Regulating Catastrophic Risks by Standards

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This article analyses the role played by standards of protection in the regulation of catastrophic risks. It examines how to protect people against the occurrence of catastrophic events, considering that the related risk is highly uncertain and difficult to predict using rational methodologies. In this perspective, the article focuses on environmental risks and terrorist threats affecting common goods – namely environment and security – areas where any damage is susceptible to producing ruinous effects and huge casualties. Both natural and man-made disasters are capable of altering the normal legal relations that States are institutionally to ensure to their citizens. Therefore, the severity of the consequences of catastrophic events cannot be ignored, despite the low probability of their occurrence. However, in the absence of emergencies, exceptional measures may be adopted as a means of altering the legal framework, and thus the enjoyment, of fundamental freedoms and priorities in the allocation of public resources. No precautionary approach can escape from rational reflections about the opportunity-cost of any action, the cost-benefit analysis of countermeasures and the proportionality of every regulatory decision. In order to understand how to face those "low probability – high cost" risks, the article considers a specific method of regulating risks by resorting to standards of protection. By using thresholds of alarm, public administrations can decide upon best-fit countermeasures that will correspond to specific risk characterisations. To this end, the article analyses the administrative process of formulating standards and how they enable uncertain risks to be managed, thus promoting the development of a sound and accountable administration.

I. Introduction

Catastrophic risks present extremely serious challenges to the methodologies of risk regulation, because they are related to a high level of uncertainty and also to elevated consequences in terms of casualties and losses when they do occur. In the description of different kinds of risks which have in common the capability to produce disasters, these threats show up the very problematic issues of risk regulation, concerning both the content and the means for achieving objectives.

From the first standpoint, a pragmatic approach to risk regulation should recommend not reacting to low probability threats[1], because with regard to the real costs, the benefits of the protection are only just possible, indeed rarely achievable. Moreover, it is absolutely clear that the severity of the consequences

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1 See C.L. Comar, "Risk: A Pragmatic De Minimis Approach", 203 *Science* (1979), p. 309. Identifying the area of the relevant risk to be regulated in those phenomena where control could produce benefits would not be easily avoided, and that would not be rare and of small proportion; the author admits that catastrophic risks fall outside the category of significant risk, with serious consequences ("100 per cent chance of harm") for the parts eventually affected. Showing the need to rationalise risk regulation in order to improve both the efficiency in the use of resources and the effectiveness in the improvement of health and welfare, the author must recognise a gap in his model, which is the logical impossibility to give a coherent protection from low probability-high loss risks.

of catastrophic events cannot be ignored by states or by the international community, not only in the short run in their role as political actors charged with guaranteeing collective security, but also in the long run as institutions responsible for the respect of an inter-generational pact aimed at assuring sustainable development and use of scant resources.

For this reason, the consequences contribute towards re-definition of the notion of 'significant risk'[2]: A risk that cannot be accepted by society because it poses a threat affecting the ordinary management of legal, economic and political relationships. As a result, the concept of 'tolerable risk' does not overlap with a merely mathematical or statistical analysis of its probability, but is a regulatory concept that affects the effectiveness of the regulation[3].

It is therefore essential to have methodologies that may be employed to avert such kinds of risk in order to determine the right balance between the costs actually borne of facing up to a possible disaster and the expected benefits from such an investment of public resources. In particular, the precautionary approach cannot avoid rational reflections about the opportunity cost of any action, the cost–benefit analysis of countermeasures and the proportionality of every regulatory decision. The difficulty in quantifying these variables involves a high discretionary power on the part of regulators, a power which should be rationally limited in order to prevent abuses and to guide provision of due protection against uncertain risks.

On these grounds this article aims to analyse the role that could be played by standards in the regulation of catastrophic threats, looking at them as a balance between the absence of any precaution against disastrous events and the political will to anticipate them. First of all, focusing on environmental risks and terrorist threats, the traditional emergency approach to catastrophe is promoted in the light of the need for precautionary protection. Hence the analysis is centred on the management of uncertain risks and compares the solutions suggested by the precautionary principle with the ones offered by the categories found in economic analysis of law. In the absence of clear-cut results, the article considers the increasing protection set up by systems of thresholds of alarm which provide a standardised protection for every level of alert, and it investigates the administrative process of drawing up standards. In the final remarks, the analysis focuses on the limits and potential of the regulatory model, showing how they can contribute to the promotion and development of a sound and accountable risk administration.

II. The common good and catastrophic risks

The notion of catastrophic risk is highly descriptive, but it does not comprise any specific category of uncertain risks: Hence any menace, when combined with the particular conditions of the reference con-

2 The notion of significant risk is based on an efficiency assessment, according to which the regulation, when faced by the impossibility of eliminating risks, should be focused on their reduction to the extent to which the costs do not exceed the benefits, avoiding any inefficient regulation (that S. Breyer called the "tunnel vision" or "the last 10 per cent" regulation). See in the leading case in American case-law *AFL-CIO v. American Petroleum Institute*, 448 US 607 (1980); but also *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991); *United States v. Ottati & Goss, Inc.*, 900 F.2d 429 (1st Cir. 1990). The EU system does not endorse the zero-risk approach as well, and provides that the level of protection against risks should be based on a case by case analysis of the severity of the threat to human health, the degree of reversibility of its effects, the possibility of delayed consequences and the perception of the menace based on available scientific data. See in particular CFI, *Pfizer Animal Health v. Council*, Case T-13/99, [2002] ECR II-3305, paras. 145–146, 153; CFI, *Alpharma v. Council*, Case T-70/99, [2002] ECR II-3495, paras. 157–159, 165–166; see also ECJ, *Bellio F.lli Srl*, Case C-286/02, [2004] ECR, para. 58; ECJ, *Safety High-Tech*, Case C-284/95, [1998] ECR I-4301, para. 49. In the literature see P.F. Ricci and L.S. Molton, "Risk and Benefit in Environmental Law", 214 *Science* (1981), pp. 1096–1097; S. Breyer, *Breaking the Vicious Circle. Toward Effective Risk Regulation* (Cambridge, Mass., 1993), pp. 11–19; G. Majone, *Dilemmas of European Integration* (Oxford: Oxford University Press, 2005), pp. 133–135; A. Alemanno, *The Shaping of European Risk Regulation by Community Courts* (Jean Monnet Working Paper 18/2008), available on the Internet at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1325770>, pp. 33–36.

3 This approach is shared by EU regulatory system; indeed, the Commission acknowledged the "political responsibility" to "find answers" to "unacceptable risk, scientific uncertainty and public concerns"; see Communication from the Commission 2 February 2000, COM (2000) 1, "on the precautionary principle", paras. 5–6 (summary) and 1, 6.3.4. Moreover, EU courts settled that scientific evidence is a necessary condition, but not in itself sufficient for the exercise of the regulatory function. As a result, other non-scientific factors, such as interests and values, play a fundamental role in the definition of the tolerable risk. See CFI, *Pfizer Animal Health v. Council*, Case T-13/99, cit., para. 201; ECJ, *United Kingdom v. Commission*, Case C-180/96, [1996] ECR I-3903, para. 89. On this point see A. Alemanno, *The Shaping of European Risk Regulation by Community Courts*, *supra* note 2, pp. 41–45, who stresses the relevance of such approach in the *Hormones* dispute between EU and US before the WTO Appellate body (see Appellate Body Report, European Communities-Measures Concerning Meat and Meat Products, WT/DS26/AB/R, WT/DS48/AB/R, 16 January 1998). In this perspective, incorporating the fundamental issue of the right exercise of discretionary power, risks affect the same administrative organisation and action. See E. Fisher, "The Rise of the Risk Commonwealth and the Challenge for Administrative Law", *Public Law* (2003), pp. 462–466.

text, is potentially susceptible of producing ruinous effects impacting the population and the legal order[4].

