and Technology (IHEST)*

12h05 **Precaution: from risk assessment to risk management**

Gérard LASFARGUES - Deputy Director General for Scientific Affairs - ANSES

12h25 **Prudent precaution and plant protection products**

Harrie VAN DIJK - Scientific Officer - Health Council of the Netherlands

12h45 *Lunch (not included)*

## SESSION 2: MANAGING HEALTH RISK IN A SITUATION OF UNCERTAINTY (CONTINUED)

14h00 **Innovation : managing risk, not avoiding it**

Claire CRAIG - Director - Government Office for Science - United Kingdom

14h20 **Discussion - Session 2**

## ROUND TABLE: PRECAUTION AS A FACTOR OF DIFFERENTIATION AND INNOVATION

*Modérateur: Benoit VERGRIETTE - Head of the Risks and Society Unit - ANSES*

14h40

### KEYNOTE SPEECH

Incentivising positive corporate responses to early warnings: insights from the late lessons case studies 1896-2013

David GEE - Retired, Senior Adviser "Science, Policy, Emerging Issues" - European Environment Agency / Visiting Fellow at the Brunel University - london

15h00

### ROUND TABLE

Michel CAPRON - Professor emeritus in management science - University Paris 8 Saint-Denis

Gérard COLLETTE - Group General Manager Industrial - Solvay

Michel GRIFFON - Chairman of the sustainable development committee - GIS "plant biotechnologies"

Eric VANLABECK - Director R&D ISR - OFI Asset Management

17h00

### CONCLUSION

Bernard CHEVASSUS-AU-LOUIS - Inspector General for Agriculture

17h15

*End of the conference*

# Contents

<b>Contents</b>	<b>5</b>
<b>Marc MORTUREUX</b>	6
Director General of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES)	6
<b>Laurence TUBIANA</b>	7
Director of the Sustainable Development Center, Sciences Po Paris, Special Representative of the French Minister of Foreign Affairs for the 2015 Paris Climate Conference	7
<b>Session 1: Origin, Scope and Evolution of the Precautionary Principle</b>	<b>9</b>
<b>François-Guy TREBULLE</b>	9
Professor, University Paris 1, Panthéon Sorbonne	9
<b>Precaution and the Myth of Over-Regulation</b>	<b>12</b>
<b>Steffen FOSS HANSEN</b>	12
Senior Researcher, Technical University of Denmark	12
<b>The Precautionary Principle in International Law and Related Trade Issues</b>	<b>15</b>
<b>Nicolas DE SADELEER</b>	15
Professor of Law, Saint Louis University, Brussels	15
<b>Discussion</b>	<b>17</b>
<b>Keynote Speech: The Many-Faceted Nature of the Precautionary Principle: Science, Technology, Social Justice and Accountability</b>	<b>19</b>
<b>Nicholas A. ASHFORD</b>	19
Professor of Technology and Policy – Massachusetts Institute of Technology	19
<b>Session 2: Managing Health Risk in a Situation of Uncertainty</b>	<b>25</b>
This session was moderated by <b>Marie-Françoise CHEVALLIER-LE GUYADER</b> , Director of the Institute for Advance Studies in Science and Technology (IHEST).	25
<b>Marie-Françoise CHEVALLIER-LE GUYADER</b>	25
<b>Precaution: from Risk Assessment to Risk Management</b>	<b>25</b>
<b>Gérard LASFARGUES</b>	25
Deputy Director General for Scientific Affairs, ANSES	25
<b>Innovation: Managing Risk, Not Avoiding It</b>	<b>28</b>
<b>Claire CRAIG</b>	28
Director – Government Office for Science, United Kingdom	28
<b>Prudent Precaution and Plant Protection Products</b>	<b>30</b>
<b>Harrie VAN DIJK</b>	30
Scientific Officer – Health Council of the Netherlands	30
<b>Discussion</b>	<b>32</b>
This session was moderated by <b>Benoit VERGRIETTE</b> , Head of the Risks and Society Unit, ANSES.	35
<b>Michel CAPRON</b> , Professor Emeritus in Management Science, University Paris 8 Saint Denis <b>Gérard COLLETTE</b> , Group General Manager Industrial – Solvay <b>Michel GRIFFON</b> , Chair of Sustainable Development Committee, GIS “Plant Biotechnologies” <b>Eric VANLABECK</b> , Director R&D ISR-OFI Asset Management	35
<b>Keynote Speech: Incentivising Positive Corporate Responses to Early Warnings: Lessons from 1896-2013</b>	<b>35</b>
<b>David GEE</b>	35
Retired Senior Advisor on Science, Policy and Emerging Issues – European Environment Agency	35
<b>Discussion</b>	<b>37</b>
<b>Bernard CHEVASSUS AU LOUIS</b>	44
Inspector General for Agriculture	44

# Opening Session

---

## Marc MORTUREUX

Director General of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES)

These yearly sessions jointly organised by Sciences-Po (Sustainable Development Center), IDDRI and ANSES are always a pleasure. They are an opportunity to explore a topic which the three organisations have deemed of timely interest and, moreover, do so in the original and particularly fruitful manner that has become our tradition.

Is France overly precautionary, or perhaps even “precautionist”? It would probably be difficult to answer such a question and, indeed, such is not our purpose today. Much has been and will continue to be said and written on the topic. We did not set out to organise yet another of the all-too-frequent debates featuring, on one end, self-styled fear-mongers feeding anxieties and stirring individuals to increasingly recoil behind safe barriers, and on the other, free-wheeling advocates of a bold march forward, without regard for ethical considerations of any kind, or for consequences in the long-term.

Has innovation begun to desert France? This equally overstated idea also appears to us to be irrelevant today.

Rather, we chose to take up this issue in a manner we hope was original, guided by three chosen principles.

First of all, we wished to look beyond our traditional French preserve, where the everlasting debate between the precautionary versus the innovative appears to have come to a standstill, despite the many reports and documents resulting from them, hence the presence today of experts from across Europe and indeed across the world, as well as from different walks of life.

Secondly, we endeavour to contribute to the scientific expertise upon which decision-makers draw in situations of uncertainty, in reference to Article 5 of the Charter for the Environment: “When the occurrence of any damage, albeit unpredictable in the current state of scientific knowledge, may seriously and irreversibly harm the environment, public authorities shall, with due respect for the principle of precaution and the areas within their jurisdiction, ensure the implementation of procedures for risk assessment and the adoption of temporary measures commensurate with the risk involved in order to preclude the occurrence of such damage”.

It could be concluded from this that the precautionary principle is applied solely by the relevant authorities managing risk who must base their decisions on the best available knowledge. While this is true overall, even the best available scientific knowledge is sometimes patchy, if not non-existent, and often challenged. When our scientists perform assessments on health-related risks, they do so facing multiple uncertainties, and are no less required to identify, ferret out and attempt to characterise, qualify and even quantify each of these. The methodology adopted by each party can, in that sense, have a significant impact on the outcome of any study, confirming, magnifying, or minimising the nature and potential for occurrence of each risk.



Recent research on endocrine disruptors such as bisphenol A offer an excellent example of the scientific debate that can have an influence on public decision-making itself, where the approach, rather than the precautionary principle, is also a scientific matter.

Lastly, we wanted this conference to bring to light the conditions most conducive to generating more “virtuous” innovations, i.e., capable of incorporating, over the long term, a varied range of health-related, environmental, social, etc. factors that are still too often seen as restrictions. If it is true that, “to govern is to foresee”, then “to innovate” should not necessarily mean “to be the first to release a product to the market”. Some entrepreneurs or companies have caught on quickly, and do not wait for governments or regulatory authorities to come out with their decisions before acting in their own best interests. They are forerunners, in that sense, moving ahead of the game and “inspiring” regulation. This is not the case with all sectors, however. Competition or indeed the playing rules are not necessarily conducive to consideration for the longer term, in all of its ramifications.

What lessons can we learn from both the errors and successes of the past? Which initiatives have already been taken or still need to be encouraged? Which drivers need to be triggered? Which responsibilities should be shared, in order to stir innovation that brings ever-more complexity into play? The topic is, obviously, immense in scope and we will not reach its outer bounds today. I hope, nonetheless, that the outstanding speakers invited today and the quality of the discussions that will take place throughout the event, will open up new and interesting avenues for each and every one of us.

### **Laurence TUBIANA**

Director of the Sustainable Development Center, Sciences Po Paris, Special Representative of the French Minister of Foreign Affairs for the 2015 Paris Climate Conference

ANSES feels very much at home here at Sciences-Po, thanks to our long-standing cooperation with the Sustainable Development Center, to which I am pleased to pay tribute once again. This year, as I have the honour of representing France in the climate negotiations and serving as Special Representative in the lead-up to COP21, I will not be able to remain with you as long as I usually do.

The issue of innovation and precaution is particularly topical in health-related matters, and it is true that there was long a fundamental opposition between the two, one on the side of progress and science as the supreme guiding force, and a safer, warier and purportedly wiser approach on the other. Over time, however, as the topic permeated the public arena, I have seen debate mature in striking fashion. The community of those taking an interest in the environment and ecosystems, now significantly broader than in the past, has established concurrently the uncertainties, implications and interactions in play. The same considerations have indeed reached the level of decision-makers, who also approach the matter differently, taking the time to ask questions and ensure that they are the right ones

Moreover, in the face of growing public awareness – not only as regards the climate, but also, for instance, emerging diseases, pandemics, etc. – there is also great demand for innovation. For many years, innovators attempted to create their future markets, probing public desire to see in which directions they might be most successful. Today, public and societal demand is very clear and, indeed, pressing, most recently when it urged for a rapid response to the Ebola virus crisis, or for instance, with orphan diseases. As risk-avoidant or rigid as governmental structures may be, they can only recognise that innovation holds the response to this demand, facilitated by both “push” and “pull” mechanisms.

How will we approach the implementation and institution of the solutions adopted? How, proceeding from that, will we anticipate the resulting interactions and effects on other aspects, from the economic and social to the health-related? The very fact that these questions are being asked today demonstrates how radically discussion has changed.

We know that innovation is the result of multiple factors, such as: research and, underpinning that, human intelligence; and the organisation of programmes and institutions. If we speed up the latter and invest more in innovation, how will we manage the two still-valid and crucial questions of uncertainty and interactions? How will we organise our existing institutions? In the early 1960s, the widely-held belief was that, with large-scale organisations in place, we would be able to take up issues just as large in scale. Will we know how to effectively discern the right solutions which these organisations offer?



# Session 1: Origin, Scope and Evolution of the Precautionary Principle

---

This session was moderated by Sébastien TREYER – Director of Programmes at the Institute for Sustainable Development and International Relations (IDDRI).

## *Legal Implications of the Precautionary Principle*

**François-Guy TREBULLE<sup>1</sup>**

Professor, University Paris 1, Panthéon Sorbonne

The topic I will be addressing today is both particularly interesting and particularly adventurous within the setting of an event dealing conjointly with health risks, the precautionary principle and innovation. The precautionary principle is a concept far more common in environmental decision-making than when it relates to health, where it appears a mani-fold paradox:

- a form of regression when compared to innovation, though in fact it supports innovation and research;
- an abstention in principle, when it is a principle for action;
- a principle which is feared as handing over power to the courts, when it is built on a distinction between different forms of legitimacy;
- a principle rooted in fear, when it is a principle intended to restore confidence;
- a principle that tends to muddle roles, when in fact it makes it possible to redistribute them.

The paradoxes do not stop with theory. Though the ink on the new Article enshrining the precautionary principle in the Constitution has barely dried, a bevy of constitutional bills are already being put forth, by the very parties who crafted the original article, in order to remove it, the principle being suddenly seen as frightening, counteractive to growth, and counter-productive. Much of what I have to say today will reassure you as to the fact that it is none of these.

The precautionary principle gives neither fodder nor a blank check to those wishing to sow fear across society. That is said to be the role of “precautionism”, an offshoot of caution, a precautionary approach dyed through and through by television news reports. That is not my topic either, though I am a believer in legal realities first and foremost, and indeed in the belief that they should prevail over the sociological and the media.

The precautionary principle is intended to provide a response to societal issues. It was created not by and for those who craft the law, but by the legislative powers, to organise the response to challenges that are indeed comprehensive. My position will thus be quite uncomfortable, as I attempt to share with you what I believe about the precautionary principle, knowing how distorted it has become in the eyes of those receiving it.

Much has been said about the precautionary principle and how it has been taken up by the judiciary, when in fact, there are few concrete cases from which to work. While Article 5 of the Charter for the Environment is a powerful turning point, it cannot be said that many people are familiar with the complete Charter, or even the Constitution, though the latter governs all of us. The only actual instances that can be cited here are Article 110-1 of the Environmental Code as well

---

<sup>1</sup> The entire talk is available in French on Chaire Développement durable of Sciences Po and Anses websites

as another Article relating to GMOs, in the same Code. Article 191 of the Treaty of the European Union only quotes the precautionary principle.

The precautionary principle is, simply put, a sly creature: indeed in our midst, but hiding away. This has been the case since it was first formalised in the early 1990s, as it took shape much more in the dynamics it set off and the awareness of risks which these generated. While it does exist in the law, it does so in ever-transforming, technically coded forms.

