ELSEVIER

The Precautionary principle: its misunderstandings and misuses in relation to "GMOs"

Research Paper

Giovanni Tagliabue

Carugo, Como, Italy

References to the Precautionary principle (PP) in relation to ''GMOs'' are commonplace. Those who oppose the DNA recombinant approach to create new agricultural products either have not read the PP (misunderstanding), or they want to exploit the PP for their propaganda while forcing it (misuse). Proponents of a stricter approach to the regulation of biotechnologies must forge a new expression, since the PP is something else – historically and theoretically. In any case, a legitimate very circumspect attitude, to be coherent, must be applied to each and every biotechnology, not only to ''GMOs''.

In the *Rio Declaration on Environment and Development* (1992), a Precautionary approach is stated: ''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'' [1]. Originally created with the aim of protecting the environment, in its subsequent interpretation by the European Commission (2000) the approach was renamed as a ''Precautionary principle'' and was then extended to cover policies to safeguard consumers and human, animal and plant health [2: Summary, 3]. During the years around the turn of the millennium, the expression ''Precautionary principle'' (PP) became more and more common, and today it is widespread.

The best example of an optimal application of the Precautionary approach is certainly the Montreal Protocol [3]: this treaty even predates the PP, but expresses the very spirit of it. The international agreement was created to ban certain chemical substances which were considered responsible for thinning out the beneficial ozone layer; the scientific analyses were heading in the same direction but were not definitive, and yet the global community – and for once this expression is not just empty rhetoric – took action in time to prevent the damage worsening. Studies started in the 1970s and, before the end of following decade, the treaty was signed at global level: concerted international action inspired by the PP was making a difference.

The treaty on ozone has a specific objective, a clearly identified target: precaution was applied for a defined purpose, to address a real problem, the inherent risk of which for most scientists was not open to any doubt – despite discussions about its quantification and expected development.

That is *not* the case for ''GMOs'' (inverted commas are mandatory!). The oft cited acronym does not indicate a group with even a minimal amount of homogeneity and so cannot be subject to any all-encompassing evaluation, whether positive or negative, let alone be subject to the PP. Since the mid '70, scientists have been recommending any regulatory approach to be focused on single (agricultural) *products*, not on the *processes* used to create new varieties of plants (or microorganisms or animals). Instead, for various reasons, for many years a gigantic and persistent flaw has persisted, deriving from what has been appropriately called ''genomic misconception'' [4]: a rickety fence has been tentatively erected on a fuzzy border, which is supposed to separate the fake category called ''GMOs'' from more traditional biotech methods (comprising physical and chemical mutagenesis), even when the traits obtained are the same; prudence is applied *en bloc* to DNA recombinant cultivars, and not to all the others!

To be clear: the countless recommendations of geneticists and biologists, the numerous statements issued by scientific societies, do not call for a general, hazardous deregulation of biotechnologies; they reasonably recommend that each new cultivar,

E-mail address: giovanni.tagliabue@uniedi.com.

http://dx.doi.org/10.1016/j.nbt.2016.02.007

created via any method, be examined and assessed according to its own traits, its unique profile of risks and benefits. The same approach is outlined in the food safety standards of the *Codex alimentarius*.

Instead, the ''GMOs'' are considered as a real category in almost all national and international regulations by creating heavier bureaucratic obligations and related costs. The most clear example of this approach, which is indefensible on theoretical grounds and counterproductive in the real world, is certainly the Cartagena Protocol [5], explicitly dedicated to alleged inherent dangers related to ''Living Modified Organisms'' (i.e. ''GMOs''): in the very first phrase of Article 1, reference is made to the Rio PP. But the supposed risks were fortunately a (conscious?) blunder, as is honestly recognised by one of the main negotiators of the appendix to Cartagena, the Nagoya–Kuala Lumpur Protocol on Liability and Redress: ''unlike oil spills polluting the ocean or nuclear power plant accidents spreading radioactive material, there has not yet been a scientifically confirmed case of environmental damage caused by LMOs. The treaty negotiators were tackling a hypothetical problem of environmental damage that may eventually be caused by LMOs without any actual experience of it'' [6, p. 9]. This was written in 2013, thirteen years after the signature of Cartagena and almost twenty years after the start of the cultivation and use of the first agricultural ''GMOs'': during this period, a number of experimental DNA spliced cultivars were discarded before reaching the market, due to unsatisfactory results [see 7,8 for lists of failed ''GMOs'']; just what should be expected with the trials of agricultural novelties; just what happened in innumerable cases, for millennia, throughout the history of the domestication of plants and animals. On the contrary, when DNA recombinant ''events'' (i.e. successful outcomes), after careful individual checking, have been cultivated and consumed, no credible adverse effects have been reported.

