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Does the precautionary principle need to be supplemented?

Ethical considerations on the 'innovation principle'

Executive summary

Discussions about the relationship between the precautionary principle and the 'innovation principle' are based on two misconceptions: (1) the precautionary principle is hostile to innovation, and (2) it is a risk evaluation principle.

As regards (1), the precautionary principle applies in situations where serious harm could occur but the probability of its occurrence cannot yet be stated. As a result, precautions must be taken to protect against this harm as much as possible. At the same time, the data required to determine the probability must be collected, with a view to ascertaining the risk, i.e. the product of probability and harm.

Understood in this way, the focus in a precautionary situation is on the harm aspect. However, this is not to say that the potential benefits do not matter. On the contrary: the relevant ethical theories make clear that potential benefits should also be investigated and, insofar as permissible in a precautionary situation, data on the probability of these benefits materialising should be collected. In this respect, considerations on the innovation potential and associated opportunities are an integral part of a precautionary situation. The criticism that the precautionary principle is hostile to or inhibits innovation is therefore unfounded. The precautionary principle does not need to be supplemented by an 'innovation principle'.

Concerning (2), the precautionary principle is not – as often claimed in discussions on the 'innovation principle' – a principle for evaluating risks (in relation to opportunities), but rather a principle for dealing with situations of uncertainty in which such an evaluation is not yet possible due to a lack of risk knowledge. Once this knowledge is sufficient, we are no longer in the precautionary arena. It is only at this point that we can decide whether the risks, as now known, are acceptable or not. The relevant ethical theories say different things about how opportunities arising in this context, for example regarding the implementation of innovative technologies, should be assessed. However, here too, the label 'hostile to innovation' cannot be justified.

Once these misconceptions are removed, it can be seen that there are no irreconcilable contradictions between the precautionary approach and the development of new technologies. However, at the same time it becomes clear that the authorisation of such technologies and related products is subject, for ethical reasons, to a relatively demanding process that cannot be compromised, even if this means that it takes longer for the technologies or products concerned to reach the market. This aspect must be given due consideration, including in periods of accelerated technological progress – and even if this progress appears necessary to address pressing global challenges.

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1. Background

Though an established and tested legal principle in both Switzerland and the European Union (EU), the precautionary principle has been criticised again and again since its introduction. For some time, an increasingly common criticism has been that it focuses solely on uncertainties and risks, ignoring the opportunities associated with new developments. It thus impedes or slows down technological progress, thwarting or delaying the introduction of novel, marketable products. In this sense, the precautionary principle 'inhibits' or is even 'hostile' to innovation and therefore needs to be supplemented by an 'innovation principle'.

This criticism is not generally directed against the precautionary principle, but against the allegedly excessive weighting of risks associated with it.. Opportunities should be considered on a par with risks, the argument goes. Failing to do so not only holds back scientific and technological progress but is also morally problematic as scientific breakthroughs and innovative products are among the most, if not *the* most, important means of solving pressing global problems.

The term 'innovation principle' was coined in 2013 by the European Risk Forum (ERF), a think tank closely allied with the chemical, tobacco and fossil-fuel industries. Initially, it was understood primarily in economic terms. Most references stressed that it was complementary to the precautionary principle, with the latter taking precedence in hazardous situations, notwithstanding the general equivalence of the two principles. For example, in an article published in 2014, Kurt Bock, then CEO of BASF, wrote:

> "The innovation principle is not about promoting innovation per se, regardless of its impact on health and the environment. Where a real danger exists, precautionary considerations should take priority. But the principle does advocate an evidence-based approach underpinned by provable science. If Europe embraces this principle, it can dare to be innovative."

At a hearing in the German Federal Parliament, the Bundestag, on 28 February 2017, Markus Steilemann, a member of the Research, Science and Education Committee of the German chemical industry association VCI, said:

> "In our view, Germany is lagging well behind other regions: it lacks a culture of innovation and a fundamental openness to progress. (...) To address this, an 'innovation principle' should be established alongside the precautionary principle, meaning that new legislation would be examined for its potential impact not only on health and the environment but also on the innovation climate. To this end, an 'innovation inspection' should be an integral part of the assessment, alongside a competitiveness check. This will enable us to counteract the trend whereby innovative ideas are conceived in Europe but developed into marketable products elsewhere."