For the judiciary and for the general public alike, the precautionary principle makes it possible to assess and reason away uncertainty, precisely for those whose duty it is to manage it, those who stand at the border between creation of risk and exposure to risk in the society. It is not aimed at achieving zero risk, nor is it an excuse to abstain; it is one that interconnects with other necessary principles in our society, such as that of proportionality.

Although all the legislation and regulations I have mentioned today pertain to the environment, there is obviously good reason to discuss the precautionary principle within the context of health. The communication issued by the European Commission in 2000 and relating to the precautionary principle indeed establishes a much wider scope, especially where prior scientific assessment has given due reason to fear potentially hazardous effects for the environment, and human, animal or plant health. It was not until 1 February 2012 that the French National Assembly timorously stated that the precautionary principle would be taken into the judiciary system.

As to the European Court of Justice and the European Court of Human Rights, it was with the 27 January 2009 ruling in the Tatar vs. Romania case that they emphasised the importance of the precautionary principle, as a means of “securing a high level of protection for health and safety of consumers and the environment”. It can thus be said to be effectively acculturated into the law and potentially citable when in the face of a potential (and not hypothetical) risk.

It has been stated that precautionary principle is applicable to situations of uncertainty. It is indeed the very tool by which they are taken into consideration by the law. Is this as dangerous and counteractive to growth as it is asserted? Is the growth to which we aspire one that is built on cancer, extinction of species and other indeed troubling occurrences?

I will first endeavour to explain the temporal boundaries of the precautionary approach by looking at its end-point: when uncertainty ceases to exist and the potential hazard manifests. The overwhelming majority of risks that exist today are no longer potential; they are known, averred and are addressed not by precautionary, but indeed by preventive efforts. Risk can also end up proving unlikely, when after lengthy and persistent efforts, no proof is found. Lastly, in an analogous model, the risk is neither confirmed nor disproved, and tension turns into attention – watchfulness.

As to the starting point, precaution can be said to begin when there is enough uncertainty to warrant interest. Let us mention, as well, that the precautionary principle cannot be invoked in just any manner.

- It follows from the aforementioned endpoint that it cannot be referred to when there is no uncertainty about the actuality and extent of the risk, given the current state of scientific knowledge. It cannot apply to flood risk, fire risk or lixiviation risk, though government orders were issued within the last year on all of these and in these terms.
- Furthermore, it is not enough to allege uncertainty; proof thereof must be established.
- The risk in question must also be serious and have irreversible consequences, should it materialise (consequently, neither hydrocarbon nor shale gas research were deemed suitable ground on which to apply the precautionary principle).

The precautionary principle's realm begins where an initial scientific assessment has confirmed the existence of risk. It is through science, applied as comprehensively as possible, and taking into account the specifics of the circumstances at hand, that the precautionary principle can be called into use. These precepts are held by both the European Court of Justice and the European Union for the simple reason that the boundaries of scientific investigation have been pushed back. The recent and much-discussed Monsanto case confirmed once again that Europe is not ready to prohibit practices on the basis of conjecture.

The only positive behest found in Article 5 of the Charter on the Environment is to conduct assessment, in greater depth and to an excellent standard. Where deemed necessary, additional action can be taken, as the French Government recently did in response to asbestos fibres; in contrast, decision-makers can also choose to refrain until such time as further information is available, or adopt restrictive measures relating to the identified risk. These course of actions must, of course, be taken in both due time and due proportion.

The precautionary principle is a principle of action and, specifically, public action, fully in compliance with existing functioning principles, and under the supervision of the judiciary. The more I look at the rulings handed down by the French courts, the less I understand the aggressive opposition that continues with regard to this principle. Perhaps it arises solely from the fact that they are the last force reining in human hubris.

### **Sébastien TREYER**

Thank you for that far-from-neutral, yet comprehensive overview of the precautionary principle in recent French and European jurisprudence.

# Precaution and the Myth of Over-Regulation

---

**Steffen FOSS HANSEN**

Senior Researcher, Technical University of Denmark

I am Associate Professor at the Technical University of Denmark. I was invited following the recent re-publication from the European Environment Agency, *Late Lessons from Early Warnings: Science, Innovation and Precaution*. The work, first published in 2001, looks at 15 cases in which the precautionary principle was not used in time as well as cases of proclaimed over-regulation. I have attempted to analyse the cases of over-regulation to derive lessons that might be helpful to future policy-makers.

## Background

The publication from 2001 concludes that there had been a serious lack of action, with very dire consequences, both for the environment and for human health. In some cases, decision-makers ignored not only late but also very early warnings: asbestos, PCBs, etc. Tragically, they did not take action until the evidence could not be ignored anymore.

There has been a great deal of criticism of the precautionary principle, most often that it goes against technology, science and innovation, and instead, promotes regulation of invalid risk and over-regulation overall. Is this true, however? In preparing the first volume of *Late Lessons from Early Warnings*, the European Environment Agency and David Gee were unable to identify a single case of over-regulation, whereas they had no problem identifying 14 cases of under-regulation. In 2003, we made it our aim to review the literature, at last document cases of over-regulation in the precautionary principle, and learn the relevant lessons from these. The 2013 edition of *Late Lessons from Early Warnings* contains new cases of under-regulation and our chapter on over-regulation, “The Precautionary Principle and False Alarms: Lessons Learned”.

Our starting question was: should we, as society, fear unnecessary precautionary action? If there is reason to fear such false positives, what can we learn from these? In order to identify over-regulation, one must first define it. Though perspectives can vary, we described it as follows: “where regulatory action is taken on the basis of a precautionary approach that turns out to be unnecessary”, wherein regulatory action is “any kind of action taken by a regulator, other than sponsoring further research” and unnecessary is, in line with the IPCC’s scale, that confirmed as such to a high degree of certainty in the scientific literature.

## Methodology

Our literature review showed 90 different cases that had been deemed to involve unnecessary regulatory action. As soon as we looked at the supporting evidence, however, we found many of them to involve actual, factual risk, for instance cases with asbestos, DDT or pesticides. In other instances, no certainty has been reached and we could not assert a high level of confidence in the evidence such that we could deem the action unnecessarily precautionary (e.g., GMOs, nanotechnologies).

In the end, four cases of over-regulation were identified:

### **The Southern corn-leaf blight case**

The United States experienced a devastating disruption of corn production in the early 1970s due to blight. The government subsequently authorised over-production of corn the following

year, to offset and anticipate the return of the blight. When this happened, the excess corn production caused the commodity's price to drop for the first time, in turn generating revenue losses for farmers.

## **Swine flu**

In 1976, the American government anticipated a flu epidemic and chose to vaccinate the entirety of the American population. The vaccine had unanticipated side effects, however, and led to drastic consequences.

## **Saccharine**

Banned in the United States, it was subsequently found not to cause cancer in humans.

## **Food irradiation**

It has long been known by science that food irradiation is not hazardous to the human body. However, this has not been accepted by the public or by regulators.

We subject each of these to stringent methodological analysis, asking the following questions:

- When and why was it believed that the risk was real?
- When and what were the main actions taken?
- Were there alternatives to the course of action taken?
- When and why was it realised that the risk was not real?
- What were the resulting costs and benefits of the action taken?
- Were there indirect benefits from the action taken?

I will use the swine flu case to illustrate how we applied these questions. It began with a flu outbreak at Fort Dix, New Jersey, in 1976. The cause was identified as a new strain of virus, similar to that which had caused the Spanish Flu, responsible for more than 50 million deaths, just after World War I. Three months later, over 500 people had been infected. Scientific experts at the time could not pinpoint the probability, but knew that if it returned during the following season, the consequences would be dramatic. Decision-makers knew that, as only five months remained before the new season, vaccine production, if such were the option taken, would have to begin immediately. They opted for the combined approach: the Government would purchase 200 million vaccines, enough for the entire US population; safety and trials would be the responsibility of two government agencies; and the vaccine would be distributed by a combination of national and local governments.

At the time, scientists knew that flu usually surfaces to a limited extent at the end of a flu season, in order to dramatically return in the subsequent season. They also believed in a “recycling theories” of flu epidemics: at the time, it was believed that epidemics recycle every 11 years, while pandemics returned in 60-year cycles. Yet, as Myers aptly stated: “You have to realise that science can only take you so far. It is a social and political decision”. Matthews, meanwhile, asserted that “the political system simply had to react”. Eventually, President Ford also made the decision to vaccinate the entire US population, stating that he would rather “gamble on the side of caution”, preferring to “be ahead of the curve, rather than behind it”. Eventually, the programme failed, running into one obstacle after another and was largely condemned in the media as a fiasco and waste of money.

It is very difficult to draw parallels between the four cases, so as to understand the mechanics of false positives:

- with both swine flu and blight, there were early indicators as to what might lie ahead;
- in the case of saccharine, there had been new knowledge that the substance could cause cancer in rats;
- while in the food radiation case, there was recognition that some of the approvals had been given on faulty evidence, causing approval to be retracted.

It is also not clear why action was taken in these four cases and not in all of the cases of under-regulation. As to the absence of risk, it became clear simply over time in the first two cases, while with saccharine, science eventually showed that there were no similarities between the rat and human bladders.

The swine flu and mass vaccination case did have very palpable consequences: vaccine production and distribution came at a high economic cost, a number of deaths occurred due to adverse reaction to the vaccine, and secondary impacts were felt in other sectors due to the redistribution of resources necessary in order to implement the flu response.

Overall, however, the four cases also contain multiple examples of benefits resulting from the action taken. In governance, science and industry, innovation was propelled by these crises: swine flu led to the first nationwide surveillance programme in the United States, still in use today; while the saccharine ban led to research for new alternative sweeteners.

Were I to list one lesson as the most important, it would be as follows: the precautionary approach should be implemented only following an assessment of the impacts of taking action and taking a flexible stance that allows room for adjustment based on further review. I would leave you with a question, rather than an answer, in the hopes that you will also be able to help us in our efforts: why were we able to identify only 4 cases of over-regulation identified as opposed to 28 cases of under-regulation picked up on easily by the European Union's team?

# The Precautionary Principle in International Law and Related Trade Issues

---

**Nicolas DE SADELEER**

Professor of Law, Saint Louis University, Brussels

In International Trade Law, the implementation of the precautionary principle can be likened to a Napoleon pastry, held together by the World Trade Organisation's rules, themselves based on Agreement on Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade. The TTIP Negotiations will include sections on both of these, and be based on World Trade Organisation rules as well.

The World Trade Organisation rules are intended to foster investment, remove unnecessary obstacles to trade, in order to heighten competition between businesses. As such, they contrast with the European Union's rules, which are aimed at harmonising legislation, regulation and administrative practices between nations. Instead, they are intended to do away with obstacles that might result from customs duties, fiscal systems, or technical rules, whether regulatory or non-regulatory in nature.

As the World Trade Organisation rules thus do not seek to create a common playing field, it becomes in essence impossible to adopt rules that, treating its members as a homogenous group, would improve public health, protect the environment and protect cultural production. The public law rules established by France in this regard thus come out in opposition to the main obligations set out by this international treaty.

The WTO rules furthermore foster the non-binding ISO rules, in particular under the Agreement on Technical Barriers to Trade, and the standards adopted by the FAO's Codex Alimentarius in connection with the Agreement on Sanitary and Phytosanitary Measures.

It should also be noted that the WTO's system contains a number of built-in obstacles, in that they require unanimous agreement from all parties in order to make changes to the 1994 text. The challenge for the future TTIP Agreement and the future agreement between the Americas and Asia-Pacific will be to go further than the requirements set out by the World Trade Organisation, given that the latter can no longer progress. The TTIP Agreement can be seen as a failure to move forward since 1994, on the part of the World Trade Organisation.

Lastly, the World Trade Organisation is an independent, autonomous legal order, equipped with a system for settling conflicts, specifically between nations or groups of nations. It is composed of different bodies, based in Geneva: a panel of diplomats that makes decisions in the event of conflict between nations; an appellate body composed of international trade law specialists with experience in academic environments, and which tends to take a far more stringent stance on positive law and thus stands apart from the decisions made by the diplomats. Individuals and companies faced with State-enforced measures do not have access to this legal system; they must turn to their respective nations in order to do so. States losing their cases do not necessarily have to change their own legislation or regulatory practice, and instead may be called upon to provide compensation to the other party. It should be noted also that science is given a place of choice.

The SPS is aimed at encouraging the signatories to comply with the Codex Alimentarius. National governments can, however, determine the level of protection most appropriate to them and can take exception with the Codex, provided that they are able to demonstrate the necessity of their action toward protecting human, animal and plant health. They may do so on the basis of a risk



assessment study, which must be proven appropriate to the circumstances; such is the burden of proof, so as to prevent the adoption of unfair rules that would hinder the trade in products on the international market. Diverging States are also required to uphold the proportionality principle, as valid as their reasons may be, and thus strive to make decisions that impact as little as possible international trade.

