The administrative ordering of nature and society – precaution and food safety at the molecular and global level

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Published in 'Symposium on the Risk Regulation Reflex', in: *European Journal of Risk Regulation* (2012)

Abstract

Responding to public fears and the loss of confidence in the aftermath of several food safety crises in the 1990s and 2000s, more and more regulatory fields have come increasingly under the influence of the precautionary principle. In order to clarify that such a development has adverse consequences, we discuss two very different cases. First, at the molecular level we discuss the problems the system encounters by strictly applying the linear no-threshold (LNT) model, which was adopted in response to public fears about nuclear war and energy. Second, at a global scale, we discuss the problems associated with the precautionary regulation on Illegal, Unreported and Unregistered Fisheries that came into effect January 1, 2010. The technical aspects of food safety testing and their impacts are perhaps unknown to high-level policy makers but they do dominate safety politics. Both cases show that strict application of the precautionary principle (PP) produce deleterious side effects, which go against the very political values that the regulation is supposed to protect. We show in particular that overly precautionary food safety regulation may harm the values related to food security. Third, we critically discuss the (strict application of the) PP. Finally, we conclude that even in the EU and other wealthy Western nations, problems of food security are much more relevant to human health and life expectancy than food safety. We recommend that current food safety regulation based on the precautionary risk-regulation reflex will be re-evaluated with the values of food security – inside and outside the EU – in mind.

Introduction

Due to several food-safety 'scandals' in the 1990s and 2000s regulation in this area has come increasingly under the spell of the precautionary principle (PP). This happened not only in the European Union (EU) but also in the United States of America (USA).[1] Especially the BSE crisis in 1996 had a very strong impact on regulatory earliness and stringency, two hallmarks of precaution.[2] The perceived scandal of the BSE case also led to a crisis in public confidence in public and scientific authority, which promoted transparency and public participation in food safety regulation,[3] which in turn enhanced precaution.[4] In the EU this was decisive for the GMO moratorium where the EU Commission was confronted by a hostile European Parliament that frequently asked "When will the Commission learn the lesson from the mad-cow disease."[5]

The turn towards precaution in ensuring food safety dates from before BSE. For instance in 1990 the PP was used in order to ban rBST and six beef growth hormones, along with imports of beef treated with these hormones. This ban led to a WTO dispute, which resulted in the judgment that the ban was not based on sound scientific risk assessment.[6] In the 2000s the highly precautionary regulation of GMOs also led to a WTO case, in which the EU again was convicted of breaking international trade regulations.[7] The precautionary ripple effects of the BSE crisis extend beyond the realm of food safety and affect other regulatory problems as well. For instance, Burgess describes how experience surrounding the Philips Report in the BSE Inquiry led the government in the United Kingdom (UK) to adopt precautionary regulation for cell phones.[8]

In this contribution we analyze some deleterious consequences of the highly precautionary nature of EU food safety regulation. We are, of course, not the first to do so. Benedictus *et al.*, for instance, discussed the price of the PP by calculating the 'Cost-effectiveness of BSE intervention strategies in the Netherlands".[9] By their calculation, the price of the PP in this case increased 'from 4.3 million euros per life year saved in 2002 to 17.7 million euros in 2005.' They predicted that, if present policies were continued, "the cost-effectiveness of BSE control strategies will further deviate from regular health economics thresholds as BSE prevalence and incidence declines."[10] Our analysis will not be focused on cost-effectiveness in monetary terms but will, instead, deal with systemic shortcoming and problems of two very different EU regulations.

In this contribution we look at two regulatory problems, one at quite a microscopic level while the other is to be found on a global level. On the one hand, we discuss the situation on the molecular scale, where for certain –(suspected) genotoxic carcinogenic– substances the regulatory approach is essentially characterised by zero tolerance. On the other hand, we discuss the way the European Un-

ion (EU) tries to ensure the sustainability of global fisheries. The connection between these two topics is the precautionary approach that is characteristic of both regulatory systems. We shall use practical problems in both systems to illustrate critical points that are more generally put forward with respect to the PP. The three topics of our contribution, therefore, are food safety, sustainability and precaution. Our fourth topic is food security; that is the availability of safe and nutritious food for all people. This topic relates to both the zero tolerance regime for (suspected) genotoxic substances and the goal of sustainability for fishing.

We start with the semicarbazide (SEM) case, which illustrates how low levels of prohibited chemical substances may result in the destruction of food supplies. This relates to the idea that ostensibly maximising chemical food safety by excluding certain chemicals may result in reducing food security. The Illegal, Unreported and Unregistered (IUU) Fisheries case we discuss subsequently is related to food security in another way. Here the administrative formalities put in place to ensure fish is caught legally and sustainably, seem to enhance inequalities and may promote fraud and bribery in developing nations. These problems endanger the income of the poor and result in their limited access to food.