VCI President Marijn E. Dekkers made a similar argument in a 2015 editorial entitled 'We need an innovation principle in Europe':

> "In Europe, the reflex is always to place risks front and centre of the evaluation, rather than the benefits of new products. However, the political weighing-up of opportunities and risks has to be balanced, otherwise technical progress is all but impossible."

2. Juridification of the concept

The term 'innovation principle' first appeared in a 2015 European Commission document.[1] A later Commission report from 2018 gives the following explanation:

> "The Innovation Principle is an integral part of the EU Better Regulation approach, and ensures that whenever policy and legislation are developed, the impact on innovation is fully assessed."

EU politicians have thus responded to a demand from business, and parts of the scientific/academic community, although it is not yet sufficiently clear how this 'principle' is to be understood and applied in individual cases. To date there is no binding legal definition of the principle,[2] although its intended basic function in the legislative process can be identified. Its intention is to create "innovation-friendly framework conditions", i.e. to design legislation in such a way that all phases of an "innovation cycle", from research and development through to commercialisation (and recycling), can be optimally harnessed in order to fully unleash the potential economic, social and/or environmental benefits associated with an innovative idea.

This helps to clarify what is meant by the term 'innovation'. On the one hand, it refers to the fact that something is new; on the other hand, new technical developments or scientific approaches are 'innovative' insofar as they bring economic, social and/or environmental benefits with far-reaching practical implications. This use of the term 'innovation' only partially coincides with everyday usage, in which 'innovative' means not just new and of (great) practical benefit but rather novel in the sense of unconventional, forward-looking, pioneering, revolutionary, creative, original or inventive. It is this meaning that gives the word its positive connotations: to call something 'innovative' is to judge it positively. Using the word in the context of the innovation principle creates the risk that new scientific and technological developments will be excluded, at least to some degree, from critical discussion.

However, simply thinking about the legislative function of something referred to as the 'innovation principle' does not actually make it a principle, even though it could be one.[3] For the time being at least, it is rather a suggestive coinage relating to a set of demands based on certain value assumptions. These assumptions have two main thrusts: firstly, that application-oriented scientific research should not be held back by rigid regulatory requirements,

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[1] More information on the historical background of the 'innovation principle' can be found in: Kathleen Garnett, Geert Van Calster & Leonie Reins (2018), 'Towards an innovation principle: an industry trump or shortening the odds on environmental protection?', in: *Law, Innovation and Technology*, pp. 1-14, https://www.tandfonline.com/doi/pdf/10.1080/17579961.2018.1455023?needAccess=true.

[2] Although there are now some official documents that contain clues as to how the 'principle' may be operationalised. Notable examples include: the *Better regulation Toolbox 21* (2017) https://ec.europa.eu/info/sites/info/files/file_import/better-regulation-toolbox-21_en_0.pdf; and the *Management Plan 2018* of the European Commission's Directorate-General for Research and Innovation (DG RTD), https://ec.europa.eu/info/sites/info/files/management-plan-rtd-2018_en.pdf. The latter document states: "The Innovation Principle was introduced by the Commission in 2017, under a Task Force of DG RTD, with the purpose of systematically assessing the impact of new EU policy and legislative initiatives on innovation. As from the adoption of the Commission Work Programme 2018, future initiatives will be screened to identify those where the innovation principle could be implemented." (DG RTD 2017:4, see also p. 9). The Horizon Europe research and innovation framework programme (2019) is the first EU legal text to include the term 'innovation principle'.

[3] This issue has been considered by, among others, the European Political Strategy Centre (EPSC). See EPSC (2016), Towards an Innovation Principle Endorsed by Better Regulation, https://ec.europa.eu/epsc/sites/epsc/files/strategic_note_issue_14.pdf.

especially if it opens up opportunities which, if they could be exploited, would be of potentially great social or environmental benefit; secondly, that new products with (great) commercial potential should be allowed to be marketed without complicated and costly authorisation procedures.

In addition, its more politically-minded advocates emphasise that the innovation principle is about harnessing innovation in the interests of sustainability. They also claim that this is the criterion for differentiating 'good' innovations from 'bad' ones.[4] Whether this interpretation of the 'innovation principle' will prevail remains to be seen. But even if this were the case, it would have no bearing on the ethical reasoning set out in this report concerning the relationship between the precautionary principle and the 'innovation principle'.