A great deal of tension emerged around Article V, Paragraph 7 of the SPS Agreement, under which States may take temporary measures where scientific evidence is insufficient, as some construed it as reflecting the precautionary principle, not recognised under the World Trade Organisation. Clearly, there is a dichotomy between the above and Article 1 Paragraph 5, under which States are required to substantiate their action.

To wit, in 2008, the Appellate Body made a much-noted ruling on a hormone allowed by the European Union, 17-beta-estradiol. It is the second part of this decision that attracted the most attention, in that it called for a critical mass of evidence, calling into question all previous evidence and in effect requiring a change in paradigm in scientific development. It deemed that this would challenge the very essence of Article V Paragraph 7, placing a disproportionate burden on the Member State. At the same time, it recognised that qualified scientific sources could call into question the existing relationship between scientific proof and the conclusions.

The TBT Agreement covers an extremely wide range of rules pertaining to products. Its most notable function is the requirement it places on Members to notify the WTO of any proposed regulation on products. It also allows them to adopt product safety rules based on the level of protection for the environment, animals and humans, provided that the said rules are necessary to upholding Article II, Paragraph 2 of the same Agreement. Once again, the aim to balance out the States' right to seek protection levels beyond those established by the ISO with the need for the measures, which much hinder international trade as little as possible.

While no jurisprudence exists in this area, it could be stated that, as the restrictions are much less stringent when it comes to risk assessment, the States have more room for manoeuvre, where they are capable of establishing cogent, proof-based action.

The TTIP negotiations, currently underway, are far more transparent than previous negotiations between the European Union and third-party States. That being said, only those proposals made by the European Union are known to us at this point; the United States' proposals remain secret. It should be noted that these are not direct negotiations between EU Member States and the United States, but rather between the latter and a European Union body exclusively empowered, by the Council of Ministers, to address international trade issues.

The sections proposed by the European Union do not aim for harmonisation, but rather cooperation between the United States and the European Union, by involving civil servants from both legal systems in risk assessment. The devil is, as always, in the details: Article IV, Paragraph 4 of SPS establishes the principle of mutual recognition, authorising the import of a product subject to approval in the United States directly into the European Union. A similar clause can be found in Article IX, Paragraph 1, containing the Technical Barriers to Trade. At stake here is the regulatory cooperation between entities and possible mutual recognition clauses, rather than on the stand-out issue of Investor-state dispute settlement (ISDS), on conflict settlement.

There will never be a prospect for enshrining the precautionary principle in the WTO's Treaties, and accordingly, this has not been made an aim of the negotiations in progress. The said principle can only come into play incidentally, under exemption measures, as described above.

### **From the floor**

As a lawyer working in the NGO community, I was particularly delighted with the presentations heard this morning. My question has to do with the international judicial order. The United Nations' Rotterdam Convention or the Stockholm Convention both place obligations on Member States, but have no conflict settlement bodies, and thus are difficult to make binding. Thus, in effect, while mechanisms and guarantees exist for trade, they do not exist for hazardous products, as addressed by the Rotterdam Convention, or severe pollution in Southern countries.

### **Alfred LECLERC, Réseau Environnement-Santé**

Just one week ago, the company Plastics Europe sought to have the French legislation limiting the production of plastic materials containing BPA struck down, on the basis of two claims: the precautionary principle which it claimed to apply only to the environment; and the 2013 ANSES Report, which stated that bisphenol A poses little if any potential danger.

### **From the floor**

Mr Foss-Hansen, the four cases of over-regulation could be said to be a problem specific to the United States in the 1970s.

### **Nicolas DE SADELEER**

International law is deeply "Balkanised" and imbalanced. As you stated, the Stockholm Convention (on persistent pollutants), Rotterdam Convention (requiring notification of hazardous pesticide products) and similarly, Basel Agreements (on cross-border movements of waste), allow for conflict settlement only through international arbitration or the International Court of Justice. Meanwhile, WTO law is virtually a jurisdiction in and of itself, distinct from national and international systems. In that sense, it does play a pivotal part. At the same time, its original mechanism has enabled agreements that would not have been possible in other settings.

### **François-Guy TREBULLE**

I will not endeavour to make any prognosis as to the French Constitutional Council's decision on bisphenol A expected in the next three months. It has come out with some astoundingly misguided statements on the temporary nature of certain measures, in two decisions issued in 2013 and 2014.

As to the hesitation that can be seen regarding the nature of this particular endocrine disrupter, I can be almost certain that the Constitutional Council will not attempt to establish itself as scientific judge. It remains to be established whether the French legislator, in adopting the prohibitive measure, did uphold the precautionary principle, informed by the scientific information available to it.

### **Steffen FOSS HANSEN**

We also noted and were disturbed by the connection between the cases of over-regulation and the United States. The latter are often seen as anti-precautionary, while Europeans are seen as pro-precautionary. However, this was not the case in the 1970s, when the US were very protective of health and environment. This does not explain why no such cases are in Europe. It may be that it simply takes time to solve an issue and find it risk-free. The precautionary principle in Europe is actually most often based on very solid science.

## **Laurent CAILLEUX, FNSEA**

Is the precautionary principle in France, as enshrined in the Constitutional Charter, the same as that which exists in Europe? Having watched many a debate in the French National Assembly and Senate and listening to you today, I wonder about this, not to mention further possible differences at the international level.

Secondly, on what basis do so many Parliamentary bodies raise the issue of barriers to growth?

## **Bernard CHEVASSUS-LOUIS**

The Cartagena Protocol typifies the ambiguity which Mr DE SADELEER described. The two texts, in French and in English, though described as being equal in value, use different terms: *le principe de precaution* and the precautionary approach. Having participated in Codex debates, I can attest to the very different implications of these two terms. Moreover, the Protocol states in its preamble that it by no means calls into question the WTO Agreements. I have been repeatedly told that the international agreements are not legal in nature, but instead diplomatic. How do lawyers find their way through these contradictions?

## **François-Guy TREBULLE**

Their validity today comes from the very misunderstandings that enabled them to be adopted in the first place. In the late 1990s, the Indian Supreme Court made a very interesting statement in a Velor law, in response to unbridled questioning from all corners as to whether the precautionary principle was even part of Indian law. It responded that the said principle is part of the international legal order and, therefore, part of Indian law. The European Court of Justice has stated that it is a fundamental principle of the European Union. France receives, from the international legal order and from the European Union, this same precautionary principle, so much so that during the Monsanto ruling in 2011, the Council of State accepted that the precautionary principle as read at the European level is the same as at the domestic level. To have the French reading adopted at the European level is another matter.

As to the Constitutionalisation of the precautionary principle, it was stated in the Stockholm Convention that all citizens possess the right to live in an environment free of contamination, echoed by the Rio Convention and European Court of Human Rights. The attempt to separate health from the environment at the French level was skewed from the start, though the Charter we have today indeed refers only to the environment.

Lastly, regarding the Parliamentarians' leanings, I would invite you to read the grounds for the Woerth and Bizet proposals, respectively, the first extremely blunt and the latter raising all sorts of potential dangers which the precautionary principle itself might awaken. They continue to ask such questions because we failed to take the appropriate educational action, perhaps even from the University level.

## **Nicolas DE SADELEER**

France is the only State to have enshrined the precautionary principle in its Constitution at the European level. There are thus many grey areas around its application, as we will continue to see in the debates over bisphenol A.

The European Union regularly asks, in light of its twenty-four official languages, which approach should prevail, either the "Germano-Latin" or the "Anglo-Saxon". At the international level, there is almost no jurisprudence. I would call attention to the Vienna Convention on the interpretation of WTO Law, in particular, where health, the environment and trade are concerned: *lex specialis*

versus *lex generis*; and *ratione temporis*. You might also wish to refer to one of the many doctoral dissertations produced on this topic, despite their great complexity.

## **Sébastien TREYER**

We will now have the pleasure and honour of hearing our Keynote Speaker, Mr Nicolas ASHFORD, who has penned multiple works including *Transforming the Industrial State*, on technology, globalisation and sustainable development, and *Reclaiming the Environmental Agenda* on environment law, policy and economics. He thus adroitly blends and interlinks the issues, and will give us his singular perspective on the application of the precautionary principle.

## **Keynote Speech: The Many-Faceted Nature of the Precautionary Principle: Science, Technology, Social Justice and Accountability**

---

### **Nicholas A. ASHFORD**

Professor of Technology and Policy – Massachusetts Institute of Technology

At the outset, it is important to contrast two very different formulations of the precautionary principle:

- A permissive formulation, wherein “in the event of large or possibly irreversible effects, scientific uncertainty should not hinder a preventive action from being taken”;
- A mandatory formulation that requires action under the same set of conditions, in that sense reflecting risk averseness in the face of possible negative impacts on environmental health and safety (such as climate disruption, cancer, damage to reproductive systems).

When the precautionary principle was first put forward, in the United States and in Germany, even the scientific community was more antagonistic than enthusiastic about it. It was incorrectly seen as rejecting objective risk assessment. Thus the precautionary principle and risk assessment were seen as opposing traditions. This, of course, was completely incorrect. In addition, missing from these formulations of the principle is the role which technological processes can play in providing a rational process for implementation. This symposium is dedicated to the words “precaution” and “innovation”. This relationship has two very different characteristics.

From the industry’s perspective, too much precaution inhibits innovation, while the evidence shows just the opposite. Another conceptual way to connect regulation and innovation is that regulation can set into motion the processes that will bring about innovation that solves the health, safety, or environmental problem. The theoretical withdrawal of funds from productive activity and specifically R&D does not necessarily mean that less research will actually take place. New regulatory demands could change the entire landscape for technology, substitution and R&D.

Limits on the precautionary principle, as some have advocated, will limit social protection and environmental restoration, as scientific uncertainties can be trumped by the potential high cost of protection. In the European Union, the concept of “proportionality” calls for regulatory decision-makers to pay attention to hazards, while being cognizant of the seriousness of the dangers involved but taking care that the initial stimulus for innovation will be not unnecessarily hurt.

The two approaches to developing ideas about the precautionary principle, namely the Anglo-Saxon tradition of case law, and the Franco-German tradition of law codification, have sometimes led to different outcomes, depending on the political landscape at the time in different places.

The origins of the precautionary principle actually lie in the United States legal system. International and European code-driven law provided subsequent formulations. After the Reagan and Thatcher Revolutions, however, precaution fell out of use altogether as a means of protective standards in the Anglo-American world, while Europe took growing interest in its possibilities.

The tension appears to lie between the triumph of utilitarian ethics, in which cost-benefit analysis as the main foundation for determining what and how much to regulate, and tenets of John Rawls' theory of justice (ensuring that the least advantaged are made relatively better off, rather than attempting to increase total wealth). Taking into account distributional effects are essential for an alternative system of justice than that emerging from the use of cost-benefit rationales. Rather than risk analysis and the precautionary principle being in tension, it is cost-benefit analysis and the precautionary principle that are in conflict.

The United States subsequently rediscovered the precautionary principle on specific occasions, citing European practice worthy of emulation, just as Europe may cite the so-called American or Asian model as a means of pushing reform through in its own policies. Regulations for addressing environmental and occupational health and safety standards incur costs and deliver benefits. The costs can express in economic metrics, and the benefits in improved environment, health and safety metrics. Risk assessment and analysis help us quantify the benefits in terms of ecosystems preserved, fatalities and disease prevented, etc. In conventional cost-benefit analysis, the benefits are given monetary value that must exceed the costs. Not only are human lives and environmental effects expressed in monetary value, they are also discounted to what is called "present value." Using discounting means that long-term benefits are suppressed, and short-term preventive investment costs dominate the calculus in cost-benefit analysis.

Yet another path exists to making decisions about health, safety, and the environment. One can leave the various impacts in their natural units – money, lives saved, etc. – and force government regulators or firms to explain the tradeoffs that they make amongst different effects and over different time periods. There are no unique or inherently correct answers to how much safety is enough or how much to spend on preventing global climate disruption, but decisions can be made very transparent as to what tradeoffs are being made. There is no inherently correct answer to the question of how precautionary one should be because there is no single metric that measures justice or fairness. . However, political decision-makers and corporations can nonetheless step forward and be accountable to the society for having made a decision that is acceptable. Accountability is to be preferred to accounting.

One of the earliest and most significant pieces of legislation in the United States passed in 1970 was the Occupational Safety and Health Act. The data pertaining to chemicals came predominantly from the workplace, where large numbers of individuals remain for a lengthy period of time, in whom exposure can be measured. The Act in essence required the Secretary of Labour to set standards, "such that no employee suffers material impairment based on the best available evidence, to the extent feasible". It is important to see that the limits of protection here are determined by feasibility and more specifically, technological possibility and to some extent economic feasibility for the regulated industry as a whole.

Another distinctive feature of the United States system lies in the practice judicial review: after a standard has been proposed, it can come under challenge by industry and the unions, which determine whether it is too lax or too stringent. What the reviewing courts are looking for is whether, in the setting of the standard, the agency has satisfied the policy judgement made by

Congress, when the issues involved are on frontiers of scientific knowledge? In the area of protecting workers from toxic materials, there is often no strong established knowledge but, instead, there is an indication that problems exist, but with no final answers.