The SEM case is linked to this as well, as the food supply at stake here was provided to the EU by fishermen from developing nations. In the third part of this contribution we shall discuss several critical points regarding the PP and the concomitant risk regulation reflex. Based upon our two cases we contribute to the on-going debate of this highly controversial issue. In particular we address the critique that regulatory measures will produce their own uncertain risks. We stress that regulatory decisions, including decisions about institutionalising regulatory regimes, should take fully on board such adverse side effects. Negligence in this respect may result in regulation amplifying complexity and ambiguity, the very two facets precautionary regulation tries to amend. We shall argue that in our two cases, serious adverse side effects are spawned, warranting fundamental rethinking of the underlying regulatory approach. More generally we conclude that the laudable goals behind precaution and sustainability need to be disconnected from hubris and utopian dreams. Reasonable and realistic limits must be respected.

Food and precaution: the semicarbazide (SEM) case

Setting scientific and policy standards that benchmark the benefits and risks of foods is of great consequence for industry, policymakers and consumers. In Europe, the core regulatory framework in food law is Regulation 178/2002/EC.[11] According to this Regulation, ‘food’ (or ‘foodstuff’) de-

notes ‘any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans’. The scope of Regulation 178/2002/EC concerns ‘all stages of the production, processing and distribution of food ...’ and its general objective is to provide ‘a high level of protection of human life and health and the protection of consumers’ interests, ...’ This Regulation thus sets general rules for all products that are brought to market. To that effect, the general requirements of this Regulation deal with food safety, presentation, traceability and related responsibilities of food business operators. Importantly, the Regulation also establishes the European Food Safety Authority (EFSA) and defines the Authority’s task and fields of competence and authority.

Scientific uncertainty, provisional risk management, and policy review seem the precautionary characteristics to assure the ‘high level of health protection chosen in the Community’. One such precautionary topic is to forestall exposure to antibiotics used in animal rearing and aquaculture beyond a certain limit.[12] The chloramphenicol (CAP)-episode in the first half of the 2000s launched a debate about the limits of science and technology and the risks and uncertainties of low-level antibiotics-exposure through food consumption, especially when genotoxic carcinogenicity is involved, as is the case with the SEM example.

The detection in 2001 of CAP in shrimp imported into the EU from Asian countries was regarded as a food scandal. The initial European response was to close European borders to fish products from these countries and make laboratories work overtime to analyse numerous batches of imported goods for the presence of this antibiotic. Some European countries went so far as to have food products containing the antibiotic destroyed.[13] The actual measurement of low-level concentrations in food, irrespective of toxicological and pharmacological concerns, on the consumer-level, heightened the awareness and anxiety of the presence and exposure to ostensible man-made chemicals in food.

Subsequent EU regulation (EC No. 470/2009) so far did not fundamentally amend the regulatory situation that arose since the mid 2000s.[14] Although the new regulation points at the ‘scientific and technical progress’ by which the ‘presence of residues of veterinary medicinal products in foodstuffs’ is detected ‘at ever lower levels’, a fundamental solution is not given other than making the MRPL (Minimum Required Performance Limit) level, whatever low concentration levels regulatory laboratories in the European Community could detect and confirm, an explicit level of concern.[15] Although the EU officially moved away from zero tolerance, laboratory competence is still the deciding regulatory factor in terms of accepting or rejecting food products. Again, ‘scientific and

technical progress', instead of toxicological relevance, is the determining factor in regulating chemical compounds deemed undesirable in foods. Put differently, the EU does not decide upon health issues with respect to the presence of certain chemical compounds but on the detectability thereof.

In order to appreciate the regulatory problem of genotoxic carcinogenicity, grasping the linear non-threshold (LNT) model is crucial. This regulatory model holds that for genotoxic carcinogenic substances and ionising radiation, *any level* of exposure –except for zero- implies a health risk.[16] This is why we spoke of a zero-tolerance approach: only zero exposure is ultimately deemed to be safe. This so-called 'one hit' model holds that exposure to even one molecule or ionising photon may result in irreversible health damage.[17] The potential effects of genotoxic carcinogenic substances and ionising radiation at very low-level exposures are theoretical: they are derived from this model as, of course, actually observing those effects in human populations would be out of the question. The effects, if at all existent, are simply far too small to measure.

In practice, the application of this model rests wholly on the technical ability to detect trace amounts of illegal substances of anthropogenic origin. This ability has greatly increased over the past decades. Whereas once one part per million (1 ppm; 1 mg/kg; 10^{-6}) was possible to detect, we can now detect one part per billion (1 ppb; 1 µg/kg; 10^{-9}) and sometimes even smaller amounts on a routine basis. Indeed, we have entered the realm of atto- (part per quintillion; 10^{-18}) and zeptomoles (part per sextillion; 10^{-21}) of detectable analytes.[18] Basically, this means that the zero tolerance level is shifting to ever lower exposure levels. Advances in 'cleaner' food production, is thus offset by increased detection capacities. The unspoken 'logic' of the LNT-model implies that a 'clean bill of health' can never be truly issued.