As far as can be ascertained, the term 'innovation principle' has yet to enter the debate in Switzerland. Of course, this only applies to the term itself, not to what it is intended to express. In Switzerland too, there is criticism that the precautionary principle is skewed towards risks and tends to overlook the opportunities associated with new technologies.[5]

In the following ethical appraisal of the 'innovation principle', the Federal Ethics Committee on Non-Human Biotechnology (ECNH) builds on its earlier discussion of the precautionary principle.[6] It maintains its view that the precautionary principle is not 'hostile to innovation'. On the contrary, precautionary measures can act as a spur to innovation in the quest for alternative, less risky development paths, while also addressing legitimate safety and security concerns.

The ECNH's main aim in this report is to draw attention, from an ethical point of view, to misconceptions regarding the significance and function of the precautionary principle and the possibility of 'balancing' the risks and opportunities that shape the discussion on the 'innovation principle'. In the process, it will be made clear how and why the proposal to supplement the precautionary principle with an equivalent 'innovation principle' is not plausible.[7] No judgement is made about the importance of innovations from a business, economic, social or environmental perspective. In particular, the ECNH does not dispute the

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[4] See the video streamed as part of the European Research and Innovation Days (24 September 2019): 'The Innovation Principle. What can it do for sustainability and what can we do for it?' https://ec.europa.eu/digital-single-market/events/cf/european-research-and-innovation-days/item-display.cfm?id=23457. It is not clear if this is the EU's official understanding. There is some reference to the issue in the aforementioned Management Plan 2018, although not under the heading 'Sustainability' or 'Sustainable Development Goals', but under 'A Resilient Energy Union with a Forward-Looking Climate-Change Policy' (DG RTD 2017: 5) as one of four objectives and in the context of promoting the bioeconomy and circular economy and of batteries (DG RTD 2017: 7f.). But even if the innovation principle is geared primarily towards sustainability, it is not easy to infer from the Sustainable Development Goals (which are politically binding for the implementation) whether an innovation, such as a new technology, is 'good' and how good it is.

[5] A typical example is an article in the *Tages-Anzeiger* newspaper of 12 May 2018 under the headline 'Precaution, not prevention' *('Vorsorgen, nicht verhindern')*, which complains that the precautionary principle is being politically instrumentalised and thus abused by being interpreted as an (unattainable) "requirement for zero risk". Consequently, the article claims, the ability of "agricultural biotechnology (...) to help solve environmental and food security issues" is not being adequately considered.

[6] See ECNH (2018), 'Precaution in the environmental field', https://www.ekah.admin.ch/inhalte/ekah-dateien/dokumentation/veranstaltungen/Veranstaltung_7._Mai_2018/EKAH_Broschu__re_Vorsorge_Umweltbereich_e__18_Web_V2.pdf

[7] This is not to exclude the possibility of regulatory approaches that introduce innovation-friendly aspects into law while at the same time being compatible with the step-by-step process that is key to implementing the precautionary principle. Keywords to be discussed in this context include 'experimental legislation', 'innovation deals', 'sunset clauses', 'experimentation clauses' and 'outcome-oriented legislation' (EPSC (2016), Better regulation Toolbox 21 (2018)).

fact that innovation and competitiveness are closely linked and that innovation has a vital role to play in the transition to a (more) sustainable society. What it does dispute is that:

1. the idea of weighing up precaution and innovation against each other is based on ethically sound assumptions;
2. these assumptions provide an ethical justification for the political demand – sometimes associated with the innovation principle – for faster market access for new products that are deemed potentially hazardous from a precautionary point of view, even if they offer considerable potential for opportunities from a sustainability perspective.

3. Uncertainty, risks, opportunities and the precautionary principle from the perspective of ethical theories[8]

Risk is defined as a function – usually the product – of probability and harm (or damage). Opportunity is defined as a function – usually the product – of probability and benefit (or utility).

A precautionary situation is one in which harm could occur but in which there is only limited knowledge about the probability of this possible harm occurring. The precautionary principle is a response to such situations of uncertainty. The ethical idea of precaution justifies an obligation to take measures to prevent possible serious harm or, if harm does occur, to limit it to an extent not exceeding a permissible degree. This obligation exists even if no more is (yet) known about the probability of occurrence other than that it is greater than zero.

In situations of uncertainty we know the potential harm but cannot assign it either a qualitative or a quantitative probability of occurrence. We are therefore unable to state the risk. If we cannot state a risk, we cannot evaluate it: we cannot say whether it is acceptable or unacceptable. Both are possible.