The courts specifically endorsed the regulatory agencies erring on the side of caution, whether with worker exposure to asbestos, or community exposure to SO<sub>2</sub>, NO<sub>x</sub>, particulates, ozone, etc. The determination of feasibility allowed the agencies to consider the likelihood that the needed technology would emerge or be developed in the future; it did not have to be in existence at the time of the regulation. In the Clean Air Act, my second example of a precautionary approach in US law, the aim of Congress was “to protect public health with an adequate margin of safety through ambient standards, not taking into account costs”. This was not because the latter were of no importance, but because Congress made a judgement that the protection of public health could well be achieved at the level of protection needed

In 1980, the Court of Appeals directed the EPA Administrator to err on the side of caution in making judgements on airborne lead from using lead in petrol, in what was clearly a mandate, and not a recommendation. Congress stated further that the rules established should take into account the sensitive populations, rather than the average person, as well as allowing an adequate margin of safety in setting primary air quality standards, in order “to provide some protection against effects not yet uncovered by research”. While not explicitly referred to as such, this is requiring the precautionary principle to be applied. In our joint experience of regulating environmental hazards, the whisper of possible harm ultimately turns into a shout. When dealing with health safety, epidemiology and toxicology, it is essential to understand that only the robust effects are picked up upon by epidemiology. In the case of lead, ambient air exposure ceilings, previously set at 1.5 micrograms per cubic metre, have since fallen to 0.15, following the emergence of new data. In its seminal work on Late Lessons from Early Warnings, the European Environmental Agency has forcefully documented this universal principle which underlies the rationale for the precautionary principle.

## Innovation

Much has been said about the effects of regulation on innovation. Michael Porter, of Harvard University, noted that stringent regulation stimulates incumbents to develop new technologies. The regulated firms utilize or develop slightly different inputs, process changes and process formulations; according to Porter, when these incremental improvements are made, companies also reduced the costs of water, energy and materials, thus enjoying cost-offsetting that made innovation in itself profitable. We, at MIT, saw first and foremost that as a result of very stringent regulation, dramatically-different products and processes were developed – principally by non-incumbents, i.e., new entrants -- consequentially disrupting the existing market. The process of regulation stimulating technology – what some call technology forcing -- has been extensively documented from studies in the United States and in Europe. It can be summed up in the distinction between static efficiency, which is that latently sought by industry at all times, and dynamic efficiency, the result of regulation-induced innovation – specifically, innovation directed toward environment, health or safety goals.

When the continued use of existing technologies starts to prove too expensive, or when compliance requires improved performance, it represents an opportunity to effect disruptive technological change. The OECD has argued that stringent environmental policies are necessary for addressing well-being objectives, emphasising that they need not be detrimental to aggregate productivity. OECD wrote that, “a temporary boost in productivity growth materialises for technologically-advanced firms and countries, provided flexible instruments”. Standards can be flexible because they specify a target, but leave to industry the mechanism of achieving that target.

To achieve both economic and environmental objectives, new ideas, technologies and business models are needed. It is important that environmental policy-makers do not prevent new technologies from entering the field by being overly sympathetic to the incumbent. There is no evident trade-off between stringency and competitiveness for society as a whole, and by ensuring swift reallocation of resources, governments can help assure economic outcomes.

The precautionary principle has been recognised as being of use where large uncertainties, indeterminacies, and ignorance exist regarding the serious irreversible harm to health or the environment. Persistent bio-cumulative chemicals are examples of this. Because the benefits and costs of intervention span different timeframes, cost-benefit analysis is an entirely inappropriate way to measure where we should stand and to what extent we should regulate. The distributional effects are very important, not only because the poorest bear the brunt of poor environmental policies, but also because firms are affected.

Risks continue from production and product technologies that have remained static for some time and, therefore, there are opportunities to change technologies through innovations. The failure to articulate technological options in formulating the precautionary principle was a serious methodological and strategic mistake, because the toxicologists and epidemiologists who first owned the precautionary principle know little of technology and innovation. Taking the costs of regulating health, safety, and environmental hazards as projected from the incumbent industries ignores the power of learning and innovation. The pre-regulatory assessment by incumbent industries of the cost of compliance routinely proves at least three to five times more expensive than they actually are in the end.

We will create a sense of accountability when we take into account not only risk, but also the opportunity to stimulate new technology. We must foster that accountability rather than accounting, look clearly at technology options analysis and, as suggested by many lawyers, ensure that the burden of proof varies with the seriousness or extent of the health, safety, or environmental problem. The more serious the problem, the more forgiving regulatory systems should be regarding the lack of air-tight evidence of potential harm. As to the burden of persuasion, it is not the same as the burden of proof, and it should be placed on industry.

Successful implementation of the precautionary principle requires us to move from risk reduction to actual sustainable development. Our options are these:

- Minimising uncertainty by refining risk analysis (if this is all one does, no real progress will be made because risk assessment will inevitably be a bottleneck),
- Exploring different technological options (not just existing technologies, but ones that could be developed),
- Clearly determining which types of mistakes can be accepted (while errors in risk assessment has dominated the concern about precaution, making mistakes in not stimulating new technologies can be more serious),
- The cost of pollution control limits based on existing technology (these clearly ignore the benefits of new technology).

Do not be influenced by assertions to the effect that regulation kills innovation and jobs, that technology is not adequate, or that cost-benefit analysis is needed to determine the appropriate balance between protection and cost. We have been far too timid, in a world that is becoming increasingly hazardous. This is a historic time, both environmentally and economically, and it is our responsibility to take the regulatory and political action that will not only secure our future but make us proud of what we have done. We must do so not only with regard to the environment and to finance, but also, crucially, to labour.



## **Sébastien TREYER**

Thank you for that very clear message.

### **From the floor**

Could you comment on the problem of technological lock-ins and how they play into your description of innovation?

## **Nicholas A. ASHFORD**

It is one of the most significant problems facing the industrial nations. As the incumbents are set in their ideas, there can be no innovation from those firms which economists refer to as “bounded rational”. All organic organisms, from people to bacteria, need change and displacement. Schumpeter referred indeed to the “wings of creative change”.

The lock-in would not be such a problem were it not connected with politics. Thomas Piketty has shown the tremendous disparities that remain in distributional wealth. The solution will lie in uncoupling the disparities of wealth with self-serving political power.

Two very important political scientists at Princeton University asked: do the American people receive what they want from the American political system? They analysed 1.700 major pieces of legislation, for instance on raising minimum wage, regulating mercury, etc. Indeed, 96% of the time, the elite's interests are served by political policy and the public's are not. We know who runs the government: it is a very small number of people. Democracy, as an institution, must be made workable. Eliminating technological and political lock-in is essential. The start must come from the reform of the financial system.

The US learned from the Depression, establishing the Federal Reserve System, and effectively making it impossible for different interest rates to apply in different states. The European Central Bank, meanwhile, allows Germany to make attractive loans to Southern countries, who closed their own factories, and suddenly cannot pay their bills. This issue needs to be considered squarely.

### **From the floor, ANSES**

I was very interested by your comments on competitiveness as it relates with compliance. Compliance with a new regulation implies that industry must speed up the development of new technology.

That means that, if new standards are to support continued competitiveness for countries, regulators must be informed and aware. What is the right balance between industry and governments in developing regulation standards? Does industry have a role to play in ensuring that due information is provided?

## **Nicholas A. ASHFORD**

Not all industry is inherently innovative industry. If the technologies available are not adequate, the debate cannot be limited to incumbent industries. If technologically and environmentally literate, NGOs could be invited to the table. In contrast, academics, in the United States at least, are almost entirely co-opted and compromised by industry. Two scholars at MIT published a most important analysis called The Second Machine Age. The book by Erik Brynjolfsson and Andrew McAfee, is very compelling, putting forth the following argument: the technological future will be made of ICTs and artificial intelligence. These advances will require a very small number of technological specialists, while the Dow Jones will reach 18,000 to 25,000. These technologies will also hollow out the middle class and push most workers to a very the low and insecure employment situation. The

country will thus fracture. The real economy, not represented on the stock market, is suffering immensely, while the reported economy is faring very well.

### **From the floor**

In the United States, thanks to shale gas production, employment is experiencing a real resurgence, factories are opening and jobs are being created. Yet the actual situation of shale gas is dominated by a relatively dreary cost-benefit outcome. What is your response to the US decision in this respect?

### **Steffen FOSS HANSEN**

How can disruptive technologies be ushered in effectively, when at the same time, there is a move to protect jobs and maintain workers in their existing positions? Unemployment, you have said, is one of the greatest threats to development overall.

### **Nicholas A. ASHFORD**

I have written widely on this. For 75 years, we have been replacing labour with capital and energy. In the United States and Europe, we are approaching a situation in which we do not need individuals to work 40 hours per week, on full employment terms. To change that process, we can: spread work out between workers so that everyone is employed, within a shorter work week; or design work back into the production system. One analyst has astutely asked why there is no taxation on pollution when it is that which we want to reduce; instead, we tax labour, which we are trying to foster. Selective de-growth is one of the many ways in which the situation can be reshaped.

While the unemployment rate has gone down, the total money transferred into labour has also decreased. Workers can thus hold jobs at a fraction of the previous wages. Those who stop looking for jobs are, furthermore, not accounted for in the rate. Thus, the actual unemployment rate in the United States is closer to 12.5% than to the stated rate of 5.5%.

We are energy exporters and see shale gas as a means of continuing that. Robert Ayers, an expatriate American based in Fontainebleau sees us as having come to “the end of exponential growth”. The prior period of great innovation is explained by access to cheap energy. No party engaging in fracking has earned any money, simply because it cannot be earned there.

Europe 2020 promises the most economically-competitive, environmentally-sound, job-creating economic unit in the world. Actual performance, however, has been dreadful, whether on property, unemployment, or ideas.

## Session 2: Managing Health Risk in a Situation of Uncertainty

---

This session was moderated by Marie-Françoise CHEVALLIER-LE GUYADER, Director of the Institute for Advance Studies in Science and Technology (IHEST).

### Marie-Françoise CHEVALLIER-LE GUYADER

Before welcoming our first speaker, I would like to address one concept that has made its way through our European societies: zero risk. While we may be heirs to an Age of Enlightenment, and thus have a yearning for the calculable and controllable, we have also have gained a heightened awareness of technological risk and the manner in which precaution is now conceived of.

Today's presentations have shown that, with the progress achieved by science and technology every day, new forms of risk and uncertainty also surface. Like my colleagues, I am faced with two dimensions in risk management: an objective outlook, based on probabilities, action, rationality; and an entirely subjective view, rooted in perception imagination, and social representations. Because of these transformations, enabled by the major crises since the 1960s, a two-fold approach both temporal and cultural is adding to State strategies, such that we do not always experience the precautionary principle in the same manner.

## Precaution: from Risk Assessment to Risk Management

---

### Gérard LASFARGUES

Deputy Director General for Scientific Affairs, ANSES

There is a widely-held belief that the precautionary principle is the sole responsibility of risk managers. I will argue, to the contrary, that it impinges on all of risk assessment and also relates to the responsibility of scientists and risk assessors. Today, the risks we face are so complex and so surrounded by uncertainty that scientists must take these into account in their assessment at all times, if they want their findings to be of use, as opposed to only a recapitulation of the past.

The Agency for which I work deals with environmental health, health in the workplace, food health, animal safety, plant safety, etc. All of these themes are tinged with uncertainty, whether in terms of assessing hazards or determining the risks that that result from them. The problem lies in the fact that traditional quantitative risk assessment is often difficult, when not impossible.

Risk assessment takes place in what I call the best of uncertainties, whether in the regulatory or non-regulatory area. They can be:

- epistemological (due to lack of knowledge, for instance, data on human exposure, latency in technological developments, interaction between agents),
- due to research methodology,
- related to variability, now greater than ever, in particular where exposure is concerned, above and beyond sensitivity levels, etc. or as a result of life pathways,
- related to modes of action,
- ambiguity (also due to divergences in interpretation).

I will explain how scientists, by taking these factors into account from the start, can produce avenues for exploration and recommendations that are useful to risk managers.

A prime example is offered by nano-materials, which may entail irreversible damage and on which numerous uncertainties remain, regarding everything from their physical-chemical characteristics, to the methods by which their properties can be determined, the reference protocol, target population, and biological and toxicological profiles.

We made it clear that quantitative risk assessment would be impossible, given these factors. The recommendations we made about the materials, exposure levels and action, were aimed at facilitating subsequent decision-making about the risk probability levels and resulting possible impacts. For instance, it was recommended that the nano-materials be grouped together by family, though it is well-known that the toxicity levels within any given family can be very different. The use of forecasting tools was also advised, as a means of understanding the level of danger posed by the nano-materials, from the very point of design as well as at specific points in the life cycle. We also wanted to develop qualitative or semi-quantitative tools that would make it possible to mitigate risk, such as control-bending.

Bisphenol A and endocrine disruptors in general are another informative example. The methodological challenges encountered have given rise to multiple uncertainties: there are few if any epidemiological studies; the effects on human health can be found not in the generation studied, but in their descendants; the animal data are difficult to transpose to a human environment; the effects of low-doses are difficult to detect and thus express in risk assessment; toxico-cinetic and bio-availability factors.