The further analytical technology advances, the more likely it becomes that we will encounter some irreducible level at which regulated chemical compounds normally associated with human activities are naturally present in foods. Thus, the prospect of natural detectability increases with decreasing concentration-levels, thereby fostering the uncertainty about human contribution.[19] In this section we present evidence of low-level concentrations stemming from natural sources instead of human interference.

The SEM case shows that, in spite of the new regulatory regime, problems persist with regards of the detection of low-level concentrations of antibiotics and their markers. In 2009 there was an increased incidence in Belgium in the detection of SEM, a marker molecule for the banned antibiotic nitrofurazone, in the freshwater prawns *Macrobrachium rosenbergii*. This was in contrast with all

other European countries where no significant increase in SEM-positive samples could be detected. A possible explanation for this phenomenon was that at the request of the Belgian Federal Agency for the Safety of the Food Chain (FAVV – AFSCA) all approved laboratories were asked to analyse complete prawns (meat and shell) for the presence of tissue bound metabolites of nitrofurans from December 17th 2004 onwards. This procedure is not common in other countries, as only meat is tested for the presence of SEM.

Nitrofurazone belongs to the nitrofuran group of antibiotics that, because of their potentially carcinogenic and mutagenic effects on human health, are prohibited within the European Union (EU) as therapeutic or prophylactic medicines in food-producing animals.[20] DG SANCO regards the presence of SEM as solely indicative for the illegal administration of nitrofurazone to live animals when it is found as a bound residue in unaltered/unprocessed food.[21] Nitrofurazone is still used as human medicine, especially in topical applications, that is medications applied to the body surfaces.

Now, it has been pointed out earlier that SEM seems a poor marker for nitrofurazone in light of the discovery that under certain conditions SEM in food arises from sources other than this illegal antibiotic.[22] These sources, until now, have been found to be man-made. Indications for a natural source were reported as well, however.[23] Belgian research revealed that *Macrobrachium rosenbergii*, cultivated under controlled lab conditions in the absence of nitrofurazone, was shown to have SEM present in the shell.[24] *Penaeus monodon*, cultivated under controlled lab conditions, also showed the presence of SEM in its shell, albeit at lower concentrations, signifying that crustaceans might produce SEM endogenously. Indeed, other wild-caught crustacean species that were tested by the research group (such as *Scylla serrata*, *Portunus pelagicus*, and *Nephrops norvegicus*) were shown to have bound-SEM in the shell at varying concentrations. The physiological source of SEM, now recognised as a natural metabolite in crustaceans, is as of yet unknown.

In conclusion, SEM cannot be used anymore as a marker molecule for the illegal use of nitrofurazone.[25] The ambiguity of SEM-sources confounds transparent and consistent regulation. The legal causal link between the presence of SEM and the prohibited use of nitrofurazone, and the corollary that if SEM is found in reported wild-caught produce then this produce must by implication have been cultured in the presence of nitrofurazone, is severed. Analysis of meat only as a straightforward solution to this conundrum is not watertight as in some cases SEM was detected in the meat at very low concentrations.

Generalising from the SEM case and other cases such as CAP, we hypothesise that given present capacities to detect extremely low-level presence of chemical compounds, the LNT-model in its practical application has encountered the limits of its usefulness, ignoring for now the science behind the model. This conclusion harks back to the application of the PP. The LNT-model with its built-in zero-tolerance attitude is a practical regulatory application of an extreme precautionary approach. The entrenchment of the LNT-model in the regulatory environment spawns the risk regulation reflex that ostensibly tackles unwanted exposures to chemicals through food consumption. The problems discussed above thus illustrate the more general critique that precautionary measures generate their own problematical uncertainties and insupportable stringencies. To this we return after presenting our IUU-case below.

Food and the sustainability catch: an inside look at the Illegal, Unreported and Unregistered (IUU) Fisheries Regulation

Sustainability has become a many-faceted goal comprising much more than the original idea of *Our Common Future*: 'development that meets the needs of the present without compromising the ability of future generations to meet their own needs.'[26] However, the abolishment of extreme poverty and hunger, the very first millennium goal, remains crucially important. In this context food security means making sure that our present and future generations have access to sufficient high-quality food.

Precaution is thought to be the tool of choice en route to a more sustainable society. *The Bergen Ministerial Declaration*, for example, states that in order to 'achieve sustainable development, policies must be based on the PP. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty *should* not be used as a reason for postponing measures to prevent environmental degradation.'[27] Equally, the European Commission sees the dimension of the PP going 'beyond the problems associated with a short or medium-term approach to risks. It also concerns the longer run and the well-being of future generations.'[28] We shall point out that the IUU –although quite a laudable policy with the essential objective to implement sustainable fisheries practices- generates negative side effects that violate the prime objectives of sustainability and precaution.