If we want to formulate this situation in positive terms, we need only replace the term ‘potential harm’ with that of ‘potential benefit’. The inadequate or lacking knowledge of probability remains the same. In other words, in situations of uncertainty we are also unable to state and evaluate the opportunities.

Situations of uncertainty have to be distinguished from, on the one hand, situations of certainty, in which we have secure causal knowledge, i.e. we know whether a certain harmful effect or benefit will occur; and, on the other hand, situations of complete or certain risk knowledge, in which we know the statistical probability with which a certain harmful effect (or benefit) will occur.

The precautionary principle focuses on the negative aspect, that of the harm, but opportunities do also play a role, even if they are not to the fore. The precautionary principle regulates the handling of uncertainties. Let us assume that serious harm of a particular kind could occur. The probability of this happening is only vaguely known. From a deontological ethical perspective, this means that people could be exposed to an unduly high and therefore unacceptable risk. Therefore, clarification is required as to whether such a risk actually exists

[8] See ECNH (2018)

or not. Precautionary measures serve to shape the situation, with regard to new technologies for example, in such a way as to minimise the probability of serious harm occurring while also enabling the necessary data to be collected to acquire the risk knowledge needed to assess the level of the risk.

Deontological approaches involve positive as well as negative obligations. Negative obligations are obligations to refrain from something; they refer to what must not be done (prohibitions). Positive obligations, on the other hand, refer to what must be done (requirements). For example, not doing harm to others is a negative obligation, whereas doing good is a positive obligation. Most approaches give primacy to negative over positive obligations. Nevertheless, positive obligations must be fulfilled, as long as they do not conflict with negative obligations. One example would be the obligation to provide assistance with regard to basic needs such as food or healthcare. The living conditions of hungry or sick people who are unable to help themselves must be improved. In such situations, there is a requirement to investigate context-relevant opportunities provided that this does not entail unacceptable risks to others. In this respect, a deontologist might argue that, subject to the above condition, there is likewise an obligation to determine and exploit the opportunities that arise with new technologies, in areas such as nutrition or the treatment of diseases for example, by developing the associated products.

This shows that opportunities play an important role in deontology, including in precautionary situations, even though the primary aim there is to determine whether or not there is an acceptable risk exposure. From a deontological point of view, such situations require more than the generation of risk data. Where this is justifiable in the context of precautionary measures, efforts must also be made to generate data that enable a better assessment of the opportunities, at least insofar as these opportunities relate to positive obligations. And at the same time, possible alternatives, with less potential for harm, should always be envisaged.

For consequentialists, what matters in a precautionary situation is avoiding a negative overall outcome, taking into account possible harms and benefits. If the probabilities of such harms and benefits cannot be ascertained, neither the risks nor the opportunities can be determined. This removes the central basis for fulfilling what consequentialism deems to be the only moral obligation, namely to maximise the expected overall benefit for all concerned. To overcome this situation, the data required to determine opportunities and risks must be generated. But until these data are available, what is to be done? In particular, how should one respond to the fact that serious harm is possible?

If there is scientifically plausible evidence to suggest that serious harm could occur and that the probability is greater than zero, but no more is known than this, it cannot be ruled out that this situation is suboptimal vis-à-vis other situations in terms of achieving the greatest possible overall benefit. One must therefore try to ascertain what the probability of occurrence of the serious harm in question is, albeit subject to the restrictive condition that appropriate precautionary measures are taken to keep this probability extremely low. In this respect, consequentialists in precautionary situations also focus on the negative aspect, i.e. the harm. In this context, however, there is a requirement to start investigating the opportunities at the same time. For in this respect too, the following generally applies: a potential benefit is known but not the probability that it will materialise.