In this perspective, the field of research is reduced to two emblematic catastrophic risks related to the protection of the common good: Environmental risk and international terrorist threats, which both need public regulation to prevent the disastrous effects from occurring. Despite their apparent dissimilarities, these areas nevertheless display many points in common.

First of all, concerning the protection of the environment and global and national security, any significant damage to their integrity is likely to produce ruinous general effects and huge casualties: Both natural and man-made disasters are capable of altering the ordinary legal relations that States must institutionally guarantee to their citizens. To cite one example, in the long run, global warming is capable of jeopardising even the survival of the human race; from the same point of view, international terrorism represents a stable (i.e. controllable) danger to global, regional and national security.

In line with this reasoning, ever since the 1980s, nation states – in particular, the USSR after the Chernobyl disaster in 1986[5] – and the UN have begun to consider the environment and non-military menaces as new issues on the global security agenda[6]. Moreover, it should not be forgotten that terrorist attacks may be launched against the environment, thus provoking environmental disasters. From this perspective, the objectives of protecting the environment and human health are not so distant from the premises and the goals of counter-terrorism, even though their specificity is apparent not only in terms of objective competence but also regarding the means employed to guarantee their defence.

III. The public law approach to catastrophes: Emergency *versus* risk regulation

In the traditional command-and-control model of regulation, protection against catastrophic risks is generally achieved through recourse to the category of emergency, which represents a safety valve for legal order that allows the introduction of exceptional powers aimed at restoring the normal course of legal relations. However, the system is designed not only to react to the emergency situation, but also to anticipate forthcoming emergencies of the same kind through integrating counter-measures in the ordinary system of public management. This physiological process of overcoming emergencies may possibly produce paradoxical effects, but at the same time it brings to light a fundamental social and political need to anticipate and prevent the incidence of the emergency.

The maintenance of an extraordinary order beyond the period that could be considered an emergency in the strict sense involves making permanent any powers and measures planned for a temporary period[7], expanding the capacity of the controlling authority, even though this might be to the detriment of enjoyment of individual freedoms, and legislating for the failure of the legal system while overcoming the hazard. Indeed, this approach encourages an altered interpretation of the regulatory principle, which prescribes that risks should be reduced to the lowest possible level: According to this second-best rule, any risk that cannot be eliminated should be reduced as far as possible[8]. However, where catastrophes are concerned, such a model of regulation (like the one developed in the USA in the field of health risks) ends up by legalising a permanent emergency state, which is at odds with the nature of emergency powers and with the need of Western democracies to limit their authority over the restriction of personal liberty.

Therefore, if the overarching need to prevent emergencies cannot be ignored, it must be considered as an opportunity for risk regulation to allow

4 For an overview on disaster definition, characteristics and classification see A. Minhans, *Disasters and Disaster Management*, paper available on the Internet at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1590128> (2010), pp. 1–9. Moreover, on the catastrophic outcomes of risk tradeoffs in regulation see F. Wharton, "Risk Management: Basic Concepts and General Principles", in J. Ansell and F. Wharton (eds), *Risk: Analysis, Assessment and Management* (Wiley, 1992), pp. 12–14; G. Little, "BSE and the Regulation of Risk", 64 *The Modern Law Review* (2001), pp. 735–736.

5 See S. Lonergan, "Security and Environment", in D.J. Cuff & A.S. Goudie (eds), *Global Change* (Oxford University Press, 2009), pp. 553–554.

6 More specifically, the UN Resolution 1625/2005 links the prevention of conflicts with the sustainable development and, afterwards the UN Doc. SC/9000 (2007) enhanced the issue of global warming to a relevant issue for the maintenance of peace and security. In the literature see F. Sindico, "Climate Change A Security (Council) Issue?", 1 *Carbon and Climate Law Review* (2007), pp. 29–34.

7 David Dyzenhaus, "The Permanence of the Temporary: Can Emergency Powers Be Normalized?", in R.J. Daniels, P. Macklem and K. Roach (eds), *The Security of Freedom: Essays on Canada's Anti-Terrorism Bill* (2001), p. 21.

8 See G. Majone, "Dilemmas of European Integration", *supra* note 2, pp. 132–133. According to the author, this regulatory principle is the American equivalent of the precautionary approach, because it does not involve any consideration of the costs and benefits of regulation.

the prevention of not only the sudden incidence of an emergency situation, but also any paradoxical effects or abuse of the necessary recourse to emergency powers. In this context, a flexible system of alarm thresholds could be viewed as a rational instrument for managing uncertain risks ahead of an emergency and for mitigating the impact of its occurrence.

As a matter of fact, in the absence of disasters and casualties – therefore in the absence of an emergency situation – the adoption of extraordinary measures would highly alter the ordinary legal framework and thus both the enjoyment of fundamental freedoms (such as the right to economic initiative or the right to privacy) and the settlement of priorities in the allocation of public resources.

From this point of view, the management of the terrorist threat is symbolic: In the aftermath of 11 September 2001 the fight against terrorism has rendered arduous the recognition of fundamental rights simultaneously with the emergency rationale; in fact it has pushed the historical tension between liberty and public powers to a critical stage and shown that the *acquis* of democracy and the rule of law itself can be openly questioned when the survival of the state is at stake. Indeed, in the face of the terrorist threat, collective security has become an unavoidable issue which governments want to ensure and improve as far as possible. Pursuing this duty, governments have introduced restrictive regulations in order to prevent further attacks from occurring and in order to reassure the public about the effectiveness of the state reaction[9].

As a consequence, the emergency has become the ordinary means of ensuring security, thus the model of emergency administration becomes an ordinary method of administration and provides bias in the national anti-terrorism regulations, showing the very political side of the law. In this way the notion of emergency expands from an exceptional order for regulating unknown and unforeseeable events to an alternative instrument for achieving efficiency in the legal system. In widening the emergency regulation into a method of governance for critical situations[10], not only is the relationship between exceptional facts and temporary countermeasures altered, but also the exercise of fundamental rights is brought into question in the attempt to prevent any further uncertain catastrophe from occurring.

From this viewpoint, resorting to risk regulation has become a necessary step to reduce the use of special and derogatory powers and damages in the management of emergencies: This way, the governance of uncertainty gets back to a state of balanced combination of risk prevention and emergency management.

In this perspective, catastrophic risks are regulated in order to preserve the collective capability to make choices: By making use of precautionary measures, flexibility in decision-making can be preserved for the future[11]. However, it should be stressed that applying risk regulation methodology to uncertain risks means introducing models of risk management where supportive risk assessment is sparse. As a result, the legal situation prevails over the scientific one and deals with the notion of significant risk and the available resources. Consequently, the specific principles of risk management play a fundamental role in addressing the strategy against risks: Reference is made to the precautionary principle used in the European legal framework and to the cost–benefit analysis, which is more popular in US regulations.

IV. Precautionary approaches in the management of catastrophic risks

The research into anticipated protection against disasters collides with a double uncertainty: The probabilities that a ruinous case will occur and the range of the effects related to such occurrence.

