

# The non-scientific base of coexistence legislation in the European Union

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## Abstract

*The low consumer acceptance of both GM plants and GM food form the political starting point for establishing regulations for labelling and coexistence. The EU pursues two general goals with these regulations: one is the producers' and consumers' freedom of choice to reject GM crops; the other is to establish the precautionary principle. Both goals depart from the realm of traditional risk assessment based on scientific knowledge. Rather, social and political science factors play a crucial role.*

## Introduction

In the past year (2008), GM crops were planted on 108,000 hectares throughout the EU. This is a rather modest area compared to the 125 million hectares cultivated world-wide.<sup>1</sup> The number of GM plants which are currently approved for import into the EU for processing or which are licensed as food or animal feed is also rather small (July 2009: 29).<sup>2</sup> No more than two GM plants are presently approved for cultivation within the EU.

The majority of the EU's population view GM food as not being useful, as morally unacceptable and as a risk for society. On average, only 27% of the European population endorse GM food and advocate its financial support. Various other surveys confirm these results, which are particularly remarkable when compared to the US: there, 61% of the population support GM food.<sup>3</sup>

The low consumer acceptance of both GM plants and GM food form the political starting point for establishing regulations for labelling and coexistence. The EU pursues two general goals with these regulations: one is the producers' and consumers' freedom of choice to reject GM crops; the other is to establish the precautionary principle. Both goals depart from the realm of traditional risk assessment based on scientific knowledge. Rather, social and political science factors play a crucial role.

The freedom of choice enables consumers to make their own decisions regarding whether they judge GM plants to be safe or dangerous, or whether they reject or accept GM plants for other reasons. A precondition for this freedom of choice is the labelling of products made from GM crops, which is subject to Europe-wide standardised regulations.<sup>4 5</sup> The decision to establish a labelling system also necessitates a market segregation of GM plant products and GM plant-free products. Part of this market segregation is agricultural coexistence. EU specifications on this topic are directly built upon the labelling regulations. On this basis, a threshold of a 0.9% share of GM crops in food and feed must be adhered to, above which value products must be labelled accordingly. While the 0.9% threshold value is standardised and binding EU-wide, EU specifications regarding coexistence are only of a recommendatory nature.<sup>6</sup> The concrete implementation is incumbent on each individual EU member state.

The precautionary principle recognises the fact that there are risks which at this point in time can be neither proved nor completely ruled out (unknown unknowns).<sup>7</sup> This is one reason why GM crops are subject to monitoring even after being approved for cultivation within the EU, with the aim of identifying any yet unknown side effects. Another reason is that licences must be renewed after 10 years. The precautionary principle is not only implemented by establishing coexistence rules, but is already laid down in an EU-wide valid approval procedure for GM plants (e.g., through prohibiting antibiotics resistance genes).<sup>8</sup>

## Freedom of choice and the precautionary principle with regard to labelling

The landmark decision to implement labelling in order to achieve market segregation is already a first political decision. Laying down the precautionary principle in regulations for licensing and coexistence rules is another. Beyond setting the general course with these decisions, the precautionary principle gives further scope to considerations and decisions that are not exclusively based on scientific criteria. But more about this later.

A comparison of international standards shows that how the question of labelling and consumer sovereignty regarding GM plants is addressed is nowhere near uniform. In the US, for instance, consumer sovereignty was not made possible. Certainly, the low level of public acceptance of GM plants and food in many EU countries in particular led to special regulations being drawn up for licensing and labelling.