The aim is to generate the data needed to enable a 'weighing-up' in the consequentialist sense. Such a weighing-up must be done at the latest when a complete knowledge of the risks and opportunities exists. However, it does not entail a 'balancing' in the sense of a trade-off or compromise. Rather, it is a calculus in which all relevant opportunities and risks are offset against each other. The option with the greatest expected overall benefit must then be chosen.[9]

Terms such as 'calculus' and 'offsetting' are understood by some to mean that the overall benefit can be quantified and calculated mathematically. Often, however, the constitutive probabilities for determining the risks and opportunities can only be stated in qualitative terms. Moreover, if, as consequentialists argue, the morally right action is the one that is expected to have the best consequences for all those affected by the action, then the question arises: how are those consequences to be evaluated? To do so, one needs not only a criterion for judging the 'best' consequences but also a benchmark that can be used to determine what is meant by 'benefit' and 'harm' and thus also by 'opportunities' and 'risks'. In utilitarianism, for example, this benchmark is well-being: the best consequences are measured by the criterion of maximising well-being. No matter what such well-being consists of – whether pleasure or happiness, fulfilment of preferences, etc. – it will be something that is difficult to quantify. It is in this sense that the term 'calculus' is to be understood. It refers to the process of reaching an overall moral judgement about the consequences as a whole.

Deontologists reject consequentialist impact evaluations but their approach also excludes the weighing-up of risks and opportunities, i.e. a balancing or trade-off. As long as a risk is unacceptably high, it must not be imposed on others, regardless of the opportunities that it may present (assuming the primacy of negative obligations). But if the risk is acceptable, then the focus shifts to the opportunities, insofar as they are associated with positive obligations.[10] In this case, everything must be done to carefully identify these opportunities, to collect the relevant data and then to utilise the opportunities, i.e. to develop the products and use them according to their purpose. As noted above, this approach is not based on the idea of maximising benefits, nor on that of balancing risks and opportunities. Rather, the idea is that there is an obligation to help, and/or do good to, each and every person in need of assistance, provided that they request or accept this help as autonomous individuals. By contrast, if the opportunities do not entail any positive obligations, this implies the permission to exploit them as one sees fit.

4. The 'innovation principle' and the idea of weighing up precaution and innovation

The question is not whether opportunities and risks must be taken into account. On that point, economic, scientific, political, legal and ethical considerations all yield the same conclusion: both should be taken into account. The question is rather how they should be taken into account. In this regard, the preceding discussion has provided some pointers from an ethical perspective. It is now time to consider in more detail how the idea of weighing up or

[9] Cost-benefit analysis also stems from a consequentialist tradition and follows this pattern.

[10] A separate question to be addressed is: who has these obligations? If moral obligations presuppose that someone is able to do what is required of them ('ought implies can'), the question arises as to whether there are, or may be, certain obligations that are not assigned to an individual or individuals but to collective entities such as companies, governments or supranational organisations. (This implies that such entities are moral agents, i.e. able to act and take moral responsibility for their actions.)

balancing precaution and innovation could be understood in light of the debate outlined above and the proposal to supplement the precautionary principle with an ‘innovation principle’.

First we need to distinguish between two possible interpretations of the ‘innovation principle’. On the one hand, it could be taken to mean that the expected impacts of precautionary measures on the innovation climate and on the ability of the economy or individual companies to be innovative would need to be assessed. On the other hand, it might refer to the general idea of weighing up opportunities and risks in a certain way in respect of economic and scientific/technological activities.

Under the first interpretation, the ‘innovation principle’ is not merely a requirement to carry out an empirical precautionary impact assessment. Rather, it implies a value judgement since the assessment serves to determine whether the consequences for individual companies or the economy as a whole are negative or positive. Understood in this way, it is an economic consideration. Assessment criteria include for example competitiveness, jobs or economic growth. The next question would be how to understand the proposition that the precautionary principle and the ‘innovation principle’ are equivalent and complementary. This proposition would prove especially problematic if a certain precautionary measure or practice were deemed to have a negative effect on the innovation climate or the ability to innovate. Firstly, it would be necessary to ask whether this could be proved, and if so how. Secondly, one would have to ask whether one can infer from the equivalence of the principles that in these cases the ‘innovation principle’ prevails insofar as the negative effects loosen the safety requirements associated with the precautionary principle. And if so, in what way.

What *is* incompatible with the idea of equivalence, assuming we take it seriously, is a general primacy of the ‘innovation principle’ whereby innovative technologies and products, even if plausible evidence points to possible serious harm, are allowed equally fast access to the market as technologies and products that are deemed safe. Such a general primacy contradicts the idea of weighing up, which assumes that prima facie equivalent principles must be weighed up on a case-by-case basis, precisely because there is no general primacy of one over the other. In addition, by this stage at the latest, the question arises as to which criteria should be used to assess whether a marketable product is innovative and, if so, how innovative it is. These criteria would have to be applied in a case-by-case assessment to decide which principle prevails.