Applying the precautionary principle to such kinds of risk means the assumption of decisions in a context of scarcity of scientific information in order to meet the possible damage and the severity of the threat. A clear example of such an approach is

9 B. Ackerman, "The Emergency Constitution", 113 *Yale Law Journal* (2003–2004), p. 1037.

10 This kind of regulative perspective has been called "catastrophic state", in order to portray a state which resorts to the administration of disaster as "a form of governance and a way of ruling", regularly putting at risk the ordinary system of law. From this point of view, the catastrophic state works on completely different premises from the "providential state" based on the solidarity principle, because it rests on the management of disasters, and not on their prevention. See A. Ophir, "The Two-State Solution: Providence and Catastrophe", 8 *Theoretical Inquiries in Law* (2007), pp. 123–144.

11 See C.R. Sunstein, "Irreversible and Catastrophic: Global Warming, Terrorism, and Other Problems: Eleventh Annual Lloyd K. Garrison Lecture on Environmental Law", 23 *Pace Environmental Law Review* (2005–2006), pp. 856–857. In particular, the author considers the preservation of the capability to choose in terms of an option value, applying a monetary valuation to the public decision-making issue in an environmental context, which is in line with the economic analysis of law. In this perspective, he distinguishes the willingness to pay to use a pristine area (use value) from the willingness to pay for the option to use the same environmental amenity in the future (option value), basing them both on the existence value of the place.

Principle 15 of the Rio Declaration on Environment and Development, which claims that the lack of full scientific certainty cannot be used to postpone the adoption of cost-effective measures to prevent environmental degradation from serious and irreversible harm[12]. Therefore, the precautionary principle has been elevated to a decision-making rule that can justify and encompass the introduction of any measure which seems to be efficacious in the struggle against the loss of future chances (and the occurrence of potential harm).

An outstanding American scholar, C.R. Sunstein, defines this approach to catastrophic risks as the "irreversible harm precautionary principle", recognising the intrinsic opportunity for public proactive intervention which reduces the possible irreversible damage[13]. Looking at risks through the lens of precaution, he defends the coherence of this methodology in catastrophic instances from the incoherence generated by the European version of the precautionary principle. More precisely, Sunstein blames the strong approach to precaution which imposes a high burden of proof on the proponent of any activity with regard to its safety profile, because it is susceptible to producing paralyzing effects on social-economic development[14]; however, he makes one exception to this reasoning by adopting a weak version of the same principle in the attempt to tackle the issue of irreversible and catastrophic risks.[15] This interpretation, however, cannot ignore the fact that that the weakness of the requested burden of proof – justified by a political goal which declares that science should not govern the law – could become an unlimited delegation of the power to regulate risks where the scientific information is sparse. For this reason, framing the irreversible harm precautionary principle, Sunstein reflects also on the possible negative outcomes that such a rational approach could lead to, and from this perspective he tries to qualify its limits and potential. In particular, the precautionary counteraction should be graduated in degree in order to avoid aggressive forms of prevention that are able to produce irrationality in regulatory policies. This is the case of a *maximin* behavioural strategy towards the precautionary approach, which consists in combating the worst-case scenario without taking into account the degree of risk aversion and uncertainty and the effects of that option. Following Rawls, the choice of such an action can only be justified if the costs of pursuing it are indifferent in respect to the opposing option[16].

Sunstein tempers the irreversible harm precautionary principle by introducing some further variables that have to be balanced in the definition of the counter-measures against disastrous risks, namely "the full range of social risks", "the idea of cost-effectiveness, which requires regulators to choose the least costly means of achieving their ends", the "distributional considerations" and "the costs [...] as such"[17]. As a result, the struggle against catastrophic risks must be assessed in the light of a comprehensive analysis of the social, economic and political reasons and interests at stake; the output is a set of decisions which sets the feasible level of protection against catastrophes in a specific legal space. This

12 The United Nations Conference on Environment and Development, held in Rio de Janeiro, 3-14 June1992, adopted the Rio Declaration on Environment and Development which states in Principle 15 that "in order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

13 See C.R. Sunstein, "Irreversible and Catastrophic", *supra* note 11, pp. 13–15.

14 On the application of the precautionary principle in the EU see COM (2000) 1, cit. (in particular para. 6.4 on the reversal of the burden of proof). Moreover, in the case-law see ECJ *Sandoz BV*, Case 174/82, [1983], ECR 2445; ECJ, *National Farmers' Union et al.*, Case C-157/96, [1998] ECR I-2211; ECJ, *United Kingdom v. Commission*, Case C-180/96, [1998] ECR 3903; ECJ, *Association Greenpeace France et al.*, Case C-6/99, [2000] ECR I-1651. However, it is worth noting that the EFTA Court played a fundamental role in the definition of the content of the precautionary principle in the case *EFTA Surveillance Authority v. Norway*, E-3/00, [2001] EFTA Court Report 2000/2001, 73, at paras. 30–31. Its acknowledgement as a general principle of the EC legal order occurs in the case CFI, *Artegodan et al. v. Commission*, Case T-74/00, [2002] ECR II-4945 and in the case CFI, *Solvay Pharmaceuticals v. Council*, T-392/02, [2003] ECR II-1825. In the literature see, among others, A. Alemanno, *The Shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Certainty* (Bocconi Legal Studies Research Paper No. 1007404, 2007), available on the Internet at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1007404>, pp. 1–13; E. Fisher, *Opening Pandora's Box: Contextualising the Precautionary Principle in the European Union* (Oxford Legal Studies Research Paper No. 2/2007), available on the Internet at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=956952>, pp. 1–43; E. Fisher, J. Jones and R. von Schomberg (eds), *Implementing the Precautionary Principle. Perspectives and Prospects* (Elgar, 2006); F. De Leonardis, *Il principio di precauzione nell'amministrazione del rischio* (Giuffrè, 2005); N. de Sadeleer, *Environmental Principles: From Political Slogans to Legal Rules* (Oxford University Press, 2002); G. Majone, "What Price Safety? The Precautionary Principle and its Policy Implications", 40(1) *Journal of Common Market Studies* (2002), pp. 89–109.

15 See C.R. Sunstein, "Irreversible and Catastrophic", *supra* note 11, p. 6.

16 See J. Rawls, *A Theory of Social Justice* (revised ed., Harvard University Press, 1999), pp. 134–135. In particular, the author recommends the use of the *maximin* principle in the case of uncertain risks with potential catastrophic outcomes when the costs of resorting to the principle are relatively indifferent. On this perspective, see C.R. Sunstein, "Irreversible and Catastrophic", p. 880.

17 C.R. Sunstein, *ibid.*, pp. 893–894.

means a re-introduction of a burden of evidence on the regulator, which should demonstrate the effectiveness of the precautionary measures.

In this framework, the admission of the public capacity to face catastrophic risks must be analysed concretely in the regulative process, in view of its becoming a rational principle of legal decision-making affecting the correct exercise of discretionary power. Administrative law seems to provide fundamental instruments for weighing up all the variables at stake in the definition of public protection. In particular, the guarantees of participation and analysis of interests in the administrative procedure seem to define a specific method to allocate public resources. The issue at stake is the way the risks and the legal positions are balanced: The core of the public decision-making rests upon the analysis of different variables, without a predetermined result.