Another political decision is how to specifically organise the labelling. In 2003, the EU replaced the proof-based labelling regulation, initially implemented in 1997, with a process-oriented labelling system that is independent of detectability of GM content in the end product. For unapproved GM crops there are no thresholds, as any traces are prohibited. Only GM crops approved by the EU are permitted. In cases where their admixture to a product was inadvertent and technically unavoidable, the product must only be labelled if the GM yields exceed the 0.9% threshold. However, detectability is not the decisive factor in labelling. It is sufficient that the respective percentage has been present in the supply chain of a food product. This necessitates a comprehensive certification system to ensure the retraceability of a product. Thus, current law requires that, for instance, not only soya beans but also soya lecithin generated from such beans has to be labelled as genetically modified. However, the supply chain does not need to be completely retraced. There is no obligation to label animal products, meat and milk, if the animals have been fed on GM crops. Also, substances derived from GM micro-organisms do not require labelling. Thus, GM products are always GM products according to the legal definition.

How far does the precautionary principle go in this area? Changing from a proof-based to a process-based labelling system means that labelling is now required for products that within the supply chain may be very far removed from the ingredients that were actually genetically modified. Many critics of GM plants continue to believe that there may be health risks, even if the genetic modification is not detectable on the DNA level. However, the present state of knowledge in this area is not advanced enough to talk of any scientifically valid initial suspicion that goes beyond mere speculation. One goal of the precautionary principle is the future discovery of yet unknown side effects. It is questionably, however, to what extent it will actually be possible to validly relate a side effect that manifests itself later on to the genetic modification of the plant, if it was introduced so far back in the supply chain that the GM plant is no longer detectable. Also, the further back it was introduced, the greater becomes the number of factors potentially responsible for an observable effect.

The precautionary principle is not the main reason for the decision to introduce labelling that is independent of detectability. Strengthening consumer sovereignty is much more pertinent. In this way, the paternalistic principle of a collectively binding decision by the state is complemented by the democratic principle that every citizen is capable of making sovereign decisions. However, one could say that the precautionary principle established by the state, grounded on approval and coexistence, is complemented by a personal philosophy of precaution – based on the labelling system – which every individual puts into practice when shopping at the supermarket.

The explanation for this dualism can be identified not through the natural sciences but through political science. Enabling freedom of choice is a reaction to today's pluralistic society with its diverging and sometimes conflicting opinions, interests, and basic beliefs. At the same time, technological progress has been confronting us with a plethora of complex issues and risks ever since the Second World War. To some extent, consumer sovereignty shifts control back to the people. This can mean that consumers establish their individual risk perception, which may differ from the perception and evaluation of the experts, who carry out a risk assessment based on scientific knowledge. This may also mean that decisions are made on the basis of personal beliefs or ethical judgements which have little to do with actual scientific safety issues regarding health or ecology. Personal beliefs need not even necessary be directly related to genetic engineering. For instance, consumers' assessment of genetic technology depends upon their general faith in governmental institutions, their attitude to multinational corporations and globalisation, their individual concept of nature, and their general evaluation of technological progress.<sup>9 10</sup>

Reasons for rejecting GM plants and food can be based both on rational judgement as well as on a rather vague, unconscious rejection. There is no distinct line between these two reasons, and both are equally legitimate in terms of consumer sovereignty. As with democratic elections, consumer sovereignty does not mean that citizens have to provide informed reasons for their decisions or base them on factual information only. It would certainly be unrealistic to expect this from every citizen in respect to a buying decision.

Having a legal approval process, in which potential health and ecological hazards come under scrutiny, does not necessarily mean, however, that many consumers – even those who would not be counted as hard-core opponents – will no longer assume GM plants to be hazardous. In this case, the collective legal framework established by the EU may end up being “overruled” by individual single-case decisions.

The decision to permit freedom of choice builds on insights regarding risk perception. According to these insights, people rate imposed risks as much greater, and object to them more strongly, than to risks that are taken on voluntarily and believed to be under control (e.g., smoking). Another question is whether this principle also works the other way round, i.e., whether the possibility to choose and the voluntary assumption of risks lead to a rise in public acceptance. The chances are that the equation is not as simple as that and that other factors need to be taken into account. For example, a real or perceived risk must be associated with an adequate benefit in order to be taken. Another influential factor is the public debate. As

individual consumers rarely have time to acquaint themselves in detail with specialised scientific background information, they must rely on media reports.