One of the aims of the Common Fisheries Policy of the European Union is to regulate the access to and use of the waters of the European Community. In the Communications from the Commission the resolution of the Member States of November 1976, which transfers the responsibility of sus-

tainable fisheries development to the Community, is reiterated.[29] At the World Summit on Sustainable Development (WSSD) in Johannesburg in 2002, the Community subscribed to the aim of global sustainable fisheries including the objective to maintain or restore stocks to levels that can produce the maximum sustainable yield with the aim of achieving these goals for depleted stocks on an urgent basis and where possible not later than 2015.

Inspired by the FAO, who have set up an international action plan in 2001 to prevent, deter and eliminate illegal fisheries (point 31d),[30] the European Commission started its own effort against IUU Fisheries in 2002.[31] The Commission has worked out a legal concept in relative silence and conducted several impact assessments until the first version of the IUU regulation was made public in 2007.[32] In the meantime a special task force of fishery inspectors was installed, guided by the Community Fisheries Control Agency (CFCA).[33] The CFCA inspectors were given mandates to inspect any vessel fishing under European flag on illegal practices within the European fishing zone.

The IUU-proposal would hypothetically ensure a fully traceable international catch certification scheme throughout the whole food chain for products introduced on the EU market. Third countries that export their wild caught fishery products to the EU were given the responsibility to create a system, which would ensure full traceability of the catch towards registered vessels or fishery management organizations.

On the 29th of September 2008, Council Regulation 1005/2008 was published,[34] which announced that the implementation of the regulation was to be effected before the first of January 2010. For all the stakeholders this time span proved to be too short to prepare for the implementation. In the time left, many applications for postponement of the regulation were sent to the Commission by both third countries and EU member States, but all of them were declined as not to delay implementation.

The implementation-regulation 1010/2009/EC was published on the 22nd of October 2009[35] and immediately it became clear that not only the third countries had to adapt their systems with respect to the issue of IUU, but the EU Member States as well. However, for Europe there was no regulation to deal with *internal* IUU, as was pointed out by third countries, despite the fact that Council Regulation 1005/2008/EC clearly indicated the notification obligation of both Member States and Third countries as stated in preamble 7: ‘In line with the definition of IUU fishing, the scope of this Regulation should extend to fishing activities carried out on the high seas and in maritime waters

under the jurisdiction or sovereignty of coastal countries, including maritime waters under the jurisdiction or sovereignty of the Member States.'

Within the EU, the so-called Control Regulation was developed alongside the IUU regulation but wasn't finished before the deadline. Nevertheless, it had to be put in place as to level the playing field between Europe and the rest of the world when dealing with IUU. This Regulation (1224/2009), which deals mainly with technical requirements of the European fleet and its control, had been announced in 2009 to regulate and control fisheries under the European flag (the third largest fisheries fleet in the world). It was published on the 20th of November 2009, and it considerably enhanced the regulatory clout of the European Fishery Inspectors.[36]

In order to create a level playing field, the IUU regulation demands from vessels sailing under EU flag that when their catches are processed outside the EU and return afterwards at the EU borders for re-import, it needs to be considered as a third country catch. This implies that this part of the import into the EU needs to be accompanied with catch certificates, validated by the EU member state under which flag the fish was caught. This has created quite a regulatory burden.[37]

Considering the IUU certification problems within Europe itself, it came as no surprise that exporting third countries had great difficulties with IUU-regulation. In all exporting countries, especially where knowledge of European languages is limited, the authorities were struggling with this new set of rules. Apart from the Certificate of Origin (customs) and the Health Certificate (health), now a new set of certificates (sustainability) needed to be validated by an as of yet non-existing Customs department. It is not difficult to imagine the costs involved, which have to be paid by the exporters.

Russia, responsible for the biggest import volume of fishery product in the EU, refused to fulfil the IUU restrictions and did not register on the flag state list even in January 2010.[38] The Russian authorities threatened to refuse all exports from EU countries on the basis of doubts of illegal fisheries within the EU. Since the Russian whitefish catch had been one of the main points of concern in relation to global IUU fisheries, the exclusion of Russia from the system would mean a complete failure of all efforts. On the 13th of February 2010 both could come to an agreement. As a consequence, all fish that was caught under the Russian flag from the first of January to the 13th of February 2010 was *not* considered legal and has been refused for import into the EU.[39] In other third countries it appeared that many vessels (sometimes up to 60%) were registered in an exotic non-listed flag state for economic reasons, excluding them from export to the EU and devaluating their catch for the internal market. For all those operators, the regulation came as a severe setback.

All countries have had a ‘non-intended’ period of grace for frozen seafood imports, because catches from 2009 did not have to undergo the IUU formalities. With a written declaration from the authorities confirming the catch-date in 2009 or earlier, these goods were readily accepted by all EU ports in the first months of 2010, giving the EU port-authorities some time to install the system. For fresh seafood catches the system appeared to crash completely in the first weeks of 2010, as expected, because the airports were not ready for all the formalities. Interim solutions and concessions have been put in place to keep the trade of imported fresh fish going, but for many consignments this failed. Again, like in the SEM case, food had to be destroyed.