Moving from the same necessity to provide a precautionary protection against uncertain risks, R.A. Posner suggests responding to those very low probability – very high cost instances by making use of the instruments of the economic analysis of law[18]. In order to avoid costs exceeding benefits in the prevention of catastrophes, this distinguished law and economics scholar draws up an inverse model of the traditional cost-benefit analysis: The approximated probability of the occurrence of a calamity is worked out by dividing the public resources devoted to the prevention of a particular catastrophic risk by the social costs of the possible materialisation of such an event[19]. As a consequence, uncertainty can be quantified and contrasted in an economic way, namely by considering that the optimal expenditure must equate marginal cost and marginal benefit. In this perspective, independent assessments of the probability of such kinds of risks may be used as a hint about the correctness of the allocation of public resources. Moreover, waiting for a scientific reduction of uncertainty and delaying the precautionary action means an increase in the expected losses from an unexpected catastrophe.

This approach to uncertain risks deals with a kind of *public insurance* against such risks that appears to be an economic assessment of the precautionary principle. However, this approach is based on estimating the amount of the possible losses by pooling uncertain cases as if they were similar, without taking into account their distinguishing and unique characteristics[20]; and so there is distortion of the same foundation of the insurance principle. Moreover, Posner's model risks ending up with the application of the *maximin* rule: Imagining the worst-case scenario, i.e. that only higher expenditure of public resources will reduce the possible losses without jeopardising the economic balance of marginal costs and benefits. As a result, the system runs into a double anomaly which neglects probability and consequences. Indeed, the payment of an "emotion premium" disregards the probabilistic analysis without giving a sufficient certainty of being prepared against disasters, because catastrophes are unique events and most likely "virgin risks"[21].

Furthermore, it has been noted that Posner's analysis is a "mathematical trick" used "as a justification for fundamental changes in legal institutions"[22]: By proposing different administrative reforms – which refer to education, fiscal tools, reorganisation of administrative agencies and redefinition of the role of science in the legal procedure before courts[23] – the author seems to provide a common response, that is, an enhancement of the administrative control which implies an irreversible sacrifice of civil liberties.

However, the case of terrorism is a clear example of the ineffectiveness of such an approach: The mere at-

18 See R.A. Posner, *Catastrophe: Risk and Response* (New York: Oxford University Press 2004), p. 56.

19 See R.A. Posner, "Castastrophe", *supra* note 18, pp. 176–184; *id.*, "Efficient Responses to Catastrophic Risk", 6 *Chicago Journal of International Law* (2005–2006), p. 523. More precisely, the author considers that expected cost (C) is the mathematical product of probability (P) and losses (L), according to the formula C = PL.

20 In this perspective see F. Knight, *Risk, Uncertainty and Profit* (Italian edition, Florence: La Nuova Italia, 1960), pp. 233–234. The author claims that in the case of risks – whose probabilities are known – the distribution of outcomes can be inferred by grouping ("consolidating") similar instances on the basis of *a priori* calculation or statistics; on the contrary, in uncertain situations – that is, where probabilities are unknown – this grouping strategy is not possible, because every case is unique by definition.

21 See A. Berger, C. Brown, C. Kousky and R. Zeckhauser, *Five Neglects: Risk Gone Amiss*, paper available on the Internet at <http://www.hks.harvard.edu/fs/rzeckhau/Five_Neglects.pdf>, p. 3. Moreover, about *emotion premium* in the case of *probability neglect* see C.R. Sunstein and R.J. Zeckhauser, *Overreaction to Fearsome Risks*, paper available on the Internet at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1319881>, pp. 7–9; C.R. Sunstein and R.J. Zeckhauser, *Dreadful Possibilities, Neglected Probabilities*, paper available on the Internet at <http://www.hks.harvard.edu/fs/rzeckhau/Sunstein4-6-09.pdf> (forthcoming). As it concerns *consequence neglect* in the case of *virgin risks*, cf. C. Kousky, J. Pratt and R.J. Zeckhauser, *Virgin Versus Experienced Risks*, paper available on the Internet at <http://www.hks.harvard.edu/fs/rzeckhau/kousky-pratt-rjz-revised.pdf>.

22 See R.A. Posner, "Book Note: The Days After Tomorrow: Catastrophe: Risk and Response" (New York: Oxford University Press, 2004), in 118 *Harvard Law Review* (2005), pp. 1343–1344.

23 See R.A. Posner, "Book Note", *supra* note 22, pp. 200–244.

tention to the harm caused by attacks has determined "the permanence of the temporary" which does not guarantee the collective security that it promises and puts at risk the protection of fundamental liberties. This instance shows that such a model of protection does not consider the opportunity cost of precautionary measures, compromising the coherence and the capability of defining priorities in regulation[24]. From this point of view, the US Supreme Court clamped down on the possibility of reacting to low probability risks in an extreme manner, interpreting the administrative duty to consider the worst-case scenario in the environmental assessment statements only where it was not completely speculative[25]. That means creating a balance in catastrophic risks between the scientific assessment of probabilities and the possible effects of the materialisation of the risk to the legal order.

V. Regulating catastrophic risks by standards

The analysed approaches to catastrophic risks do not arrive at conclusive statements on the principles of regulating disasters, thus avoiding any considerations of the opportunity costs in regulating instances of very low probability/very high cost and demonstrating a constitutively limited effectiveness of the counteraction.

For this reason, it is possible to reconstruct the problem of catastrophic risk regulation on a more traditional basis, one that balances the interests at stake in the light of the characteristics of the risk at issue against the expected effectiveness of the measures. This reasoning relies on analysis of proportionality in the adoption of precautionary rules that does not ignore the cost–benefit equilibrium, even though it is included in a more ample analysis of qualitative and quantitative variables. From this standpoint, the administrative procedure is the regulative venue of such a kind of decision-making process, and the definition of standards of protection can be a useful instrument for regulating the uncertainty that divides catastrophic risks from disasters.

Indeed, the fundamental principle of fairness which dominates the administrative procedure is able to provide significant guarantees of protection for individuals in public decision-making. The elaboration of standards of protection through recourse to this kind of procedure allows for the outlining of the social acceptability of risks and of introducing accountable methods to govern risks and uncertainty.

More precisely, the regulatory administration sets up a rule-making process allowing the different interests at stake to participate, thus allowing private and public parties to submit their legal situations and even their risk analysis. If the participation of other administrations is important in order to coordinate the different public interests and policies (also taking into account the settlement of regulatory priorities), the contribution of private parties has an intrinsic defensive character: Any public decision that affects single individuals must respect the right to be heard or, at least, to have a written cross-examination. This is a cultural guarantee, inherent in Western tradition, which affects the human dignity. Moreover, a further participative model has been recognised where public decisions do not directly affect the private legal sphere because of their general nature, so that in some cases the administrative procedure appears to substitute the political process for interest assessment[26]. The regulatory process has been developed from public consultation to forms of co-regulation, giving different relevance to the private contribution to the settlement of public regulation: In the first case the administration tries to reduce its asymmetric information by submitting the draft decisions to the interested parties, while in the other case the public

24 On the relation between opportunity-cost and precautionary principle see G. Majone, "What Price Safety?", *supra* note 14, p. 101.