However, this interpretation focuses solely on the ‘innovative’ aspect. From a business ethics point of view, though, it is questionable whether this issue is even relevant for market authorisation. Even if clear criteria existed to decide whether a product was not just new but also innovative, why should this affect its market authorisation? Similarly, the innovative aspect does not always seem to be a key factor in determining competitiveness and commercial success. It is by no means the case that unquestionably innovative products are always more successful on the market than conventional products, even where these are of lower quality. Ultimately it is consumers who determine the success or failure of a product. And rightly so, at least if we assume that consumer freedom is the only normative criterion for deciding which products deserve to be commercially successful.[11]

[11] This assumption is open to dispute. For example, one might argue that, from a moral point of view, consumer freedom is limited by the moral obligation to live as sustainably as possible, and that the degree to which a product deserves commercial success is measured by how far it contributes to such a lifestyle.

However, advocates of the innovation principle seem to be less concerned with the innovative (as opposed to the new) and more with the fear that excessive safety requirements will lead to competitive disadvantages. They claim that it takes too long for new products considered potentially hazardous from a precautionary perspective to obtain authorisation. This, it is argued, is a disadvantage vis-à-vis other countries, where the safety requirements that new technologies, materials and products must meet before they can be authorised are less stringent.

It may be asked what evidence this assumption is based on and whether it is empirically plausible. Is it true that the precautionary principle, as applied in the EU and Switzerland, has a negative impact on the 'innovation climate'? Is there really a "trend whereby innovative ideas are conceived in Europe but developed into marketable products elsewhere" (Steilemann 2017)? If so, this would – from an ethical perspective – be a regrettable yet unavoidable situation, assuming that the precautionary principle was being properly applied as an ethically justified legal principle. In that case, it should be demanded that the precautionary principle be recognised as a universal principle and hence applied universally, i.e. globally.

According to the second interpretation of the 'innovation principle', the focus is on the function and evaluation of opportunities and risks with respect to novel products and technologies that promise economic, social and/or environmental benefits. Its advocates see the precautionary principle likewise as a principle that evaluates opportunities and risks. They seem to assume that it has, at the least, a tendency to overweight risks and underweight opportunities and therefore see the 'innovation principle' as a counterweight to this, designed to compensate for the one-sidedness of the precautionary principle. This is particularly important if the 'innovation principle' is understood not only economically but also as a principle that ties innovation to the concept of sustainability, and also if one assumes that our economy and society should be transitioning to a (more) sustainable state as soon as possible, and this cannot be achieved without the use of new technologies.

However, this notion of 'compensation' is based on a misunderstanding of the precautionary principle. As has been demonstrated, the precautionary principle applies in situations of uncertainty – and not (or no longer) when the risks (and opportunities) are sufficiently well known to be evaluated. These two aspects or levels need to be kept separate, but in reality they are routinely conflated in economic, legal and political discussions of the innovation principle.

A typical example is the statement by Kurt Bock quoted above: "(...) Where a real danger exists, precautionary considerations should take priority." The precautionary principle is not intended for situations of "real danger". In such situations we know the risk, i.e. we know that there is a significant or near-certain probability that (potentially major) harm will occur. However, in situations of uncertainty, where the precautionary principle applies, we do not know this. The two types of situation are to be judged differently from an ethical point of view. In precautionary situations, we do not know the risk. Accordingly, the primary objective is, firstly, to prevent the occurrence of potentially serious harm and, secondly, to generate the data that will allow the risk, i.e. the probability of this harm occurring, to be determined. The safety requirements defined and monitored by the state are based on these two criteria. From an ethical perspective, the 'innovation principle' raises the question of when we have sufficient knowledge to be able to evaluate the risk. The 'innovation principle'

would have some justification if there were evidence suggesting a tendency to remain precautionary for too long, even once it has become clear that specific risks are of a magnitude that would have to be considered acceptable.

If we know the risks, we are no longer in a precautionary situation. Only at this point can we evaluate the risks. The risk evaluation criteria applied by the two relevant ethical theories have been outlined above. Importantly, both take a similar approach to the precautionary evaluation, albeit for different reasons. However, the risk evaluation then follows different criteria, which may lead to different results.