Overall, the future success of the IUU regulation will depend on the control system, because in the final analysis all imported produce needs to be certified. But if unregistered ships will be able to bring in their cargo without supervision, then fraudulent catch certificates should be easily obtainable. There has been a considerable amount of European budget made available for controlling *European* catches by the CFCA and other governmental control systems, but in third countries public funds for the final vessel control will be very limited. The IUU regulation will have to come up with a ‘black list’ of unregistered vessels with catch certificates being invalid. This ‘IUU’-fish, once offered to the EU, will be rejected by the competent authorities and then destroyed, or sold to ‘good cause’ institutes like zoos. This last point is worthwhile, because this might in effect create an unintended market for illegally caught fish. The IUU therefore does not only increase the risks of poverty and hunger, although any assessment on the magnitude of that risk cannot be done yet, but also threatens others important sustainability goals such as the reduction of bribery and fraud.

Although there is a broad international consensus against illegal fisheries, at the moment of writing the EU ‘black list’, which is laid down in regulation 468/2010/EC and first amended in regulation 724/2011/EC, only contains 88 vessels that have been engaged in IUU fisheries according to the RFMO reports sent to the Commission. Black lists of vessels from third countries are not available yet. When third country governments fail to develop activities to rule out IUU activities, articles 31 to 38 of regulation 1005/2009/EC provide tools to ban these countries’ wild caught products from the EU market. Although safety measures are built in to use these tools as a measure of last resort, we have learned from the EU chemical food safety measures that precautionary politics can create powerful trade barriers.

The precautionary principle and sustainability – reflections

The two cases presented here show the real-world complexities with respect to attempts to increase food safety and security for present and future generations. A common characterisation for both cases is that timely protective measures to prevent uncertain risks, i.e. risks as to which there is little or no data on their probability and magnitude, ostensibly brings the PP into focus. Uncertainty is the key driver of the PP.[40] The principle is presented as a way of handling modern uncertain threats, and is said to promote prevention of especially a long-term nature rather than cure already materialised injury.[41] The axiom put forward is that its implementation results in the reduction of those risks.

There are two main arguments to apply precautionary measures under conditions of uncertainty. First, we have to acknowledge that our actions always lead to unforeseen consequences and second, we need to acknowledge the vulnerability of the global ecosystems and human society. New technologies therefore need to be treated as a potential threat and can only be approved after extensive research and careful deliberation. As *Late lessons from early warnings: the precautionary principle 1896-2000* puts it: 'their very novelty might be taken as a warning sign'.[42]

A common criticism is that proponents of precaution tend to neglect the uncertain negative impacts of the regulation they propose.[43] Here lies the importance of the advice on *Prudent Precaution* by the Dutch Health Council.[44] In this context, we must acknowledge that all regulation is technology too. Lawmaking, for instance, is aptly named social or legal engineering since Roscoe Pound first coined these terms early in the 20th century.[45] As the Dutch Health Council recognises, precautionary policies will themselves also have unforeseen, uncertain and potentially catastrophic consequences, raising the precautionary paradox: precautionary reasoning can be used to generate a demand for a contradictory course of action as risks surround all sides of the precautionary equation.[46]

This paradox is one aspect in which precaution produces uncertainty, the opposite that it seeks to preclude. Another obvious way in which the PP generates uncertainty is the alleged prevention of future undesirable outcomes of human actions. Precautionary politics is never satisfied with research showing that no adverse effects have been reported. As 'absence of evidence' is not considered to be 'evidence of absence', proponents of precaution stress that adverse effects in spite of all the available evidence may yet arise in the future. This vacuous truism feeds on the erosion of trust in scientific knowledge; precautionary politics might accept any kind of 'smoking gun' that subsequently would necessitate precautionary action against the perceived correlated hazard.

At first glance, this would seem to suggest that the PP as such is circumvented. Incidents are used as (quasi-) 'proof beyond reasonable doubt' that will satisfy public opinion and politicians who, often in a grossly oversimplified manner, think in terms of the authority of 'scientific proof'.[47] The latter, and here's the catch, should be understood quite flexibly, as precautionary thinking fails to prohibit any catastrophic possibilities from its realm of application; it fosters 'doubt beyond reasonable proof'.[48] This is what Furedi calls a transition from probabilistic to possibilistic reasoning:[49]

'The emergence of a speculative approach towards risk is paralleled by the growing influence of *possibilistic* thinking, which invites speculation about what can possibly go wrong. In our culture of fear, frequently what can possibly go wrong is equated with what is likely to happen. The shift towards possibilistic thinking is driven by a powerful sense of cultural pessimism about knowing and an intense feeling of apprehension about the unknown. The cumulative outcome of this sensibility is the routinisation of the expectation of worst possible outcomes. The principal question posed by possibilistic thinking, 'what can possibly go wrong', continually invites the answer 'everything'. The connection between possibilistic and worst-case thinking is self-consciously promoted by the advocates of this approach. …'

This shift from probabilistic to possibilistic risk management characterises contemporary precautionary cultural attitudes towards uncertainty. Precautionary measures in the field of chemical food safety focus on dwindling amounts of increasing numbers of ostensive man-made chemicals that theoretically might be a risk to consumers, now or in the distant future. Expanding that regulatory discretion, driven by precaution, engenders the regulatory risk reflex that inconvertibly decreases our ability to further food safety. Indeed, this regulatory risk reflex simply drives policy further beyond the ecological threshold whereby uncertainty with respect to chemical sources and its risks increase. By extending our policy-horizon multi-generationally, we embrace enormous uncertainty, the very aspect we try to amend. For the most part this is done implicitly and by avoiding open confrontation or, worse still, being selective about certain risks.