In the public debate, however, the average consumer will find it hard to follow the different lines of reasoning for product labelling. Process-oriented labelling was established in order to grant freedom of choice, beyond all legitimate and verifiable safety concerns, to those who continue to have reservations – for instance, just because they “want to be on the safe side”. However, the principle of a basic freedom of choice has its limits even in respect to process-oriented labelling: if the landmark decision to permit the planting and selling of GM plants is to be retained, then threshold values for admixture, defined as technically unavoidable, must be established at some point in the supply chain. In respect to the risk perception of most consumers, it is probably irrelevant whether these threshold values are directly measurable or can be retraced via a certification system.

Also questionable is the extent to which the principle of consumer sovereignty – as the case may be, the rejection of the use of gene technology on the basis of personal beliefs, completely independently of safety issues – is transferable in a functional way to the problem of coexistence. In other words, is coexistence on a fundamental level possible at all?

Regarding consumer sovereignty, coexistence regulations will inevitably come up against barriers if basic beliefs are considered on an equal basis. Once released into nature, transgene dispersal of GM plants into nature can never be completely prevented. However, this very fact clashes with the conviction that GM crops should best not be used at all. The logical standpoint for strict opponents is initially one of “zero coexistence”, and, if that cannot be enforced, then one of “zero tolerance coexistence”. Consequently, every case in which transgene dispersals can be detected counts as evidence that the coexistence of both production systems is generally unfeasible. The absence of “zero tolerance coexistence” is, from strict opponents’ point of view, equivalent to a potential safety risk.

Defining a threshold value is a further political decision that is not primarily taken on the basis of safety issues or scientific content. At stake is far more the economic question of how to organise the required market segregation reasonably in order to enable the coexistence between GM and non-GM supply chains. The most pertinent question is therefore not about what is safe, but about what compromises can be demanded from both forms of production. From strict opponents’ point of view every compromise – and thus every threshold value – infringes upon the promise that every consumer has a fundamental right to reject GM plants and food, even if they expressly do not claim as the reason for their rejection any safety concerns, but rather, for example, personal political beliefs.

Due to the threshold values based on EU coexistence regulation, it is in fact impossible to implement a personal political belief that completely opposes the use of gene technology. This is at the very core of the ongoing controversy about the design of coexistence rules. While EU labelling tries to extend the principle of consumer sovereignty to personal considerations that are not necessarily related to safety issues, this goal cannot be reconciled with the basic idea of coexistence. This has direct consequences for organic farming, which reflects this basic belief, and

whose products promise to be completely free of GM organisms. It also affects beekeepers who would like to produce GM plant-free honey.

## The precautionary principle and coexistence

The other objective of EU labelling regulations is to give a framework to the precautionary principle. This raises the question of what the regulations for coexistence can achieve in respect to the precautionary principle, or, as the case may be, what they are meant to achieve.

For a start, it is a political decision to place GM plants under the special supervision of the precautionary principle, but not other forms of plant cultivation or farming practice. One mechanism for this is post-authorisation monitoring which is meant to help securely connecting effects that arise during the cultivation of GM crops to those plants. Another means is a more sensitive definition of risk, which does not only take into account risks that are supported by scientific facts. Rather, an emergency stop should be possible whenever a plausible initial suspicion can be identified.

What initially appears inarguably sensible and foresighted encounters difficulties when put into practice. In individual cases it can be hard even for experts to decide when there is a scientifically plausible initial suspicion and when it is mere speculation. And even experts do not always agree with one another.

Furthermore, the precautionary principle cannot solve the fundamental problem of the limitations of safety assessments. It remains an auxiliary construction. However, it shifts the starting positions of the argument in favour of the opponents of GM plants, and to the disadvantage of its supporters. In the public debate, at least, a reversal of the burden of proof may occur: it is not for the critics to provide evidence that an initial suspicion is plausible. Rather, the supporters must prove that an initial suspicion is not scientifically valid.