In deontological terms, the first question is whether or not a risk to which others are exposed is acceptable. If it is not acceptable, it must be appropriately reduced by risk management measures (assuming a primacy of negative obligations). As long as it is unacceptable, the product in question must not be authorised. If the risk is acceptable, the next question is: what opportunities are associated with it? If these opportunities relate to positive obligations (such as health protection or food security), an attempt must be made to exploit them. If they do not relate to positive obligations, if for example they can, at best, be expected to improve quality of life or boost economic growth (e.g. 5G mobile technology), they may (but do not have to) be developed. In both cases, placing on the market and/or marketing authorisation is justified if the risks are acceptable.[12]

From a consequentialist perspective, risks are unacceptable if they do not result in a maximisation of the expected overall benefit within the context of a risk/opportunity calculus (based on an overall judgement). Conversely, all the risks required for this maximisation must be accepted, regardless of their size.

5. Conclusion

If, rather than understanding the ‘innovation principle’ as an attack on the precautionary principle or as an attempt to weaken it, we take seriously what its advocates are keen to stress, namely that it is intended to complement the precautionary principle, it becomes clear that the precautionary principle does not need to be supplemented in this way insofar as, understood correctly, it neither inhibits nor is hostile to innovation. While it does stress the potential for serious harm, it also demands a broadening of knowledge about opportunities and encourages alternative development paths, which may entail less potential harm but equal (or greater) potential benefits, to be considered at an early stage of product development. This appraisal is not altered by the fact that there may be cases in which a development path that is promising, not only economically but perhaps also socially and environmentally, has so many constraints placed on it by precautionary measures that it is not pursued for financial reasons.

As long as we are in the precautionary arena, it is not a matter of ‘weighing up’ or ‘balancing’ risks and opportunities but of identifying the unknown probabilities of potential serious harm. Only once these risks are known can they be evaluated. Yet advocates of the ‘innovation principle’ seem to assume that the risks, as well as the opportunities, are already known. They therefore ignore the fact – of fundamental importance from an ethical perspective – that the

[12] If marketing these products is in the public interest, as can be argued in the case of 5G, the state must ensure that the appropriate framework conditions are in place.

process has two levels. Level one is the precautionary level (situation of uncertainty); level two is the level of risk (and opportunity) evaluation (situation of sufficient or complete knowledge of the risks). Viewed in this way, it makes no sense to postulate an 'innovation principle' that is to stand alongside and complement the precautionary principle and have equal status with it.[13]

It is also important to note that, from the point of view of ethical theories, it is not a question of 'weighing up' risks against opportunities, in the sense of 'balancing' or 'trading off' one against the other. These metaphors may be relevant in political discourse, where pragmatic issues must also be taken into account, but from an ethical viewpoint, when it comes to the development of new products and technologies and when the risks and opportunities are known, what it boils down to is either a calculus aimed at increasing the expected overall benefit or, in the context of permissible risks, the taking of market-driven decisions, possibly backed by government incentive schemes.[14]

For the reasons set out above, the ECNH believes that the criticism of the precautionary principle voiced by advocates of the 'innovation principle' is unfounded; and that, ethically speaking, there is no plausible reason to comply with the political demand, sometimes associated with the 'innovation principle', of accelerating the authorisation of innovative products with considerable potential for harm.

[13] Occasionally, one also finds formulations such as 'weighing up or balancing reasons for concern (precaution) against the promise of benefit'. 'Reasons for concern' can be understood as the possibility of serious harm, giving cause for concern. On the other hand, 'promise of benefit' is ambiguous. It could refer to a potential benefit whose probability of materialising is not known, which would effectively make it the positive counterpart to potential harm in precautionary situations. For both deontologists and consequentialists, such a promise, understood in this way, would be irrelevant to the question of authorisation in a precautionary situation – even if one should try to gather data on the potential benefit, within the limits of precaution. Alternatively, 'promise of benefit' (in the sense of 'product x promises benefit y') may mean that the opportunities, i.e. the probability of the benefit occurring, can already be adequately assessed. In which case we are not (or no longer) in a precautionary situation. Understood in this way, reasons for concern and the promise of benefit cannot be weighed against each other.

[14] See for example the EU's Bioeconomy Strategy (2018): *A sustainable Bioeconomy for Europe: strengthening the connection between economy, society and the environment*, https://ec.europa.eu/research/bioeconomy/pdf/ec_bioeconomy_strategy_2018.pdf.