Thus, the attitude of applying special rules to ''GMOs'' as a supposed group goes against the PP as recommended by the European Commission: ''A decision to invoke the precautionary principle does not mean that the measures will be adopted on an arbitrary or discriminatory basis'' [2: Conclusion]. If Precautionary measures are sought on environmental or health grounds, they must always be based on ''detailed scientific and other objective information'' [2: Summary, 1]. In a minimally rational world, the Cartagena and Nagoya-Kuala Lumpur Protocols would simply be abolished, together with any sectarian bio-technophobic regulation at national and regional levels.

Instead, mentions of the PP in relation to ''GMOs'' are legion – some being extremely deranged [9] – and are commonplace in the public discourse. The opponents of ''GMOs'' either misunderstand the PP, or deliberately misuse it: those who call for application of the PP to this ill-defined group of biotech processes and products seek to turn a correct and proactive recommendation of effective intervention in the case of potential but foreseeable dangers, into an attitude that tends to block and freeze out innovation. The enemies of ''GMOs'' either have not read the PP (misunderstanding), or they want to exploit the PP while caricaturing it (misuse). Thus, another important clarification clearly expressed by the European Commission is ignored: ''Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified'' [2: Summary, 4].

A particular consequence of this reversal of the PP is the belief that it places the burden of proof on the innovator. But, while the Rio formula of the PP does not touch on this argument, the EU reference to it, initially vague, was subsequently clarified: ''The burden of proof: In most cases, European consumers and the associations which represent them must demonstrate the danger associated with a procedure or a product placed on the market, except for medicines, pesticides and food additives. However, in the case of an action being taken under the Precautionary principle, the producer, manufacturer or importer may be required to prove the absence of danger. This possibility shall be examined on a case-by-case basis. It cannot be extended generally to all products and procedures placed on the market'' [10]. Such a position forbids any attempt to apply the PP to broad generalisations – and more so to the ''GMO'' fake category.

Proponents of a stricter approach have every right to express their view: but they will have to forge a new expression, calling it, say, the Rule of Utmost Prudence, or the Extreme Wariness Recommendation. They should not use the term Precautionary principle, which is something else – historically and theoretically. In any case, a legitimate very circumspect attitude, to be coherent, must be applied to each and every biotechnology, not only to ''GMOs''.

Therefore, following the spirit of the PP, single stops can be reasonably imposed on ''green'' biotech experiments: let us take just one example. In the mid-90s, in Great Britain, a study was made of how to combat pests which, in the traditional practice, entailed the use of considerable quantities of insecticide: an engineered virus, with the insertion of a gene taken from a scorpion, was tested on particular caterpillars which were devastating for a very common and popular crop, cabbage; the initiative was opposed by ecologists who feared the possible spread of the modified virus to an area where there were numerous species of ''untargeted'' coleopterans, and the experiment also revealed operational problems in the laboratory. Everything was quickly resolved when the project head was removed [11]. By applying the philosophical basis of the PP, although there was no scientific certainty about the possible invasiveness of the altered virus and its potential to damage harmless insects, the threat to local entomological biodiversity imposed the choice of not starting the field tests.

But this reasonable, prudential conclusion – just like any other regarding a single situation – does not allow us to make generalisations; instead, for some commentators, the (il-)logical jump from the singular to the plural seems obligatory: ''the episode underscored the unpredictability of working *with GMOs* and contributed to doubts about the commercial viability of *such products*'' [12, p. 112, emphases added]. Let us compare the hypothetical harmfulness of that modified virus with the guaranteed toxicity for humans of a variety of pumpkin, or celery, or squash obtained from unfortunate hybridisation attempts [8]; would we consider it reasonable that someone deplored ''the unpredictability of working *with crossbreeding*'' and raised doubts ''about the commercial viability of *such products*'' (i.e. in practice most vegetables)?

The vicious circle feeds itself: the «special» regulation, generated by the hyper-precautionary blunder, creates even more fear among the public; if the specific regulation on ''GMOs'' is strict, it is reasonable to think that it is because they are intrinsically risky: ''regulatory initiatives [...] increasingly justified themselves by reference to the need for public reassurance; and yet [...] the