To ensure solid, credible scientific review nonetheless, the Agency's Expert Group chose a strategy based on the following principles:

- full transparency, enabling the public and decision-makers to form an opinion as objectively as possible, alongside high quality standards and significant burden of proof;
- an integrative approach to exposure, taking into account all paths (oral, cutaneous, inhalation), and determining distribution probabilities in such a manner as to identify risk scenarios (infant exposure and risk for the mammary gland), and more importantly, establish the level of confidence which each scenario warrants.

On that basis, we recommended that the Agency give priority to recommendations and, in this instance, restrictions on exposure to bisphenol A in sensitive populations, namely, women and children. On some of the less expected risk scenarios, for instance, around cash desk receipts, we advised that further research be conducted. Then high levels of exposure, both in cashier hostesses and print factory workers, were measured by INRS (National Institute for Research and Safety).

In other instances, the determinist approach can be maintained, for instance, when attempting to determine a daily admissible dose, adding security factors, so as to protect the most sensitive or vulnerable populations, or in order to take into account a number of factors, such as co-exposure (e.g., oto-toxic solvents).

Today, one of the elements most lacking is exposure bio-metrology (professional, general, etc.). We are thus calling for improvements in exposure traceability, especially where effects (delayed, chronic, cardiovascular, neurodegenerative) are uncertain. It is important that we be able to call upon full-fledged tracing systems to address these, all the more exposure variability factors are far higher and the relevance of indicators and exposure previously established can be entirely challenged. Here too, a precautionary, pragmatic approach is needed, as the traditional risk assessment is not possible. With respect to risk probability, it is also important to note that certain thresholds accepted in the past are no longer valid today, as is the case for instance with lead.

Risk assessment should be undertaken with an understanding of its purpose and potential benefits, as much with regard to health as with regard to the environment. The resulting findings will then

more accurately express not only the potential severity of the risks, but also the extent of proof and the probability of occurrence in the relevant populations. It is important, from the precautionary standpoint, to be able to identify the populations most affected potentially, in terms of likelihood or vulnerability, and to state as effectively as possible how risks can be best monitored and exposure traced. Lastly, there may be significant gaps between the objective reality of risk and perception of the said risk, whether for the stakeholders or the scientists involved. In this regard, it is important to be able to address methods transparently and develop a research culture in which all of the uncertainties are effectively incorporated into the methodology and confidence in the findings is ensured.

To those scientists who find this not be the most comfortable position, I would quote Oscar Wilde: *"Knowledge would be fatal. It is the uncertainty that charms one. A mist makes things wonderful."*

# Innovation: Managing Risk, Not Avoiding It

---

**Claire CRAIG**

Director – Government Office for Science, United Kingdom

Unlike this morning's speakers, I come not from academia, but from the decision-making sphere, working to ensure that Government Ministers receive the best possible scientific advice and, necessarily, having a wide awareness of the context in which they are receiving that advice. This presentation will draw on key themes arising out of the 2014 Annual Report of the UK Government Chief Scientific Adviser, Sir Mark Walport, "Innovation: Managing Risk, Not Avoiding It" The report consists of twelve chapters produced by different, independent authors, together with a number of case studies and contributions from different countries. The report aims to distil leading edge EU scientific thinking to stimulate broader discussion on risk, hazard, uncertainty and vulnerability within the EU.

Innovative economies are more competitive, respond better to change, see higher returns on investment and create increased living standards. Innovation is essential for security and resilience. However, innovation is not an unalloyed good. Discussion of innovation has become almost inseparable from discussion of risk. Paradoxically, this discussion has become more prominent precisely because the innovations of previous generations have made our lives much safer and free of risk. People living in advanced economies have become more risk averse compared to previous generations.

The UK has developed a central Horizon Scanning Programme, which has in turn set out a number of priority areas to watch, all at different levels of maturity and acceptance within society. With Big Data for instance, which is a top priority, debate has become very clear and centres on privacy versus transparency. Drones, in contrast, are currently controversial but for reasons that are less well understood. With any topic of controversy, appropriate framing helps to make the public debate more manageable.

We work with the input of many scientific fields, from behavioural sciences, to ethics and philosophy; all help us understand how to present technical evidence in the public arena. Numbers, for instance, when communicated are never neutral. When a risk is reported to be on the verge of doubling, the situation is perceived as much more serious and challenging than when it is revealed that risk will increase from 1/1,000,000 to 2/1,000,000.

Trust is a central issue. Concerns about risks are often rooted in concerns about the adequacy of the institutions that produce, predict and manage them. The general public, the attention of which may be naturally more easily captured by sports or television, tends to listen more to an authoritative scientific voice, when it is already has a tendency to trust in it. The trusted expert or institution would typically be expected to act with care for those affected, to be competent, and to be free from self-serving bias.

When thinking about specific risks in the wider public context, it is important to understand that it is in times of crises (volcanos, pandemics, terrorism, etc.), specifically, that concerns around risks can be more quickly shaped. For instance, the coverage of the Ebola crisis did much more to inform and engage the public in a short time than any long-term campaigns could have, thanks to the quantity and quality of information, the way in which it was framed and the public's emotional receptiveness at that time.

One of our authors classified the framing of risk and innovation in five broad types, based on source of the risk, agent, the potential beneficiaries from the innovation, etc. For instance, medical

innovation for which there is a high level of public acceptance may be best viewed not from the angle of risk-benefit, but by addressing issues around equity of distribution and who pays. Both scientists and politicians need also to be aware that any major public policy decision can be viewed through a number of lenses (economic, social, political as well as scientific). Many of the less fruitful debates come as a result of confusion between those lenses. For instance, when debates over fracking become mired in technical and engineering issues and fail to address the broader public questions about fairness; who benefits and who carries the risk.

Cultural lenses also exist, representing a different approach to fundamentals, such as risk, hazard and, of course, the precautionary principle. The cultures can be as much national as they are professional or sector-specific. Our report authors have also observed a “drift” of the precautionary principle, from an amber traffic light to a red stop sign, such that it has become a response to risk, rather than to uncertainty.

We delegate many decisions about risk and innovation to regulators. In response to the risks identified, decision-makers can choose to facilitate a technology or not to, or can consider different forms of technology or behavioural change. One persistent problem lies in the fact that regulation as a topic encompasses a vast range of meanings, from the generic (regulating medicinal products poses completely different challenges to regulating telecommunications) to the specific (for instance, the difference between regulating a medical device from a new vaccine). One particular challenge to be addressed lies in the asymmetric incentives applied to many regulators. Put simply, a regulator who allows something to happen that causes harm will probably be in deep trouble. A regulator who stops something from happening that would have caused benefit will likely suffer no consequences.

We need to look forward as well as back. Governments today are starting to ask what new technologies mean for regulation, not only how regulation can support and enable the safe use of technologies. For instance, how can the connectivity of citizens (e.g. to the internet) be used to monitor and share information? How can all parts of the regulated system be used to create new, safe as well as flexible regulatory approaches for the future?

I will conclude by discussing the contested technology of mitochondria replacement therapy which aims to eliminate faulty DNA from the reproductive process; and so address mitochondrial disease for which there is no known cure. Here, adding to already-complex technical issues, were strong cultural and ethical concerns. In the UK, the Human Fertilisation and Embryology Authority (HFEA) led a multiple strategy public consultation process from 2011-2014. Crucially, throughout, the HFEA took no position on the issues at stake. This extended dialogue process enabled the Department of Health in July 2014 to announce its decision to put regulations before Parliament for the use of mitochondria replacement techniques.

Key areas where we can, therefore, build upon existing approaches are:

- Aligning national priorities for investment on resilience, infrastructure and innovation with an evidence and risk-based approach;
- Ensuring a more coherent and structured approach to assessing the impact of risk in policy, regulation and crisis management;
- Putting in place the right governance structures and incentives in relation to our regulators and regulated industries;
- Rooting the approach to policy and decision-making in the EU in robust scientific evidence (including strong analysis and, increasingly, in shared meta-analysis);
- Understanding that, while science is not the only lens, it is of crucial importance.



# Prudent Precaution and Plant Protection Products

---

**Harrie VAN DIJK**

Scientific Officer – Health Council of the Netherlands

The Health Council of the Netherlands' first report, entitled "Prudent Precaution", was submitted to the Dutch Government a few years ago; the second report, on crop protection and local residents, was issued last year and can be regarded as a case study for the application of the precautionary principle. Both reports are available at our websites in full English translation.

Uncertainty is a characteristic of many issues, especially environment health issues; this rather the rule than the exception. We thus recommend that the Dutch Government regard the precautionary principle as a strategy for dealing with uncertainty, in an alert, active, reasonable and transparent fashion. Ours has thus been a procedural interpretation of the precautionary principle. It does not prescribe what to decide, nor does it simplify the process of weighing the pros and cons of various policy options.

We nevertheless believe that the procedural interpretation is not empty. We believe that dealing carefully with uncertainty holds many advantages and benefits, including: more transparent decisions, enhanced prospects for a proper balance between short-term benefits and more uncertain drawbacks in the long term; attention to side effects of technological developments from the start; an iterative process of policy formulation on monitoring and review and thus less change of overlooked early warnings and enhanced prospects for early intervention.

We believe that extreme reactions to uncertainty create deadlocks. The "guilty until proven innocent" may hamper innovation and cause societal stagnation; the opposite, however, could lead to inertia, when negative effects are inherently difficult to prove. We thus feel that the precautionary principle should be used to break both deadlocks and achieve a better balance between the venturesome and the cautious. The Dutch Government embraced these recommendations, which now form a cornerstone of our environmental policy.

In the Netherlands, approximately 90 000 people live within 50 metres of fields used to cultivate flower bulbs and fruits. During the growing season, many of these fields are sprayed weekly with very high levels of pesticides (40 to 70 kilogrammes of active ingredients per hectare per year). Local residents fear that they are exposed through drift or evaporation. They worry about their health and that of their children. The Health Council of the Netherlands deemed that this issue is characterised by uncertainty, as very little attention is paid to risks for local residents when reviewing pesticides for approval, and exposure data are almost nonexistent. We also have no epidemiological studies on health effects.

As to studies from other countries, they are often characterised by weak design, the results heterogeneous and the findings of questionable relevance for the Dutch situation. The Health Council has stated that the health of local residents may be affected by these pesticides, especially where the homes are closely surrounded by heavily-sprayed fields and particularly in the case of small children.

We thus advised the Dutch Government to apply the precautionary principle, specifically recommending:

- an exposure study among local residents, using a combination of research methods (water, soil and air samples, house dust samples, wipe samples from furniture, urine samples, activity pattern records to establish the time spent indoors versus outdoors);

- improvements to the authorisation procedure itself by EFSA, in cooperation with national authorisation bodies across Europe.

Such measures require a great deal of time, however. Hence, the Health Council recommended interval measures that reduce exposure of local residents. Because of all the uncertainties, priority should be given to measures entailing low expense and to those that are worthwhile anyway because of other benefits.

To the government, we recommended to promote integrated pest management (i.e., the use chemical pesticides only as a last resort), and to stimulate farmers to comply with all legal requirements when spraying pesticides by increasing the number of inspections.

To industry providers, we recommend innovations to improve formulations, spraying equipment (catching and reusing drift materials), and to develop technical means for precision control.

Farmers have been advised to give higher priority to safety. In the Netherlands as in other countries, courses are required before the spraying license is granted; we believe that these courses should include more units about safety, including the safety of local residents. Wind-breaking plants can be used to limit pesticide drift and thus improve conditions on the ground. Farmers should contact local residents, trying to find together solutions that accommodate the needs and concerns of both parties.

Lastly, local residents have been encouraged to discuss their concerns with farmers, use the complaint structures set up by municipal health authorities and national health inspectorates and, further, reduce their own exposure by closing windows during and after spraying, avoiding the outdoors while spraying is in progress and refraining from drying laundry in the garden during those times.

The Government was also informed about more expensive action, such as the creation of no-spraying zones.

When we drew up this report, we held a number of public stakeholder sessions, involving local residents, farmer unions and representatives of the pesticides industry. We also published a draft report on which they were free to comment. All of these enhanced transparency when the report was ultimately released. It was well-received by all stakeholder parties, perhaps stirring the government to accept all of our recommendations. At the current time, a consortium of Dutch Research Institutes is preparing a very large-scale exposure study, set to start in 2016 and last until at least 2018.

## **Marie-Françoise CHEVALLIER-LE GUYADER**

I come away with a number of key words:

- robustness of scientific studies and averred facts
- transparency in procedure
- the importance of cross-referencing data
- foresight
- and time and duration.

### **From the floor**

As a representative of an NGO, it is very interesting for me to hear an IPM approach being promoted. I am very pleased that the Netherlands Government has chosen this course of action and hope that all EU Member States will take note of this. France has been having a great deal of trouble addressing neonicotinoids. Could you share your view on this class of pesticides?

As regards investment alternatives, while there is a joint funding mechanism open at the international level, most of the options funded there are nonetheless chemical.