25 See *Robertson v. Mathow Valley Citizens Council*, 490 US 332, 354–356 (1989).

26 See R.B. Stewart, "The Reform of American Administrative Law", 88 *Harvard Law Review* (1974–1975), pp. 1723–1790, who reckons the American rule-making process is an administrative proceeding based on interest representation. See also *id.*, "Il diritto amministrativo del XXI secolo", 1 *Rivista trimestrale di diritto pubblico* (2004), p. 10; *id.*, "U.S. Administrative Law: A Model for Global Administrative Law", 68 *Law and Contemporary Problems* (2005), pp. 74–75. It should also be pointed out that removing the individual concern clause from the requirements of any natural and legal person to challenge regulations, the Treaty on the Functioning of the European Union (TFEU) broadened the private chances to sue for the annulment of normative acts (see Article 263 (4) TFEU, which amended Article 230 (4) ECT). In order to reduce the potential growth in litigation, the regulator should necessarily widen the participation to regulatory proceedings and to some extent it would get closer to the American interest representation model. See A. Meuwese, Y. Schuurmans and W. Voermans, "Towards a European Administrative Procedure Act", 2 *Review of European Administrative Law* (2009), pp. 4–5, 30–31. On the present features of public participation in EU see Communication from the Commission 11 December 2002, COM (2002) 704, "towards a reinforced culture of consultation and dialogue – General principles and minimum standards for consultation of interested parties by the Commission".

agency makes a negotiated agreement with private interests and the public decision is the result of such negotiation.

This way, the administrative process allows for equilibrium between private reasons and public guidelines, through adopting general rules for governing significant risks. Thus, the cost-benefit analysis becomes a measure of efficiency, but not the sole and necessarily decisive rule of choice. Moreover, the application of the precautionary principle must take into account those systemic aspects that Sunstein indicates as fundamental variables that the public authority should consider in risk regulation. Therefore, the precautionary approach to catastrophic risks becomes the coherent result of reasonable exercise of discretionary power in the light of the proportionality principle: The administration has to show that the adopted measures are suitable and necessary to pursue the policy goal and that they do not affect the individual legal sphere beyond the required measure[27]. This involves the application of regulation impact assessment (RIA), which is aimed at verifying not only the effectiveness of such provisions but also the reasonableness of the sacrifice requested to individuals: Through the consultation process, the regulator can *ex ante* weigh up the likely economic, environmental and social implications of action and highlight the potential trade-offs in risks and benefits[28]; in doing so, the search for better outcomes and performances in regulation should inevitably absorb distributional issues in the regulatory proceeding, so that risk policies can settle the correct balance between the cost-benefit approach and the precautionary one[29]. Hence, the implementation of better regulation strategies[30] can become the roadmap for the development of a standard-based model of risk regulation: Pursuing the general suitability of rules regardless of sector specificities, such methodology comes out as "a type of meta-policy targeting the governance of the regulatory process"[31]. Therefore, this regulatory model can contribute determining more appropriate levels of protection and, as a consequence, organisational issues play a decisive role in its implementation. In this framework, the statement of reasons is the appropriate venue where those limits to the discretionary power should emerge.

Moreover, the way standards are formulated reveals how the regulator pursues the policies' goals and, thus, the methods followed by the administration in regulating risks. To this end the analysis of the characteristics of standards made by S. Breyer at the beginning of the 1980s is very helpful[32].

First of all, a standard can satisfy the regulative purpose directly or indirectly, according to the effective capability of the administration involved to control the enforcement of the same rule. Hence,

27 In this regard see COM (2000) 1, cit., paras. 6.3.1 and 6.3.4, which temper the precautionary approach with the assessment of the proportionality of the regulatory action and the cost-benefit analysis.

28 Making the RIA a systemic part of the regulatory process requires rationalisation in the allocation of the public resources. To this end, in 2005 the European Commission introduced a proportionality requirement in impact analysis, so that its deepness (and, in particular, the level of public participation and the accuracy of its findings) should be commensurate with the significance of the regulatory action and the range of the expected effects. This way RIA is strictly reconnected to the other main goal of better regulation, the administrative simplification. See Communication from the Commission to the Council and the European Parliament 16 March 2005, COM (2005) 97, "Better Regulation for Growth and Jobs in the European Union", para. 2A and Annex I; European Commission, Impact *Assessment Guidelines*, 15 June 2005, SEC (2005) 791, para. 5. Moreover, the proportionality requirement has been implemented by Impact Assessment (IA) Guidelines, 15 January 2009, SEC (2009) 92, which bases the significance of impacts on the type and the content of regulatory initiative (see para. 3.2). On the proportionate level of analysis for IA see also A. Alemanno, "The Better Regulation Initiative at the Judicial Gate: A Trojan Horse within the Commission's Walls or the Way Forward?", 15 *European Law Journal* (2009), note 76, available on the Internet at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1297170>; A. Renda, *Impact Assessment in the EU. The State of the Art and the Art of the State* (Brussels: CEPS, 2006), pp. 91–96; J. Wiener, *Better Regulation in Europe* (Duke Law School Legal Studies Paper No. 130, 2006), available on the Internet at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=937927>, pp. 20, 36.

29 J. Wiener defines this approach to regulation as a "warm analysis", because it focuses on regulatory impacts and tradeoffs, mitigating possible overreaction to risks and at the same time being not tied up to rigid measurements of cost and benefits. See *id.*, "Better Regulation in Europe", *supra* note 28, pp. 33–38.

30 In the literature on better regulation see, among others, A.C.M. Meuwese, *Impact Assessment in EU Lawmaking* (Kluwer Law International, 2008); L. Allio, "Better regulation and impact assessment in the European Commission", in C. Kirkpatrick and D. Parker (eds), *Regulatory Impact Assessment. Towards Better Regulation?* (Edward Elgar), pp. 72–105; S. Weatherill (ed.), *Better Regulation* (Hart Publishing, 2007); C.M. Radaelli, "Whither Better Regulation for the Lisbon Agenda?", 14 *Journal of European Public Policy* (2007), pp. 190–207; C.M. Radaelli and F. De Francesco, *Regulatory Quality in Europe: Concepts, Measures, and Policy Processes* (Manchester University Press, 2007); J. Black, "Tensions in the Regulatory State", *Public Law* (2007), pp. 58–73; R. Baldwin and M. Cave, *Understanding Regulation. Theory, Strategy and Practice* (Oxford University Press, 1999).

31 C.M. Radaelli and A.C.M. Meuwese, *Better Regulation in the European Union. The political economy of impact assessment*, paper available on the Internet at <http://centres.exeter.ac.uk/ceg/research/riacp/documents/The%20Political%20Economy%20of%20Impact%20Assessment.pdf>, pp. 1, 8, 10. In particular, the authors analyse the evolution of better regulation and deem it a tool that providing (more or less binding) rules about rule-making, becomes a sort of constitutional method of administration.

32 S. Breyer, *Regulation and Its Reform* (Cambridge, MS: Harvard University Press, 1982), pp. 103–107; see also R. Baldwin and M. Cave, "Understanding Regulation", *supra* note 30, pp. 118–124.

formulating standards implies considerations about the available means and resources which are fundamental in order to guarantee the effectiveness of the regulation.

In this respect, the regulator should fix the degree of specificity of the standard, settling and mixing detailed rules and more flexible and general prescriptions about the ultimate goals: If in the former case quantitative thresholds of protection control activities and products, in the latter the regulated area is defined by qualitative parameters which can be referred to as legal undetermined concepts[33].

Therefore, it is necessary to ascertain the opportunity for introducing strict requirements (*design standards*) or to assess the adequacy of the protection on the basis of the outcome, having no regard for the process (*performative standards*). This distinction shows the dimension of the administrative informative assets, because the quantitative model lays on the administration the burden of marking out the level of protection, whereas the performative reference involves an obligation on the regulated parties to demonstrate the suitability of the obtained results, but not the characteristics of the means used. As a consequence, the detailed approach implies a broader need for the private parties to participate in the administrative process of formulating standards. On the contrary, the flexible approach can be decisive should the administration not have the necessary information to set a more precise standard, so it can delay their knowledge at the moment of the enforcement.