This debate takes a paradoxical course: critics demand that supporters fully eliminate risks of any sort. Vice versa, supporters demand that critics fully prove the existence of risks. In principle, however, neither is possible. An understanding can only be reached if both parties deviate from their maximum demands (which we have simplified here on purpose) and agree on a compromise. This compromise is then reflected in the implementation of the precautionary principle.

Evidently, this means that the implementation of the precautionary principle is not just based on science. The essential fuzziness of the precautionary principle offers scope for political decision-making: to start with, scientific facts can be interpreted according to political interest. Furthermore, different basic beliefs can lead to different perceptions of what presents a risk and what doesn't. In practice both instances occur, but are usually difficult to distinguish.

In the EU's political multi-level system the scope for political decisions is implemented within the framework of the approval of GM plants:<sup>11</sup> after receiving an application for approval, the European Food Safety Authority (EFSA) conducts a safety assessment and issues a statement concerning the GM plant in question. This

is passed on to the EU Commission and all member states. Based on the EFSA statement, the EU Commission issues a recommendation, which is then presented to the “Standing Committee on the Food Chain and Animal Health”. This committee consists of representatives from all 27 EU member states. To reach a decision a so-called “qualified majority” is required. According to the currently valid Treaty of Nice, this means that sufficient member states must agree so that they represent 72.3% of the countries and 62% of the total population of the EU. This method of decision-making follows the same pattern as other EU legal procedures and is based on the assumption that the political level (i.e., the member states) will usually follow the recommendations of EFSA’s scientific evaluations. Instead, such deviating votes, which need to be evaluated on the basis of new scientific evidence, are the norm. The usual result is a deadlock, because there tends not to be a qualified majority for a rejection either.

If the committee does not decide on a new basis for decision-making, the EU Commission passes its former recommendation on to the European Council of Ministers. This committee comprises the relevant departmental ministers from all member states. If this committee is also unable to come to a decision based on a qualified majority (rejection, agreement, or referral back to the EU Commission), it is up to the EU Commission to make a final decision. In recent years, this has been the rule rather than the exception. The EU Commission is then in a position to enact its recommended decision, legally and binding, for all EU member states. This overview shows the great influence the EU member states have in the approval process. Additionally, individual member states can invoke a protective clause in order to prohibit the approved GM plants on a national level (safeguard measures). In the case of the GM maize type MON810 some countries have exercised this option, amongst them Austria, Hungary, and France. Such bans must be justified by new scientific findings, which contradict previous safety assessments. EFSA is asked for a scientific evaluation, and the EU Commission can demand the revocation of the national ban. However, in this case, again, the European Council of Ministers has the final political right to decide. In a recent case, in March 2009, the committee rejected, with a qualified majority, the EU Commission’s application to revoke the Austrian and Hungarian national bans on the cultivation of MON810, which is the only crop of the two EU-approved GM plants actually cultivated.<sup>12</sup>

To scientists, the political decisions made during the approval process often seem arbitrary, especially when decisions are justified using scientific findings that do not reflect the state of current scientific debate. GM plants constitute only one of many examples where this contradiction becomes evident. Somewhat malevolently one might say that science is simply being used as an instrument to justify political decisions and only such sections of science or individual scientific views are used which fit the political goal. This explanation certainly holds true for some cases, more generally, however, it takes too narrow a view. The seeming arbitrariness of political decisions also occurs because they are based on different basic beliefs and frames about what the problem consists of (e.g., just GM seeds or the general orientation of farming) and which concept of risk is taken as a basis.

The seeming arbitrariness becomes comprehensible when one takes into account that the job of politics is fundamentally different from that of science. The logic of politics demands intervention in the case of an initial suspicion in order to prevent

potential hazards even if verifiable scientific facts are missing at the present stage. This approach certainly reflects the preferences of most EU citizens – especially in regard to GM plants and food. In this process, it is irrelevant whether the initial suspicion later turns out to be groundless or not, because the protection of citizens outweighs the risk of having made the wrong decision. Another objective of politics is to negotiate a compromise in the case of differing basic interests or beliefs. Furthermore, politicians and parties stand for election on a regular basis and have to justify their political decisions to their electorate. This is how people's interests and values affect political decisions in democracies.