### **Harrie VAN DIJK**

The question of neonicotinoids is not quite resolved yet; serious concerns remain about bees, insects and birds, also in the Netherlands. The local residents are also very concerned about them, as slight indications have emerged as to a possible impact on brain development in young children. This class may be included in the exposure studies to which I referred.

### **From the floor**

Mrs Craig cited longer life expectancy as an indication that the outlook is not too dreary after all. I would argue that, if we are indeed to live longer lives, some certainty has to be given that we will be in good health throughout. In reality, the estimated lifespan free of health impairments is declining: it is below 62 years in France, with a very significant social gradient of approximately ten years, between manual workers and upper management-level workers. In other words, at age 60, the likelihood that a manual worker will face a health problem is more than 1 in 2, when the government is seeking to extend retirement age to 65.

### **From the floor**

You stated that the government endorsed your recommendations. Will this be visible in the regulations?

Many of you mentioned that there is not enough bio-monitoring in Europe. There is a large-scale initiative on this, to be funded by the European Commission, though it will be the Member States' to determine how they wish to organise this.

### **Harrie VAN DIJK**

The Government did accept our proposal to conduct an exposure study, providing €8 million euros from 2016 to 2018. It has also sought legal advice on the establishment of no-spraying zones. It was informed that, pending the exposure study, it is not necessary to institute no-spraying zones at the national level. At the local level, however, some authorities, farmers and local residents have agreed upon the establishment of such zones.

### **Claire CRAIG**

The point about inequality of lifespan raises multiple other issues. Many technologies are developed in response to specific problems, when policy-makers find themselves increasingly required to judge options with systemic implications. This is the case with life expectancy, which is determined by lifestyle, behaviour, nutrition, etc., as well. This opens up an entire new realm of scientific insight. You are being asked to judge technical risk benefits on the one hand against the possibility of different types of intervention to achieve different outcomes.

## **Gérard LASFARGUES**

Regarding pesticides and surveillance, France's recent law on agricultural affairs transferred to our Agency the power to rule on market release for pesticides and structure a phyto-pharmacovigilance system. We receive funding to develop a number of studies, to trace exposures and establish extremely important bio-monitoring tools. They will enable us to better understand chronic risk, but also make it possible to engage more effectively at the European level on this.

## **Martin PIGEON, Corporate Europe Observatory**

It takes resources to produce data: what policies, decisions or investments have been made to make those?

Mr Van DIJK, you described a situation which I see as disastrous through and through: a recognised biocide is being sprayed at distances well below those deemed safe by the regulatory authorities and, alongside that, a lack of data. You are one of the countries with the highest income per capita in the world, yet there are no resources to fund this?

Mrs Craig, a few weeks before the most recent elections in the United Kingdom, the Government made the strange decision to privatise the equivalent of the French ANSES, the Food and Environment Safety Agency, whose 400 researchers and infrastructures were sold to a private data provider. This is an entirely political and yet also entirely scientific matter. How can public investment be used to fund meaningful data, within this background?

## **Harrie VAN DIJK**

The high pesticide volume is an even more significant problem in Europe, where pesticides are allowed onto the market, while no methods are available to measure metabolites in urine and blood samples. For this reason, we recommended that the Dutch Government stimulate a process in the European Union, so that in the near future the dossier for the pesticide approval will include information on methods to measure metabolites in urine and blood samples.

## **Claire CRAIG**

In the UK and probably in France and elsewhere, there is a massive public investment in what can be regarded as the national infrastructure for observing, monitoring and enabling research in different areas (data collection, tissue storage, etc.). Much of this infrastructure is found in very different types of organisations, with different mixes of objective governance structures. No single nationalised or private survey will suit them all.

## **Gérard LASFARGUES**

ANSES engaged in extensive efforts to design and fund inter-agency research programmes in order to take up questions to which quick responses were needed, in essence, a National Toxicological Programme for Europe. Where pesticides are concerned, we were able to secure regular, long-term funding and aim to finally become adequately structured to take on the precautionary principle.

## **Nicholas A. ASHFORD**

Let me share my view as a trained chemist, later diverted to law and economics. I foresee that, in four to five years' time, we will look back appalled on today's situation. A very well-known environmentalist made the following profound statement: "Synthetic organics, organophosphates and chlorinated organics are not consummate with our evolutionary soup. This is not something we evolved in". I regard pesticides as the most serious non-occupational exposure facing the industrialised, if not the industrialising, nations. I do believe in science and research, but only when strategically structured so that does not stray into the irrelevant.

In Mary Wolff's landmark study on pesticides, the aim was to determine whether these substances result in higher incidences of cancer in the populations exposed. While the question sounds straight-forward enough, the study found that there was no link between pesticide levels and the women examined. Industry unjustifiably concluded that these particular pesticides were not carcinogenic. The POPS Initiative has taught us that many pesticides are endocrine disruptors. The appropriate methodology would have been not to look for cancer in the women exposed, but in the next generation, the number of receptors to which carcinogens can attach in the breast having been increased dramatically.

Failure to recognise the inter-generational path is to divert resources in the wrong direction. Rather than confronting the fact that the agricultural system in which we live is simply unsustainable and face our need to de-industrialise agriculture, rather than growing foods in a different manner and encouraging diets that reduce serious diseases, we hammer away at the wrong problems.

When El Al Flight 1862 crashed into the Bijlmermeer housing project in Holland, community members continued to report a wide range of physical health problems, extending even into the neurological. Living in the country at that time and involved in a committee on low-level chemical sensitivity, we were unable to even bring the Government to engage in discussion about the aircraft, which purportedly was carrying only flowers, yet in reality had neurotoxic chemicals in the hold. Today, the problem has faded into the background.

### **From the floor**

Do you have any specific intentions for the result of your exposure study? €8 million euros is a tremendous amount for such a study. Have you started the very important process of developing regulatory response scenarios?

### **Harrie VAN DIJK**

We have already informed the Dutch Government that this will be a very complex study. It is for this reason that a consortium of several Dutch institutes is participating. The study will not provide all of the answers, but most significantly will shed light on how exposure levels due to the environment compare to exposure levels from food, and help us sharpen our focus. It will probably also include farmer families, so that we can study exposure in farm family children from pesticides on the clothing and shoes worn by farmers returning into their homes.

Specifying that this study will stretch for many years and emphasising that uncertainties will continue to exist in many areas, we encouraged the government to step up existing initiatives, engage in better pest management, reduce the use of pesticides, etc.

### **Marie-Françoise CHEVALLIER-LE GUYADER**

Thank you all for participating. I am sure that the Round Table will come back to many of these topics.

# Round Table: Precaution as a Factor of Differentiation and Innovation

---

This session was moderated by Benoit VERGRIETTE, Head of the Risks and Society Unit, ANSES.

## *Participants included:*

---

*Michel CAPRON, Professor Emeritus in Management Science, University Paris 8 Saint Denis*  
*Gérard COLLETTE, Group General Manager Industrial – Solvay*  
*Michel GRIFFON, Chair of Sustainable Development Committee, GIS “Plant Biotechnologies”*  
*Eric VANLABECK, Director R&D ISR-OFI Asset Management*

## **Benoit VERGRIETTE**

As an introduction to our round table, and before giving the floor to the other speakers, I would like to invite David Gee. In addition to his many others projects and activities, David has also been the catalyst, European Environment Agency editor and a chapters author for the two volumes of Late lessons from early warnings. We have had numerous fruitful discussions over the last few years, including discussions for the preparation of this conference. I have asked him to give us some of his thoughts on the lessons drawn from “Late lessons”, about how corporations could more effectively take into consideration the undesirable consequences of innovation.

## Keynote Speech: Incentivising Positive Corporate Responses to Early Warnings: Lessons from 1896-2013

---

## **David GEE**

Retired Senior Advisor on Science, Policy and Emerging Issues – European Environment Agency

As the topic I will address today, corporate behaviour, is not specifically in my area of specialisation it may offer some perhaps novel insights into how to incentivise corporations to respond earlier to warnings of potential hazards from their processes and products.

My address is based on “Late Lessons from Early Warnings” (EEA, 2001, 2013), a two-volume, 1,000-page work containing 34 case studies. In each of them we looked at the first plausible early warning of impending harm; examined society’s responses to the information; studied the consequences of the actions and inactions; and identified the lessons that could be drawn. Whereas the Volume I case studies are entirely historical, Volume II also contains some emerging issues (e.g. nanotechnologies, gene food modification, mobile phones, and invasive alien species) where their full consequences have yet to be experienced. Both volumes also have some horizontal chapters: the “Twelve Late Lessons” from vol 1 (eg “more environmental long-term monitoring and timely research”) and, in vol 2, chapters on the precautionary principle, precautionary science, the costs of inaction, and the chapter I shall focus on today, “why do businesses seem to ignore early warnings?” This was authored by an INSEAD Professor (Marc Le Menestrel, and co –authored by Julian Rode ) who reviewed the case studies for a better understanding of corporate responses to early warnings.

Today I will use two of the case studies to illustrate some generic lessons: climate change, as Paris is preparing to host COP21 in December; and asbestos, as France provided some of the first early warnings, unfortunately largely ignored for nearly 100 years. Currently, the UK records 6000 deaths per year due to asbestos (50% from lung cancer and 50% from mesothelioma cancer) and the death toll is still rising some decades after asbestos was phased out. The initial harm from asbestos, “asbestosis”, (identified clinically in the UK in 1898/9, and in France in 1906, who provided the first epidemiological study), has expanded to the two cancers which now dominate the death statistics. Furthermore, the more research was conducted, the lower the assumed “safety level” of exposure became: today we assume there is no known safe level for asbestos.

Asbestos also taught us that it is never possible to adequately control the use of very hazardous substances, as the WTO concluded in the unsuccessful N American appeal against the French ban on asbestos in 1999. The WTO case also provided some generically helpful rulings eg a Member Country can take action without waiting for a majority scientific opinion; a plausible minority view can be sufficient; and while quantitative data are useful, they are not essential and, in many cases, decisions can be based on qualitative information alone.

Climate change has been accelerating since the first early warning in 1896 and the planet has not been absorbing as much carbon dioxide as was predicted. Nick Stern, the ex UK Chief Economist told the Davos meeting in 2013 that his 2006 overview report on climate change significantly underestimated the hazards. Yet a PriceWaterhouseCoopers study from 2015 shows that climate change is “not an issue for most CEOs”, failing to make the list of the top 18 issues that concerned corporate leaders. However, more recently, 43 multinational Corporate leaders have called for action on climate change, including putting a price on carbon that better reflects its true cost.

From the asbestos and the other case studies on hazardous agents we learn that:

- **exposure always expands**, from producers to users, bystanders, homes, families and children, general environments, consumers, next generations, and to non-targeted species: we never over-estimate the extent of harmful exposures which expand over time for all large scale persistent substances studied;
- **the nature of the harm also expands**, as we have seen with lead; PCBs; asbestos; and the DES pharmaceutical pill which led to cancers and life-long reproductive hazards for the daughters of the mothers who took the pill;
- **the level of exposure at which harm is caused consistently declines over time** and with more research

Corporations are not helped by the inaction of regulatory authorities. And corporate creators of hazards have little economic incentive to take action themselves as the costs of harm are always externalised onto society ie to victims, taxpayers, health services, etc.

Furthermore, the predominant business model consists of maximising economic value for shareholders, with less attention given to other stakeholders. Fear of legal consequences can be another factor that explains inaction by companies that already have difficulty in coping with low-probability/high-impact events. Other factors that explain corporate inaction include conflicts between professional and personal values; insufficient public and consumer pressure; and scientific uncertainty, often compounded by the “manufacture of doubt” by hazard deniers.

Corporate Inaction is compounded by regulatory denial as illustrated in the Canadian example where scientific warnings of cod-overfishing were dismissed by regulators as one-sided and motivated by a “political agenda”.

On a more positive note, when actions were eventually taken on the case study hazards innovations were always stimulated.



In light of the “Late lessons” case studies here are eight proposals to help incentivise corporations to take more timely action on plausible early warnings:

- **early regulatory and precautionary action**, based on a sufficiency of case-specific evidence , with corporations more time to take the required actions, including adapting their capital structures and behaviours;
- **greater stakeholder dialogue** about resolving conflicts between corporate short-termism and the longer-term interests of both corporations and society;
- **more anticipatory research**, delving into the potential hazards of the technologies being developed, so that the latter do not cause problems some years down the line where they can threaten product commercial longevity as well as health;
- **market prices that reflect the emerging costs of harm**, via taxes etc. which would then stimulate the markets for innovative substitutes, and stimulate the hazard creating firms to limit future harm; with taxes increasing over time per unit of pollution created, and with revenues used to help fund research into substitutes, as with the TURA Act in the US
- **improved liability measures**, for instance, anticipatory insurance bonds, building on experiences from the mining, nuclear, and oil industries
- **business models that are based on a circular economy**, which also emphasise the provision of services rather than the sale of products;
- **extend the legal responsibilities of corporations to other stakeholders, including future generations**
- **financial and other support for consumer and share activist campaigns** that are working towards more sustainable societies.

## Discussion

---

### **Benoit VERGRIETTE**

Thank you David for these reflections and proposals which will feed our discussion. I will now ask our five speakers to give us their own views and perspectives and then I will open the floor for discussion.