VI. Progressive standards of protection: Systems of alarm

The specificity of regulating catastrophic risks consists in the definition of a progressive scale of standards that defines increasing levels of public attention to a threat, in order to manage the period that separates the current time from a possible emergency in the attempt to preserve the legal order's ordinary route as far as possible and reduce the harm arising from the materialization of a catastrophe as much as possible. In this respect, by availing itself of gradual and continuous thresholds of alarm, regulators can settle different countermeasures corresponding to specific risk characterisations, based on scientific inferences from available and updated data. In this way it is possible to fix and gradually control the level of risk that is to be considered unacceptable for the legal order, without turning an uncertain danger into an absolute and unjustified priority (in terms of resources) of the whole society.

Both in the environmental protection and in the anti-terrorism policies there are some models of this kind, which act as informational instruments: Through the continuous monitoring of sources of risk and the constant flow of scientific findings to the interested parties, regulators can detect the possible threat in advance and promptly alert the relevant community. Such prevention systems can therefore be used for both risk regulation and the setting up of emergency plans. It is not by chance that the introduction of such instruments has been favoured in the event of a serious crisis. Clearly the sciences involved in such functions are different: Whereas the environmental risk is assessed by empirical sciences, the terrorist menace is also assessed (at least) by human sciences which investigate the origin and the activities of terrorism. As a consequence, the methodologies of risk assessment refer to different variables and, the terrorist risk particularly involves the acknowledgement of political and legal issues.

In the environmental protection the first strategic approach to disaster prevention is represented by the *global early warning system* (EWS), the UN alert program for the prevention of all natural calamities that was introduced after the South-East Asian tsunami of December 2004. However, the general field of applicability of the mechanism does not imply that the fundamental specificities of risks are not acknowledged in the attempt to prevent and meet them. Notwithstanding, the system generalizes a phased control of the preventive interventions which provide the identification of risk: The alarm, the spread of information (that is, risk communication) and the setting up an emergency plan against the risk. The alert phase in particular encompasses the moment of the risk assessment, through the monitoring of danger precursors, namely indicators of the possibility of

33 A further classification of standards is proposed by J.F. McEldowney and S. McEldowney, *Environmental Law & Regulation* (Oxford: Oxford University Press, 2001 (reprinted 2009)), pp. 5, 11–12, who in the control of pollution distinguish the "quality standards" that set directly environmental goals – namely, fixing the maximum level of pollution in the environment – from the source-related standards which fix specific thresholds of concentration of pollution ("emission standard"), stipulate the means of production ("process standards") or define the characteristics of a product ("product standard").

the materialisation of the menace: Risk regulation develops between continuous monitoring and communication to the community, providing an informative circuit between institutional bodies and social organisations.

By availing itself of progressive thresholds of alarms, European Union has carried out some sector-specific models of disaster prevention, at the same time revealing an increasing and consistent need to implement an integrated approach to catastrophic issues.

Similar systems have been mainly used in EU regulations in order to avoid the occurrence of health crises caused by the composition of human food (as in the case of genetically modified organisms)[34] and by animal feed (as happened in the spread of mad cow disease – BSE)[35]. More recently, a comparable mechanism has been used for flood risk assessment and management, based on the mapping of the significant areas in terms of probability of the occurrence of calamities and range of the possible losses for human health, environment, cultural heritage and economic activities[36]. This model is based on characterisation and mitigation of the significant flood risk through the division of the Member States' territories in distinct areas that match different levels of liability to flooding; hence, the higher the risk, the better framed the management plans.

Indeed, these more or less institutionalised procedures are based on the exchange and the coordination of information about risk assessment, in the attempt to identify and prevent in advance direct and indirect risks to human health. In order to avoid false alarms, the organisation of the informative network is bound to guarantee cross-checking of the reliability of scientific information setting up the warning with flexibility and coordination of the response.

From this perspective, risk management is based on standards of protection and is run through the organisations of those who are appointed to monitor the acceptable thresholds of risk: Where these levels are overcome, the alert system starts in order to reinstate the previous degree of risk[37].

From the same standpoint, pollution regulations provide "alert thresholds", namely concentration levels of polluting substances beyond which there is a risk to human health and at which immediate steps are to be taken by the Member States, like public information and the installation of short-term action plans. Below that level an "information threshold" is established, which is a former degree of pollution beyond which there is a risk to human health from brief exposure for particularly sensitive sections of the population and for which immediate and appropriate information is necessary; it also provides a "margin of tolerance" related to the reference standard[38].

34 See Article 23 Directive of the European Parliament and of the Council 12 March 2001, 2001/18/EC, "on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC", providing a safeguard clause, that introduces a process aimed at restricting or prohibiting the use and the sale of GMO in the case of risk to human health and the environment.

35 Article 50–52 Regulation of the European Parliament and of the Council 28 January 2002, 178/2002/EC, "laying down the general principles and requirements of food law, establishing the European Food Law Safety Authority and laying down procedures in matters of food safety", that lays down a rapid alert system.

36 See recitals 3 and 11 and Article 2(2) of the Directive of the European Parliament and of the Council 23 October 2007, 2007/60/EC, "on the assessment and management of flood risks". More precisely, the risk assessment stage is based on the arrangement of flood hazard maps and flood risk maps (Article 6) for those areas where a potential significant flood risk is likely to occur after a preliminary flood risk assessment founded on the available information (Articles 4–5). On this ground, flood risk management plans, focused on prevention, protection, preparedness and early warning systems, are established (Articles 7–8).

37 In this perspective, Regulation 178/2002/EC provides also the general plan for crisis management (Article 55–57) which specifies (Article 55, para. 2) "the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54" regarding emergency regulation.

38 See Directive of the European Parliament and of the Council 21 May 2008, 2008/50/EC, "on ambient air quality and cleaner air for Europe", which provides that at the "informational threshold" (Article 2, point 11) and the "alert threshold" (Article 2, point 10, and Article 3, para. 2) immediate information to the public and to the Commission (Article 13), and the arrangement of short-term action plans (Article 24) in order to reinstate the standard level of risk. The directive defines also the "margin of tolerance" (Article 2, para. 7) that is the acceptable percentage of the limit value (the guaranteed standard of protection, regulated at Article 2, para. 5) by which that value may be exceeded (Article 22-23). It is worth noting that this regulation represents a rationalisation and an updating of the principles and the requirements already laid down in the directive of the Council 27 September 1996, 1996/62/EC, "on ambient air quality assessment and management", in the directive of the Council 22 April 1999, 1999/30/EC, "relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air", in the directive of the European Parliament and of the Council 16 November 2000, 2000/69/EC, "relating to limit values for benzene and carbon monoxide in ambient air", and in the directive of the European Parliament and of the Council 12 February 2002, 2002/3/EC, "relating to ozone in ambient air". In a similar way, the directive of the European Parliament and of the Council 25 June 2002, 2002/49/CE, "relating to the assessment and management of environmental noise", defines at Article 3, letter *s*), the "limit value" as the noise tolerability's standard, the exceeding of which causes competent authorities to consider or enforce mitigation measures (Article 8, para. 2) and to inform the public about the arrangement of strategic noise maps and action plans (Article 9).

Thus a system of progressive protection against pollution is implemented which remains above the limit value (through the arrangement of further levels of attention and action) and below the new threshold, and identifies a target value for pollution reduction[39].