A third aspect of precautionary culture ties in with this. The long-term strategy to be protective and sustainable is expanded upon by the notion that man, nature and society are vulnerable entities, which need to be protected against potentially disturbing influences here and now and far into the future. It is this ecological outlook, which clearly informs the policies to promote sustainability. The goal of sustainability is not only to protect future generations but also to recognise the interconnec-

tions between our actions concerning different policy fields. The promotion of clean air, for instance, needs to be connected to mobility, automobile production, spatial planning, and energy policies. Recognising such connections the EU policy department for clean air has now been incorporated in the broader group concerned with climate change.

This idea to connect policy fields is however far from new. *The Club of Rome*'s principal objective, from their first and most famous report onwards,[50] was to analyse and understand the basic interdependencies that link all the problems facing humankind across the globe: social injustice, malnutrition, poverty, illiteracy, unemployment, population growth, the obsession with economic growth, inflation, the energy crisis, monetary problems, the degeneration of cities, damage to the environment, the rise of the nuclear threat and political corruption. The professed interconnectedness was coined with the term 'world problematique'.[51]

Explicitly recognising this interconnectedness is valid, but brings with it a heightened sense of vulnerability by increasing the uncertainty about the unforeseen consequences of our actions through this vast interrelatedness. The potential consequences of one policy are seen to depend on developments in other domains. Both by looking far into the future and by connecting many policy fields, precaution in fact generates uncertainty and also fears for the future.[52] This is an undesirable and counterproductive effect. Indeed, our two cases illustrate this as the LNT model must be understood in the context of post WW II fears for future nuclear war,[53] and the IUU regulation responds to more recent fears about the depletion of our natural resources.

Summarising, we identify three interlocking causes for the precautionary contribution to uncertainty, the very problem it tries to avert. First, there is the general erosion of trust in scientific knowledge; 'proof beyond reasonable doubt' has turned into 'doubt beyond reasonable proof'. Second, there is the focus on potential threats for future generations; probability has turned into possibility. Third, there is the focus on the interconnectedness of our actions with regard to different policy domains, which *The Club of Rome* brought centre-stage in the early 1970s. Instead of limiting the problem of uncertainty, it is clear that these factors are conducive to expanding uncertainty to unprecedented levels, whereby the political demand for risk regulation intensifies.[54]

The cases revisited

Regarding the IUU regulation, despite its laudable goals and the critical issues it addresses with respect to maintaining world fish stocks, the stakeholders foresaw quite a large administrative burden,

which would create trade barriers for many third countries exporting to the EU. One impact assessment predicted considerable losses of exports from poorer third countries and the inevitable and detrimental emergence of a secondary market in fraudulent catch certificates.[55] A point of concern has been the exclusion of artisanal small-scale fisheries because of the technical difficulties involved in the certification procedures of the catches like illiteracy.

Economically and socially weak groups like small and unorganised Asian fishermen are effectively barred from exporting to the EU under IUU regulation. Bigger and better structured fisheries organisations will be able to secure the necessary documents perhaps even by illegal means if that will facilitate export to the EU. This is a serious problem because fraud and bribery already are major problems in developing countries.[56] They corrupt political life and the administration of society and enhance or solidify the huge inequalities and the concomitant exploitation of the poor in those countries. Viewed from this perspective, the present IUU regulation, again keeping in mind its laudable and valuable goal of sustainability, is far from sustainable.

With respect to chemical food safety regulation has been quite selective. By simply assigning certain compounds as man-made and indicative for illegal use, a naïve dichotomy between 'natural' and 'man-made' has been generated. The biochemistry of animals (or plants or even entire biogeochemical cycles) is immeasurably more intricate than the mere allocation of marker molecules for the ostensible legal control of certain pharmacons implicitly or explicitly suggests. It is absurd that the immense complex biogeochemical reality is forced into a highly reductionist legal construct put in place to presumably protect the public against 'toxic' chemicals of man-made origin in food. It is not an exaggeration to state that most if not all molecules that can be identified as man-made or man-induced will have their natural counterparts.