Gérard COLLETTE, considering some bad experiences in chemical sector what type of action can industry take to better predict and mitigate the undesirable effects of its activities on the environment?

### **Gérard COLLETTE**, Group General Manager Industrial – Solvay

Your question is worth to be asked, as the Chemical Industry had a couple of severe accidents during its history. In addition, most of the people identify the Chemical Industry with toxic products and pollution! Of course the reality is different and the chemical industry deserves to be better known.

Solvay Group has a long lasting commitment to sustainable development, championed by each of its chair people and in particular our CEO Jean-Pierre Clamadiou. This approach is also supported by the Solvay families, our main shareholders, very dedicated to make sure that all of the initiatives we take are sustainable.

Concretely, this can be seen in following focus areas:

- Health and Safety are our first priority. Accident frequency was divided by 3 over the last 4 years with a current level below 1 (number of accidents with medical treatment per million work hours);
- Continuous process safety reviews for all our processes;
- Risks identification through permanent exposure level monitoring for all our employees; Implementation of a continuous employees pathology monitoring linked with the exposure cartography. Deployment currently in progress;
- 
- Toxicity & eco-toxicity assessment for all our products. All Innovative Ideas / Projects are assessed in this field as well as the whole environmental footprint.

## **Benoit VERGRIETTE**

Eric VANLABECK, as someone whose job it is to select investments in terms of their degree of corporate social responsibility, which criteria would you list as the most effective? What is the best way of securing a leverage effect on those investments?

## **Eric VANLABECK, Director R&D ISR-OFI Asset Management**

My organisation offers advice to prospective investors, from an extra-financial perspective, which includes: corporate governance and stakeholder relations; the environment; and social and societal responsibility. Product safety, product security and environmental safety are thus an essential part of our vision, above all in sectors such as food, textile and construction.

We then draw up a rating scale, based on their behaviour as observed on the ground, as well as on their own statements, NGO reviews, and feedback from civil society. Our investments are obviously channelled toward those whom we deem most deserving of them. Obviously intent on being a societally-responsible company ourselves, we see money as a driver, a means of influencing and shaping society. As such, we try to create conditions so that the cost of bond emission for a responsible company be lower than that of a less-responsible company.

Responsible action is made more likely and possibly even conditional upon: access to information, a challenge when some effects manifest only after the fact; access to a rare resource, which money certainly is not. We are thus in a challenging situation, but persist in our determination because we know that there is risk for emitting parties. Furthermore, we understand that this risk has not yet materialise and that companies tend to minimise it.

A few decades ago, the environment was not a costly factor for companies; today it is exceedingly expensive and thus something to which we are averse.

## **Benoit VERGRIETTE**

Michel CAPRON, there are now a number of initiatives in favour of transparency and accountability, specifically in connection with corporate social responsibility. Would you say that they do effectively incentivise companies?

## **Michel CAPRON, Professor Emeritus in Management Science, University Paris 8 Saint Denis**

The most important and compelling initiative these past five years was the publication of the ISO 26000 Guidance on Social Responsibility. They stand out from all other initiatives in that they were developed by a multi-stakeholder group of 400 to 500 people (business, government officials, NGO and unions representatives, etc.) who worked together for five years. Though it does contain a number of weaknesses, the document inspired a number of major international rules, including a

revision of the OECD's Guidelines for Multinational Enterprises, and an entirely innovative text published by the UN, on Business and Human Rights, as well as a Communication of European Commission.

All of these share the new concept, "due diligence", by which organisations must take responsibility for the impacts of their action. Two of the seven principles set out by the ISO 26000 deserve to be underscored here: the principle of transparency and the principle of accountability. On the latter, it is stated that organisations should be held accountable for their impacts on society, the economy and the environment, accountability also includes responsibility for shouldering the burden of a faulty practice, taking the appropriate measures to remedy them, and engage in action to ensure that they do not reoccur. Failure to execute shall entail sanctions, or at the very least, the duty to explain the instances of non-compliance. The above makes companies indebted to society, not only because society confers legitimacy on them, but also because they have negative impacts on the shared legacy that is the environment.

As to first principle, it is stated that organisations must ensure the transparency of decisions they make, and the activities in which they engage, when the said activities have an impact on society and the environment. This implies non-financial reporting, in other words, official disclosure not only on the state of their operations, but on their behaviour.

In producing their reports, companies are naturally stirred to reflect on the action they take in relation to the environment and to health. In France, this requirement was imposed on all companies of a certain size (from 500 employees, €100 million in sales revenue) through Article 225 of the Code of Commerce further to the Grenelle Talks on the Environment, on 42 specifically defined items. There is now discussion as to whether this article should be extended to simplified joint stock companies as well. Only two items make reference to health and the environment, specifically the health and safety conditions in the workplace and reporting on the agreement signed with employees on those conditions.

It should also be noted that, since late 2014, a European Directive on Non Financial Reporting has been adopted and will be transcribed into national law by the 28 Member States, alongside other international initiatives, such as the Global Reporting Initiative. In France, a bill is being reviewed by the National Assembly, which would require companies to enact precautionary plans to preclude violations of human rights, basic freedoms, serious bodily or environmental harm, or health risks resulting from the activities of the subsidiaries as well as that of their suppliers and sub-contractors.

Lastly, a week ago, the G7 published a statement to the effect that the G7 nations have an important part to play in promoting workers' rights, decent working conditions and environmental protection in global supply chains.

### **Benoît VERGRIETTE**

Michel GRIFFON, you offer the perspective of biotechnologies, also seen as a cause for concern and anxiousness in society. Have you developed a matrix for reviewing the technologies or processes you explore, in order to blend as best possible the concerns, needs and perhaps restrictions of those involved?

**Michel GRIFFON**, Chair of Sustainable Development Committee, GIS "Plant Biotechnologies"

Whether public or private, research organisations often come up against dilemmas, controversial rationale, often in unclear, risk-laden situations. This can result in conflict, just as it can pave the way for anticipatory dialogue, so that the research programmes planned can also be understood by

all stakeholders. In green biotechnologies, we have moved from the precautionary principle to what I might call the “discernment principle”, the ability to recognise and discern all aspects of a given issue, use critical thinking, measure their symbolic aspect, semiotic construction, see rhetoric for what it is, explore the linguistic specificities of the assertions made, not to mention review the actual scientific content. This calls for clarity, reason, wisdom and perspective, not necessarily easy to combine in the contexts we have been discussing today.

In the face of the problems encountered in breeding and agriculture, including first and foremost GMOs, we resolved that it was our responsibility to listen to all sides, review them with discernment, and turn them into questions, thus in a constructive spirit. For instance, some of the 26 questions were: Is the prospective GMO plant project likely to have an impact on human and environmental health, and if so what will it be? Can the project have an impact on animal health, whether breeding animals or fauna? Is gene transfer to surrounding organisms likely, possible, impossible, etc.? Have the risks of gene resistance been estimated?

## Questions from the floor

### **Philippe LAGUILLER**

Since this morning, I have been hankering to hear reference to regulatory action, which I see as crucially connected to the precautionary principle. Companies do engage in action beforehand, but it is preventive and relates to identified, specific risks. Precautionary action, in contrast, takes place in a much less delineated situation.

### **Martin PIGEON**

I share the view just expressed: is it reasonable to expect companies, aimed at profit, to take responsibility for precautionary action encompassing all of society?

Mr VANLABECK, you made indirect reference to the polluter pays principle in connection with asbestos. The main shareholder in the company responsible for asbestos production in Europe was Stefan Schmidheiny, a very important figure in the corporate world, in part for his role at the head of Eternit. He was sentenced to 16 years in prison and €100 million in fine, in 2012, in Italy, the first instance of a company leader being convicted for his company’s actions at that level. The ruling was reversed in 2014 however, precisely because he did not have any operational role in that action. Furthermore, Mr Schmidheiny founded the World Business Council for Sustainable Development, in which, in my understanding, companies self-regulate together, in order to escape actual regulation.

Mr GRIFFON, I would that the precautionary principle is usually put to use only once the innovation has come about.

### **Mrs MARCHAND, SNCF**

I am afraid that the precautionary principle will end up being but a convenient way out for certain parties to take unruly action and rake in profits, despite clear risk, all on the grounds that the scientific data are not yet strong enough. Farming has changed fundamentally since the introduction of new pesticides: farmers can no longer store their surplus grains from season to season, as that which remains is sterile, and are forced to buy new grains every year.

### **Sybille VANDENHOVE**

While I recognise the work of the NGO Corporate Europe Observatory as very important, I find the representative’s assertion that companies are aimed only at gain and optimised profits is counteractive to his organisation’s own purpose. Profits are also necessary resources. The same confusion between the ends and the means exists with innovation.

Mr COLLETTE, I heard about your innovation assessment system. Sometimes, however, even when the results are negative, your organisation chooses to go ahead with the investment anyway. Do you have examples in which Solvay chose to sacrifice a certain degree of profit to make an ethical decision?

### **G rard COLLETTE**

We are operating in an extremely complex and intricate zone. The only way to work through this problem is to have all parties working together, Industry, labs, Authorities, NGO's combining their forces of expertise & thinking. In order to:

- Identify at the earliest stage all kind of hazards
- To assess the risks for people and the environment

And then decide whether or not you continue to run the project. In our organisation, the decision Committee is separated from Business leadership. In my knowledge, there are no decisions that breach our ethical approach.

Finally, knowledge evolves over the years, some market megatrends as well, even public opinion. We have to be open and amend of course continuously our views.

### **Michel GRIFFON**

There is no contradiction in terms or even disadvantage to the precautionary principle's coming into play following the research and innovation phases, as it can be used to calm anxieties and extinguish concerns. The ratio between increasing societies' needs and decreasing biospheric capacity is disastrous. The only way to overcome the complexity and manifold problems here is through R&D and innovation. Public research is hampered by budget cuts throughout the world. The concept of "discernment" is, in my view, one that can bring together different parties in an appeased, intelligent process.

### **Michel CAPRON**

Oddly enough, the end-purpose of business is not often discussed in society. When one considers the term "enterprise", it is a venture, a risk taken, and even subversion of the establishment. Is the public sphere empowered to impose a course of action or thinking on enterprise? From as early as the 16<sup>th</sup> century, enterprises were prohibited by the monarchs. It was not until the 19<sup>th</sup> century and the development of industry and capitalism that enterprises began to gain freedom. Their effects have always been feared. The self-regulation called for by the WBSCD and all international business environments go back only 20 years.

### **Eric VANLABECK**

As to the payer in the asbestos case, I would cite society itself, which bore the cost of those who fell ill and required healthcare.

Regarding Eternit itself, I do not know why its leader was personally targeted in certain countries, rather than the legal entity.

### **David GEE**

The objective of innovation is to meet society's needs; this is too frequently overlooked. It does not appear that seeds that constrain farmers rather than enable them are in society's interest. Indeed, society very often ends up footing the bill for the decisions of those in power, whether at the heads of companies or governments. Lastly, I would reiterate my suggestion that pesticides should be

conceived of within a circular economy, so that the incentives are rebalanced and the burdens better shared. Unido is issuing a programme in ten developing countries, in which pesticides are aptly framed not as products, but as pest management services. This is the wisest path where toxicity is inherent and where there is a significant knowledge imbalance amongst stakeholders.

## **From the floor**

The precautionary duty should not be requested from the industry, but this is the job of the authorities.

### **Gérard COLLETTE**

I disagree. It's really the duty of the Industry duty. It's our duty first to take care about our employees. They handle the products before they come to the market. It's our duty to take care about our customers as well as the communities around our facilities.

As less than 10 % of the substances we use and/or transform have regulatory exposure limits, Industry has to start the job.

### **Benoît VERGRIETTE**

In late-2013, the European Risk Forum which gathers a number of big chemicals and biotech firms notably addressed President Barroso on the innovation, rather the precautionary, principle topic. The concept of regulated innovation cited by Laurence Tubiana comes in response to the wariness that exists in society: regarding the intentions of those spreading the substances, and about the truthfulness of those bringing information to society. How can collaborative research and cooperation be undertaken or even envisaged, with this rampant suspicion?

### **Gérard COLLETTE**

The 2013 letter asks only that legislation takes into account averred, identified risks and do not block innovation on a simple suspicion. There is no incompatibility with the precautionary principle as applied by Solvay.

### **Eric VANLABECK**

It is true that, too frequently, even information is kept hidden well after the fact, particularly when players have been subject to hefty fines for risks ineffectively managed and hide the fact. This, however, keeps society and review bodies from forming a complete picture.

We issued a ten-question survey to 60 major companies in order to determine transparency in information. Out of the 25% who responded, only half confirmed that the substances cited were of interest to them and in the end, only two entered productive discussion with us.

### **Michel GRIFFON**

We cannot effectively address this topic if we do not see also the larger picture, specifically, the fact that history is speeding up, the population is swelling and resource requirements are heightening. The responsibility for finding solutions ultimately falls to companies, which then offer innovation seen in significant cases as futile or not helpful. Regardless, the goods they produce hold public content. Any object holds a potential impact. We are moving toward a society in which the goods conceived of by private research end up having at least a partially-public function. Because of market failure and the complex status of a lot of objects, The State, as regulator, must step in and ensure that the whole functions optimally. This is a complex area which has not yet been studied

adequately. Both public and private research need as much to be kept from ramming into a wall, as from producing fruitless research. For this, trust is needed.