Thanks to this regulatory experience, the EU is going to develop a strategic approach to catastrophic risks based on the recognition of the increasing vulnerability to natural as well as man-made disasters due to the technological progress, and on the admission that only a supranational involvement is able to ensure the effectiveness of the protection. This is the reason why the Lisbon Treaty has allocated a fundamental function to the EU in protection against catastrophes, reinforcing the coordination between and supplementing the action of Member States[40]. To this end EU Commission has been working on the introduction of a consistent regulation on the prevention of disasters, building an integrated approach to those risks on the scientific research, the coordination of existing sector-based policies and, in the long run, the predisposition of a framework directive for disaster prevention[41]. In its first action the Commission showed its intention to mitigate the impact of uncertain risks through the control of the whole disaster management cycle, by improving the organisation and procedure of both risk regulation and emergency planning[42]. In this way the prevention of catastrophes should be achievable by coordination between the action of civil protection and risk management. In this framework the notion of 'standard of protection' will play a key role in outlining a suitable response, as it is relevant to both the uncertainty of risks and the distribution of competences between the EU and its Member States. Indeed, the identification of the significant risk and its possible escalation makes it possible to draw up proportional actions and reactions against threats, thus contributing to the constructive enhancement of the European cohesion.

The same integrated approach will also be applied to the regulation of terrorism risk. However, it should be acknowledged that the specific nature of this menace compared to environmental threat influences the setting up of alert systems, rendering difficult any distinction of scientific information (based on intelligence activity) from political goals. The US administration's management of the war against Iraq provides a clear demonstration: American intelligence claiming the existence of relationships between the Iraqi regime and the terrorist organisation Al-Qaida was not only declared unfounded, but also as fake and spread intentionally to generate support for the war[43].

Therefore, the arrangement of a reaction model founded on the level of terrorist menace cannot be considered as a conclusive solution against any abuse of public power, but it can contribute to restrictive abuse in that political decisions regarding the level of

39 The target value is a concentration level fixed with the aim of avoiding, preventing or reducing harmful effects on human health and the environment as a whole, to be attained where possible over a given period; on air quality see Article 2, point 9, and Directive 16, 2008/50/EC. By availing itself of another specific language, the environmental noise regulation states a target value in the "strategic noise map", a plan aimed at determining the global assessment of noise exposure in a given area; see Article 3, letter *r)*, and Directive 7, 2002/49/EC.

40 See, in particular, Article 196 TFEU on the cooperation in the field of civil protection and Article 222 TFEU stating the solidarity clause between the Union and its Member States. Moreover due reference is to be made to Article 4 and 6 TFEU on the principal areas of shared competence between the Union and the States.

41 See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions 23 February 2009, COM (2009) 82, "a Community approach on the prevention of natural and man-made disasters". In particular, this strategy "outlines specific measures to boost disaster prevention in the short term" (para. 5), providing the creation of an inventory of information on disasters (para. 3.1.1), the spreading of best practices (3.1.2), the developing of guidelines on hazard/risk mapping (para. 3.1.3) and promoting the coordination among the actors and the policies involved in "the disaster management cycle" (paras. 3.2 and 3.3). Moreover, a previous report from the European Commission DG-Environment, focusing on a long term approach to catastrophic risk regulation, suggests the introduction of a new framework directive aimed at address prevention of national as well as cross-border impacts disasters. See European Commission DG Environment, *Assessing the Potential for a Comprehensive Community Strategy for the prevention of Natural and Manmade Disasters*, Final Report, March 2008, pp. 18–19, 85–90.

42 In this regard it should be pointed out that in accordance with the principle of subsidiarity, EU has also strengthened the emergency cooperation between the Community and its Member States in case of major crisis and imminent threats, in order to meet emergencies in a more suitable manner. See Council resolution 8 July 1991, 91/C198/01, "on improving mutual aid between Member States in the event of natural and technological disaster"; Council decision 9 December 1999, 1999/847/EC, "establishing a Community action program in the field of civil protection"; Council decision 23 October 2001, 2001/792/EC, "establishing a Community mechanism to facilitate reinforced cooperation in civil protection assistance interventions".

43 See C. Savage, *Takeover. The Return of the Imperial Presidency and the Subversion of American Democracy* (New York: Little, Brown and Company, 2007), pp. 164–165. In particular, the author emphasises that the American administration had succeeded in claiming the existence of weapons of mass destruction in Iraq thanks to the abuse of power to make inaccessible certain administrative documents by Vice President R.B. Cheney, who exercised this power (for the first time in the US history) on the basis of the Presidential Executive Order I, 25 March 2003, n. 13292, "further Amendment to Executive Order 12958, as amended, Classified National Security Information".

alarm must take second place to the analysis of scientific data. Thus, regulators have to decide which level of protection of collective (and national) security is required, analysing any qualitative and quantitative data gathered and used in the respect of the law; this means maintaining security policies within legality, thus guaranteeing fundamental rights.

It is worth noting that many states have adopted systems of terrorist alert, identifying increasing levels of protection though differently coloured stages. In particular, at the increase of the threat, which represents the independent variable, there is a corresponding growth in the intensity of the response, which is the dependent variable.

In France since 1978 there has been a system called *Plan Vigipirate*, updated in 2003 in order to meet international terrorism risks[44]: The alert level represents the degree of the risk characterisation ('inaccurate', 'plausible', 'relative to evidently serious attacks' and 'relative to even more serious attacks') and against this scale the response is assessed.

Similarly in the USA, the *Homeland Security Advisory System* (HSAS) – introduced only in 2002 by the Homeland Security Presidential Directive 11 March 2002, no. 3 – matches the increase in the risk (from 'low' to 'general', 'significant', 'high' and 'severe') with the reorganisation of administrative functions and organisations.

The same is true for the English system, the *UK Threat Levels*, adopted in 2006 to replace the preceding *BIKINI state*, which defined only the level of attention without specifying the relative responses. Indeed, even if the model provides a very articulated risk analysis (from 'low' to 'moderate', 'substantial', 'severe' and 'critical'), based on a flexible outline of the characteristics of attacks, the kind of responses ('normal', 'heightened' and 'exceptional') reduces the range of the possible counteraction. As a consequence, the effort to define the threat is neutralised by the lack of a correspondent differentiation in the reactions; therefore, the thresholds of alarm end up being equivalent to the level of response, namely normal, heightened and exceptional.

VII. Final remarks: Virtues and shortcomings of regulation

The definition of standards allows an administration to face up to catastrophic risks through its ordinary powers. Indeed, this regulatory method aims at rationalising the public approach to uncertain threats and at promoting at the same time the fundamental accountability of public decisions.

The focus on increasing levels of risks to the common standard of protection makes the relative response proportionate and adequate to the specific circumstances of the case: Thus a constant relation between threat and defence is planned.

The recent volcanic ash case of catastrophe, creating the emergency blocking of airspace over many European States, shows clearly the possible benefits of the progressive standard approach: Following the ICAO guidelines[45], Member States introduced a precautionary ban on flights regardless of ash concentrations and of the economic impact of such a measure. Since no Member State was able to dismiss the international safety directives, the European Commission proposed a coordinated European approach to the crisis, substantially based on setting up progressive thresholds of alarm[46]. On the ground of available data and technical studies, the European airspace was divided into three zones of increasing risk, providing specific and proportional countermeasures for each area. In particular, the range of the decisions that could be taken on the

44 See *Présentation du nouveau plan gouvernemental de vigilance, de prévention et de protection face aux menaces d'actions terroristes: Vigipirate*, 2003, available on the Internet at <www.auvergne.pref.gouv.fr/pdf/plan_vigipirate.pdf>.