A famous example is the group of chemicals known as halogenated hydrocarbons, of which the chlorinated compounds are the most 'notorious'. Chlorine is one of the most abundant elements in the world. It was widely believed that all chlorinated organic molecules are man-made xenobiotic chemicals.[57] However, it has become increasingly clear that organohalogens are ubiquitously produced in nature. Some of these compounds are produced in amounts that dwarf human production. The sum total of different organohalogens is staggering –more than 5000 different natural organic halogen compounds have been identified so far- and come from widely diverging sources.[58]

So, regulating certain chemicals in food not only requires the still not properly addressed question of low-level exposure toxicity, but also whether an unambiguous causal link between chemical and

illegal conduct can be established. The precautionary-driven efforts to lower the levels of detection of sought-after compounds in food have increased uncertainty with regards to sources. Low levels of ecological background concentrations are present in food. With SEM (and CAP) we have crossed this ecological threshold. The LNT-model has reached the limits of its precautionary usefulness, apart from the scientific question whether the LNT-model has ever been empirically validated. This question strikes at the heart of the precautionary notion that zero exposure –as the express regulatory goal- denotes zero risk.

Indeed, already in the 1970s the US FDA acknowledged the need to *validate* linearity at low dose predictions for carcinogens. However, this effort revealed that the analysis of risks *lower* than only one individual in one hundred was not practically achievable for carcinogens within chronic animal bioassays. Thus, they referred to this study, performed with 24,000 mice(!), as the Effective Dose (ED01) study, also known as the 'mega-mouse study'.[59] This study, the largest ever undertaken, *failed* to validate linearity. Actually, a detailed re-analysis by an expert panel revealed an unequivocal *non-linear* dose-response for bladder cancer with risks *decreasing* below the non-exposed control group at low exposure doses.[60] Thus, small dosages of carcinogens were shown to increase the health-status of mice compared to non-exposed animals.

It is nowadays increasingly argued that the most fundamental shape of the dose-response is U-shaped, and hence linear models provide less reliable estimates of low-dose risk. This U-shape is usually referred to as hormesis.[61] Hormesis is in many ways the physiological equivalent of the philosophical notion that 'what won't kill you, will make you strong'.

We define hormesis in a continuum of dose-response models. Low doses could be stimulatory or inhibitory, in either case prompting living organisms to be dissociated from the homeostatic equilibrium that in turn leads to (over)compensation.[62] High doses push the organism beyond the limits of recovery. This is the classical toxicological object of research usually required as a result of public and regulatory fears and concerns, whereby hormetic responses are by default regarded as irrelevant, or even contrary to policy interests, and therefore unlooked for. Public concern about synthetic chemicals exposure seems to infuse public reluctance to view hormesis as a viable description of toxicological reality. Policymakers, similarly, are eager to address this concern and see no room for exploring hormesis and the possibilities of regulatory implementation.[63]

Therefore, precautionary-driven hazard assessments incorrectly focus their primary, if not exclusive attention, on the higher end of the experimental dose-response curve in order to estimate the No-

Observed Adverse Effect Level (NOAEL) and Lowest-Observed Adverse Effect Level (LOAEL), subsequently modelled with faulty linear assumptions whereby risks at low-dose exposures are grossly overestimated. The conjectural reduction of risk associated with the LNT-model –when it is the incorrect choice– does not reduce risk, relative to the alternative U-shaped dose-response model: it actually increases risk.

Precaution, as a means to forestall exposure to chemicals with a certain toxicological profile, is a flawed and unsustainable approach when considering chemical food-safety in light of the increasing capabilities of science and technology. It augments uncertainty with regards to the presence and sources of increasing numbers of detectable chemicals and proliferates public anxiety when a 'new' chemical is detected at ever-lower levels, whereby toxicological relevance is ignored. Clearly, more examples will come to the fore in the future when analytical capabilities have again raised the bar in detecting certain chemicals.

Overall, hormesis redefines the concept of 'pollution' and 'contamination'.[64] It questions the premise that 'pollutants' are categorically bad. This is innovative because modern environmental and public health legislation is built in large part, due to the linear models, on the moral dichotomies of safe versus unsafe, healthy or unhealthy, clean versus dirty, natural versus unnatural. Chemical substances are *not* either safe or unsafe; they are both, depending on exposure levels and adaptive responses from the exposed organisms.[65] As Ortwinn Renn remarks: 'With respect to hormesis it is ethically mandated that potential beneficial aspects of low exposure to potentially hazardous material are incorporated in the risk-benefit balancing procedure.'[66]

Very recently (2nd of July 2012), the European Food Safety Authority (EFSA) has proposed the use of the Threshold of Toxicological Concern[67] for chemicals with a known structure and for which the exposure is anticipated to be very low.[68] In this publication the EFSA wants to discuss the possibility to make a wider use of this risk analysis tool, which is to some extent analogous to the Toxicologic Irrelevant Exposure level,[69] in order to provide a food safety level for consumer health when there are no available scientific data (e.g. at low level exposure). This should, by extension, provide a strong regulatory tool to rule out food safety issues on naturally occurring chemicals with toxic effects at high concentrations.