### **Michel CAPRON**

As unexpected as it may have been, the Pope offered an explanation of why that trust is lacking, just last week, publishing an encyclical, in which he explains that corporate social responsibility is in most cases nothing more than a series of marketing and image-building initiatives.

I have the honour of being Vice-Chairman of a national-level platform for CSR put together by the French Prime Minister, and which includes representatives of business, NGOs, unions and political officials, etc. We have been able to observe that the corporate world is willing to take voluntary action, if it is allowed to determine the rules and monitor its implementation. The other stakeholders are, of course, expecting much more. Sustainable development has been re-purposed as a means of gaining profit. The platform is still only two years, but we see the difficulties which these opposing stakeholders are facing.

### **Gérard COLLETTE**

I do not see why sustainable development and value creation cannot go together. Reducing environmental footprint, taking care about resources, taking care of products toxicity and eco-toxicity is value creative!

### **Michel CAPRON**

There is no single response from the scientific or academic community on this.

### **Gérard COLLETTE**

The CO2 caps helped companies improve their facilities energy efficiency and, thereby, their profits.

### **Eric VANLABECK**

The companies with the best CSR ratings, over the longer and shorter term, are also the most profitable. I have studies to prove this.

### **David GEE**

The business models inherited from the 19<sup>th</sup> century, where the market shapes reality and little attention is paid to social costs, no longer fit the current needs. It is vital that we shape our energy pathway to 2050, rather than letting it happen by chance, and I thank the organisers of this conference for bringing together such diverse thinkers to do this jointly.

### **Benoit VERGRIETTE**

Thank you very much for your insightful contributions and thank you to the audience for this interesting debate. I now give the floor to Bernard Chevassus au Louis who kindly accepted to summarize and conclude this conference.

# Conclusion

---

**Bernard CHEVASSUS AU LOUIS**

Inspector General for Agriculture

I would first like to thank the organisers for having offered me this opportunity to draw a few conclusions. I was fortunate enough to chair the first Board of trustees at the entity then known as AFSSA and it is always a pleasure to come back and see how the youngling has developed and indeed flourished.

Those who enjoy games are perhaps familiar with Machiavelli's Chessboard. Those who are not can picture a square, in which each of the four corners is occupied by a patron figure: Science, Precaution, Economy and Innovation. In the middle stands the King – the decision-maker, who can just as well be referred to as the politician or the judge. In any case, he is the person who must be convinced. In this game, each of the patron figures tries to gain prescience over the others and become the voice that guides the King.

Today's event can be seen in much the same manner. In the game, the last to take to the stage is Precaution, and it is in the interest of the three others to rid themselves of this "odd one out". Science sees Precaution as challenging its rightfulness and opening the door to the arbitrary. Innovation describes Precaution as a hindrance to progress. As to Economy, it naturally denounces the principle of Precaution as causing pointless, disproportionate spending.

That is how the picture looked this morning. I fully suspected, however, that the combined acumen and reason of Sciences-Po and ANSES would make it possible to play the game with a more refined hand and, I must say, they exceeded my expectations.

Let us come back to the three stand-offs to which I referred earlier: does Precaution push Science back into its corner and open the door to the arbitrary? In a brief semantic aside, I would note that the arbitrary requires no justification; if it had any, it would no longer be arbitrary. It nonetheless remains that science –we saw this in particular with the presentation by the speaker from ANSES – no longer enjoys the free tribunal it used to have. The last ten years have seen the rise and instrumentation of scepticism, taking on the form of scientific doubt.

For epistemological reasons, it is important to make the distinction between scepticism and scientific doubt. The Greek philosophers tell us that scepticism is the ability to pit a counter-assertion against every given assertion, in such a way as to suspend assent and, subsequently, reaching tranquillity. In other words, the Greek doctrine of scepticism consists of suspending the decision in one direction or another, because were the wrong decision to be made, tranquillity would be dashed – for what is tranquillity, but the freedom not to make a decision.

Yet, for some time now, on both climate- and biodiversity-related issues, voices have been rising, asking where there really is certainty. Is biodiversity indeed threatened? Has global warming indeed documented? If Precaution freed us from a world in which we had to prove the existence of a problem before being able to take action, then I rejoice at its arrival. I rejoice in the fact that science is no longer hampered in a field from which it can only proffer that knowledge which is absolutely certain. To the contrary, today, it is told that, as soon as it feels it may be able to offer concrete foundations for action "beyond a reasonable doubt", it may come and engage in the public debate. This first reframing of the relationship between Science and Precaution is a step forward



indeed and I am pleased to see ANSES delve into this area, asking how uncertainties can be best reported on so that they can connect up with public decision-making.

The second area we addressed was that of the famed debate between Innovation and Precaution. It is always in crisis situations that the term innovation is used. As long as economic growth is founded on a technical paradigm that guarantees it both growth and prosperity, in a sense, there is no call for a new playing field through innovation. Players build and develop around a functioning social paradigm. The Industrial Revolution, for instance, ran for many years on an energy paradigm.

It is when economic growth comes to a screeching halt that discourse calling for economic stimulus re-emerges, mobilising innovation. That growth can be green, blue, yellow or red, as long as it brings the expected jackpot. During times of crisis, it is only natural that some see the new technological package as a source of renewed life for the economy, and those who fear the same outcome as with the previous package – received as though it were a godsend, but thorny as any rose.

The fact that we experience this as a situation of tension is only natural. I found interesting – in advance, my apologies for not citing every speaker, but such is the right of the person asked to conclude – the almost-paradoxical proposal made by Professor ASHFORD: well-designed, even strong-handed regulation is perhaps the best way to stimulate innovation that is not incremental, but instead, truly synonymous with breakthrough. Professor GEE made a similar point, referring to regulation that stimulates innovation.

I would point out only that this must happen in conjunction with clear-headed analysis of the actors in play. It is not because part of the economic community agrees to, or even pushes for, strong-handed regulation that strategic thinking is less necessary. As you are well-aware, sociological studies, whether on the much-discussed aerosols, acid rain in Germany, asbestos or even mad cow disease, showed that it was only when given industrial players were in a position to offer solutions that would make the existing ones appear ancient, that the incumbents (and owners of the latter) found that they should take interest in the matter. In other words, it is indeed important to consider, above and beyond what the public authorities may do, the interplay between the parties involved and the possibility that they may indeed call for stiff regulation where they may not otherwise have done so.

The third stand-off came between Economy and Precaution, with the interesting presentation from our Danish colleague. He reminded us that we need to be able to recognise when a question is still open. It was asked whether Precaution gives rise to inappropriate economic expenditure. I have always wondered this. When I chaired the AFSSA platform, we were in the throes of the mad cow crisis, and our main concern was to determine whether the cost measures were suited to the situation, when some estimated the cost of crisis management at €10 billion. Indeed, in a situation of uncertainty, is the risk of responding in a disproportionate manner greater? It is easy to manage an outbreak of foot-and-mouth disease; it was far more difficult to manage an epidemic fraught with much more uncertainty. The question is open, and the response offered by Steffen FOSS HANSEN, pragmatically based on case studies, more on the side of under-regulation than over-regulation, is an initial empirical response. This does not mean that it should be considered a law as such, on the claim that we have chosen, once and for all, that there is no risk of over-evaluation of needs.

Another very important point made pertained to the need to take cost-benefit analysis with a very sizeable grain of salt. I emphasise this because, very often, cost-benefit analysis is put to absurd use, with unrelated items compared and contrasted, on the implicitly-accepted grounds that it is the only valid means of justifying public investment. France's high-speed train, the TGV, for instance, was touted as enabling users to save time, yet also recognised as shifting employment

zones, hailed as lowering accident frequency, but also as impacting the environment, causing noise pollution, etc., yet also lowering CO2 emissions.

The real stroke of genius in the face of this is to convert each factor into dollars and tell the public, “worry not, get a good night’s sleep – it’s all profitable”. Refusal to engage in this game and comparing the various aspects is a warning bell, to which I would like to call attention once again.

In contrast, one of the counter-assertions made this morning and which is very compelling went as follows: “Are you really sure that public expenditure is truly being made by necessity? Did the decision to redirect funds to other objectives not also have negative impacts on health overall?” I see these as open questions. Yes, it is easy to ask questions, and difficult to answer them, but I did want to underscore this.

I will conclude on three points:

- the nature of public debate,
- the issue of interfaces,
- the issue of trust, which gave rise to a good deal of discussion earlier.

With regard to public debate and the way in which it is handled, it was stated this morning, in particular by Professor TREBULLE, that when debate is engaged about precaution, audiences more often than not respond that this was not the topic which they wished to discuss. Likewise, when discussion turns to the topic of zero-risk, people respond that they never assume that to be a possible objective; instead, they want to discuss topics which they previously said they wished to leave untouched. This is an interesting point and those who take an interest in public discourse are well aware that there are “totems”, massive figures around which people come to dance in order to evoke other matters; at a given point in time, those figures simply lend themselves well to that type of debate.

Perhaps this links in with the topic of discernment, which Michel GRIFFON introduced. Perhaps it is time to move from risk assessment to an assessment of the questions, making sure not to see everything through the prism of risk. Let me take a very current example: when the fine ewe containing jellyfish-protein was eaten by a consumer, the immediate response was that there was no reason to worry and no risk to human health – which was most likely the truth. However, the reason for which people continue to joke about it, though not really laughing, judging from the television and radio news, lies in the outrageousness of it all – how could anyone have ever done such a thing? If we assume that people are responding to risk, when they are in fact responding to what they see as an outrage, we run the risk of offering them answers to questions which they are not asking, and thus not answering questions that really are being asked. The ability to distinguish between the scandal and risk theory, or aversion theory, will come as we learn to take a broader perspective; perhaps, ANSES will eventually become an agency for the assessment of controversies and questioning.

I would mention also, on this point, a proposal from a figure very well-known in these hallowed halls: Bruno Latour, who developed, a few years ago, the concept of “cautious innovation”. What did he mean by cautious innovation? He meant that, when engineers in a company are putting together an innovation, they come see you from time to time, and do so to inform you that things are functioning better and better – meaning, that the innovation is making strides. The response should be, “No, that is not the issue we are going to address. It is, ‘have you made progress in understanding the issues and problems that your innovation will create? In other words, I am not asking whether you have made progress in finalising your innovation itself, but whether you have progressed in understanding the fact that any innovation will also cause a disruption and that you

need to understand everything that will take place within that context, bringing us back to the idea of not taking action after the fact, but as the innovation is progressing.

My second point is about the interface: in the major international texts that govern risk analysis, some state that risk assessment, risk management, communication about risk and even risk monitoring should all be handled separately, in other words, in a system of distinct boxes. Each party tries to effectively do his job: the assessors assess well, the managers try to manage well... But I am more and more of the belief that this should all be approached as a system, and that it is in the way the interfaces work that a possible all-encompassing, well-functioning system will emerge. I will cite only one example, as I do not have the time to go into detail: the response from the “assessment” segment regarding uncertainty was to significantly develop joint audit procedures, in recognition of the fact that in a situation of uncertainty, there will be bias, whether positive or negative. There are also methods for removing bias, an area on which the Americans have done a good deal of work. However, in the end, joint audit methods need to be developed. My question is: has the political sphere developed the joint decision-making methods and thus joint risk management methods? Based on my experience, work remains to be done in this area. Whatever the quality of the assessment provided by an Agency, when a decision has to be made in a situation of uncertainty, weighing out a number of factors and doing so jointly, this is perhaps a case in which instrumentation is needed.

I will conclude on the question of trust. In my view, and Michel Griffon alluded to this as well, trust is a common good. In other words, a society’s attitude will be conditional upon the trust “capitalised” in the risk analysis system. I agree with the view that this system forms a jointly-responsible whole within society. Do we trust in that system? If we do, this implies that, taking the classic metaphor of faucet and bathtub, trust is constantly being lost as more is being created. Consequently, rather than insisting that, “it wasn’t me, it was that other guy”, could we not create a joint outlook in which the capitalised trust – not reassurance, a term I do not like – seen as a common good, could become the foundation for processes that would invalidate the use of the term “tragedy of the commons”, an atrocious term that could indeed have its applications in this arena.

For, indeed, as true as it may be that the margin for improvement on the way toward perhaps not zero-risk, but infinitesimal risk, is relatively capped, the margin for improvement toward zero-contempt is considerable. Trust occurs when everyone involved feels that they are being taken seriously, when the objections made and the questions asked are treated as legitimate from the outset and given the best possible answers.

If the adventure that awaits us in the future is not only about risk management, but also about managing trust and developing zero-contempt, then it is an adventure that can keep us very busy.

I would like to thank all of the speakers and, in addition to the organisers, in particular the speakers and colleagues who joined us from abroad. They brought extremely helpful insight to this session, and considerably broadened our horizons and thinking. I wish them a return home that is smoother than their trip here.

Thank you all.