45 See sec. 3.4 *Manual on Volcanic Ash, Radioactive Material and Toxic Chemical Clouds*, ICAO, Doc 9691, AN/954, II ed., 2007.

46 The proposal was discussed and endorsed by the extraordinary meeting of Ministers of Transport, 19 April 2010, because Member States maintain their competence over the safety of their airspaces. It establishes three zones depending on their degree of contamination: In the first one ("located in the central nucleus of the emissions") being the highest degree of ash concentration, the safety goal can be achieved only maintaining the ban on flights ("a full restriction of operations"); in the second area, being there "still amounts of ash", the possibility to pursue air traffic operations shall be decided "in a coordinated manner" by Member States; the third zone, being "not affected by the ash", is subjected to no restrictions. However, even before the ash crisis, EU provided a regulation aimed at developing an integrated approach to air traffic management; see Regulation of the European Parliament and of the Council 10 March 2004, 2004/549/EC, "laying down the framework for the creation of the single European sky (the framework Regulation)", and Regulation of the European Parliament and of the Council 21 October 2009, 2009/1070/EC, "amending Regulations (EC) No 549/2004, (EC) No 550/2004, (EC) No 551/2004 and (EC) No 552/2004 in order to improve the performance and sustainability of the European aviation system" (second single sky package – SES II). It is worth noting that in the aftermath of the ash crisis, the Commission seemed to milk the occurred emergency in order to push forward the implementation of the SES II. For a reconstruction of the volcanic ash case and its main regulatory issues see A. Alemanno, *The European Regulatory Response to the Volcanic Ash Crisis between Fragmentation and Integration*, 2 *European Journal of Risk Regulation* (2010), pp. 101–106.

middle zone revealed the importance of administrative procedure in the balancing of the different interests at stake against the scientific evidence. Both cost-benefit analysis and the precautionary principle had a part to play, but the proper regulatory option could only be taken by recourse to a coherent methodology, namely the regulation impact assessment[47]. In hindsight, if this standard-based model had been working from the beginning of the crisis, a huge reduction in terms of economic losses for airlines and inestimable discomfort for passengers would have been achieved.

However, it should also be noted that such systems rest upon the tacit assumption of the reliability of the risk monitoring systems, so that continuous watching can outwit occurrences and can contain uncertainty[48]. Therefore, even chances are determined by a gap in the scientific assessment of the current situation. But the non-linear relationship between causes and effects that is typical of complex systems can alter the comprehension of phenomena[49] and can thus influence the appropriateness of the response. From this point of view, the regulatory model seems to be flawed, but its rigidity can be accommodated in a more flexible understanding of the uncertainty. For instance, the administration under precise circumstances might push the level of attention to the highest degree, skipping the intermediate levels. In the end, in the face of the unforeseeable and sudden occurrence of a catastrophic risk, the instruments of emergency should be employed: If this could seem a limit in the precautionary functioning of the system, the alert mechanism can make the difference in the management of the emergency situation, contributing to the reduction of damage.

In order to achieve the claimed prevention and the requested protection, the administration should act on the one hand by respecting the fundamental principles of impartiality and fairness, and on the other hand by taking into account the cheapness, efficiency and effectiveness of its decisions. While the former principles are typically administrative (being the inner limit of the exercise of authoritative power and an input to public participation), the latter are extra-legal concepts, borrowed from the business methodology, whose transposition into administrative law opens more general issues about the self-sufficiency of law and its relation with other sciences. This transfer not only binds the administrative decision-making to the application of economic rules, but also contributes to modifying the economic notions in the light of immeasurable public values. As a consequence, a due compromise between the participative requirement and the efficient assessment of resources can be achieved, making the proportionality principle the key tenet of the procedure and the regulation impact assessment the main methodology for addressing regulatory problems. Indeed, the proportionality principle works as a guide in the settlement of conflicts between oppositely oriented rules[50] and the impact assessment allows an advanced comprehension of the various feasible regulatory alternatives on the affected shareholders.

In this respect, administrative action not only complies with the better regulation approach, but ends also up dealing with the EU notion of sound administration, which is codified in Article 41 of the Charter of Fundamental Rights and prescribes the fundamental guarantees of a fair proceeding. This specific administrative working methodology embodies not only the ordinary management but also the special issues of risk regulation: The absence of an emergency situation justifies the refusal of extraordinary powers. Thus, the administration should convert the management of uncertain risks into an ordinary duty which must be carried out not only without affecting the necessary proportionality of its action, but also promoting the development of a sound administration in the management of risks.

The functioning of the model requires the participation of private interests as well as coordination among public administrations, which becomes an essential hurdle in order to guarantee the coher-

47 In this case RIA would have at least reduced contentions between airlines and regulatory science about the correct definition of safety thresholds in emergency conditions, because it would have pushed the airline industry to participate in risk regulation, demonstrating and challenging scientific assessments in that proper venue. On the airline executives' approach to science in the volcanic ash crisis see V.M. Branningan, "Alice's Adventures in Volcano Land: The Use and Abuse of Expert Knowledge in Safety Regulation", 2 *European Journal of Risk Regulation* (2010), pp. 107–113.

48 On this structural limit of the model see also B. Hutter, "In catostrophe's shadow", 19 *Risk & Regulation* (2010), p. 3; *Id.*, "Risk regulation and the anticipation of natural disasters", *ibid.*, pp. 6–7; L. Clarke and H. Molotch, "Scientists as Disaster Warning Systems", *ibid.*, pp. 12–13.

49 On this perspective on the environmental issues see A.S. Goudie, "Uncertainty", in D.J. Cuff and A.S. Goudie (eds), *Global Change*, pp. 605–606.

50 On this perspective see A. Massera, "Criterio di economicità e di efficacia ed efficienza", Comment to Article 1 (1) of the Italian Administrative Procedure Act (L. 241/1990), in A.M. Sandulli (ed.), *Codice del procedimento amministrativo* (Giuffrè, 2011), pp. 44–45.

ence of public action[51]. From this standpoint, the administrative coordination states how the different public interests (and mission) should be harmonized in the development of the administrative proceeding[52].

Finally, these public parties should demonstrate to some extent the need for implementation of the level of protection. The duty to give reasons of public choices becomes a general instrument for promoting the accountability of risk regulation, because it embodies the grounds and the purpose of the public action. Indeed, in order to shift from a lower to a higher level of alarm (and of protection) the administration is called upon to justify its choice. This is true even in security matters, because the eventual guarantees of secrecy must be authorised by a government which is politically accountable.

51 In the Italian literature see F. Merusi, "Il coordinamento e la collaborazione degli interessi pubblici e privati dopo le recenti riforme", in *Diritto amministrativo* (1993), pp. 22–23. The author considers that the requirement of coordination in the public administration derives from the interaction between the pluralism of public interests and the constitutional uniqueness of the executive power, exercised by the public administration.

52 On this point, F. Merusi, *ibid.*, pp. 23–24, identified three distinct roles played by other public interests in an administrative proceeding which is developed around a principal public interest, namely as (1) mere factual assumptions with regard to the decision-making process; (2) elements of the fact-finding stage, which allows the individuation of other public interests and the definition of a consistent relation between them and the principal public interest (pursued in the administrative process); and (3) dialectic factors in the administrative decision-making.