Conclusions

Above we discussed two examples of strict precautionary regulation, which can be understood as a political answer to a –supposedly– fearful population. We further discussed more general problems with applying the PP in a precautionary culture that amplifies fear and drives public authorities towards a risk-regulation reflex. Furthermore, our cases illustrate that a precautionary logic conveys idealistic tendencies. This is clearly exemplified in the closing sentences of Whiteside's *Precautionary politics*: 'Most important, the PP reflects the realization that the whole community now embraces not only fellow citizens in one's own nation-state but also people across the globe and their successor generations. Precautionary politics means that we must take responsibility for maintaining the robustness of the intricately interconnected ecological systems that sustain life on this planet – even when we are far from understanding all the conditions that make them thrive. Never before has so much wisdom been required of humanity's slowly advancing capacity for political association.'[70]

Precautionary culture generates perspectives in multiple fields on the 'good society' that is sustainable and to all intents and purposes dealing with the uncertainties of the imminent and distant future. Sustainable development seems to require the systematic integration of the social, economic, and ecological domains, perhaps even leading to a different world order.[71] The discourse on environment and development points to a world of almost Utopian design. New basic orders in politics, economics, and social relationships at both the national and international levels are on the agenda. When reviewing both cases here, an oversimplified and disparaging 'administrative ordering of nature and society' comes to the fore, as Scott discusses critically in his *Seeing Like a State*.[72] Precaution implies to change the world based on preconceived ideas, instead of taking the world as it is and pursuing ways to build on opportunities and dynamics already present.[73]

As we know from history and literature, the attempt to realise an all-encompassing utopian ideal always exacts a very high price. Although the utopian ideal is presented as inclusive for all, the historical record shows it rather to be exclusive, creating a profound division between rulers and those who are ruled.[74] We certainly do not want to be overly dramatic here, but we have shown that there is indeed a price to be paid for the EU precautionary policies we discussed above that is not divulged in full. Unfortunately, and in accord with the history of utopian thought, the weaker groups in our own societies *and* in the developing countries pay that price, whereby precaution implicitly expresses some level of egotism of those who can afford to be precautionary.[75]

Problematic is the all-encompassing utopianism expressed in the LNT model and the IUU regulation. Our criticism of this utopianism should not distract from the need to consider as many valuable

aspects involved in a decision as possible. Our plea is that when we consider strengthening food safety, we should explicitly question the impacts for food security for EU populations as well as especially for disadvantaged citizens in poorer nations. In the phase of policy formation we need to balance the recognition that all human actions will generate unforeseen and unwanted side effects with the aim to generate more good than bad results. In the near future the EU will undoubtedly be faced with new food safety crises where politicians –referring to public fears– will demand even more strict regulation. We recommend that is those situations, the hard choices of balancing enhancing both food safety and security is to be dealt with in an explicit and transparent way. As a policy rule we commend: 'when in doubt prefer food security over food safety'.

From our perspective, it is important to remind ourselves of the fact that access to sufficient food of adequate nutritional quality is far more important for human health than protection from trace amounts of potentially harmful chemicals.[76] This may be obvious for people in developing countries but it is also true for the poorer citizens in EU member states. Malnutrition is a common phenomenon. In the Netherlands, it is recognised that 25 – 40% of people admitted into hospitals are malnourished. The Dutch Malnutrition Steering Group is trying to interest other EU nations in tackling this problem.[77] Nevertheless, the EU considers such aspects of food security to be primarily problems of developing nations.[78] That the EU has shifted its own concerns in the second half of the 20th century from food security to food safety became very clear in the process that led to the establishment of the European Food Safety Authority (EFSA). The original 1999-report regarding the never established European Food and Public Health Authority clearly stated that this new institution should be focussed on food security as a human health marker next to safety issues.[79]

This advice, however, was not heeded. The SEM case and the earlier CAP case thus obtain genuine significance, highlighting the institutionalised bias of the EU towards chemical food safety. Despite this regulatory one-sidedness, major improvements have been accomplished in the fight against poverty and hunger.[80] Nevertheless, major problems remain and bribery and fraud exacerbate them. 'Corruption and breakdowns in governance are major reasons why countries are struggling to reach the Millennium Development Goals' as the UNDP remarks.[81] Indeed, corruption, according to the United Nations' program Against Corruption Today (ACT), is a 'serious crime that can undermine social and economic development in all societies.'[82]

In conclusion, if an agency or any other official group (impacting societal well-being) involved in a regulatory risk assessment fails to account for new scientific information that can contradict its own

default assumptions or conjectures, its conclusions are apt to be biased and the onset of group thinking may undermine its ability to discern and best serve the public interest. We propose that EU policies aimed at sustainable food safety and security should embrace not only naïvely understood environmental issues. The ethical, social and economic view-screen must be widened and novel scientific developments and the actual results of the policies put in place should be taken on board in the development and implementation of policies. For the foreseeable future it seems quite clear that food security should be prioritised, even in the EU itself.

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