Admittedly, the sweeping argument that yet unknown risks exist can always be raised against every technological innovation. Moreover, not making a decision can also pose a risk. In the worst case, presently unknown risks could be used to prevent a technological innovation that might have been generally advantageous for a society, or at least for a particular economic sector. This mirrors the line of argument followed by supporters of GM plants. True, this line of argument overlooks the fact that not everyone may benefit from these advantages to the same extent, or that there could also be disadvantages, or that advantages and disadvantages could be unequally distributed. However, it demonstrates the general dilemma about having to make the political decisions today despite basically having an incomplete knowledge about their future effects. From this dilemma results the conclusion that the legal precautionary principle must be taken into account in a risk assessment. In the EU, the EFSA supplies the scientific part. The governments of the EU member states contribute the political part. In this process, the EFSA is decidedly subordinate to politics, where the final decisions are made.

So far we have dealt with the approval process. The question that follows is whether this principle of a mixed, half scientific, half political, risk assessment can, and should, be translated into coexistence rules as part of the precautionary principle. The idea is that approved GM plants – after having been tested – should have no particular ecological effects nor pose a hazard to consumer health. Threshold values for transgene dispersal for GM plants and isolation distances between GM crop fields and neighbouring non-GM field with sexually compatible crops serve to organise spatial segregation and minimise economic damage resulting from GMO admixtures, not, however, to minimise ecological and health risks. The precautionary principle as another objective of coexistence rules breaks up this division of tasks between approval and coexistence.

Clearly, the goal of preventively protecting us from yet unknown ecological and health risks reaches beyond the objective of simply organising the coexistence of GM crops and non-GM crops. If we assume the attitude that every transgene dispersal of GM crops from their field to the surroundings poses a potential ecological hazard, then coexistence measures will always be insufficient and at best ambivalent in nature: they cannot completely exclude the occurrence of transgene dispersals of GM plants. However, they are certainly useful for minimising such transgene dispersals and, thereby, potential risks. Following this logic, coexistence rules are also measured by their ability to minimise transgene dispersals of GM plants, effectively as a second precautionary protective barrier in addition to approval. At this point, therefore, the issue is no longer about complying with EU-

wide threshold values for admixture. The coexistence measures now additionally aim at in fact lowering these threshold values.

One could argue that double safety is not necessarily detrimental. However, this additional safety does indeed have a downside: the greater the restrictions on intermixing and the requirements for coexistence, the lower the economic efficiency of the use of GM crops. Here we encounter the same problem as in the discussion about threshold values for GM plant traces, which ended in a political compromise about threshold values for labelling. The transfer of these threshold values into rules of coexistence, i.e., the concrete implementation of the EU-wide compromise, is incumbent upon the member states.

Outwardly, there is an ongoing controversy in the individual member states about how to prevent as far as possible the threshold values being exceeded. However, the fundamental conflict of whether or not to use GM plants at all resonates in these discussions. Against this backdrop, the member states use the precautionary principle as their core argument to renegotiate the compromise between forms of production that use GM crops and don't use GM crops.<sup>13 14</sup> This can lead, for example, to differences in the required minimum isolation distances between GM crops and conventional maize fields, ranging from 25m (Netherlands) to 800m (Luxembourg). The required isolation distances between GM crops and organic crops can be considerably higher (in the Netherlands: 250m as opposed to 25m).<sup>15</sup> Those differences in national standards can, to some extent, be attributed to the regional variation of agronomic, climatic and other factors determining the probability of GMO admixtures occurring. However, the regulations are only partly based on scientific knowledge. Political considerations play a major role, on the one hand by imposing maximum restrictions for the purpose of the precautionary principle, while on the other hand preventing the requirements from being so severe as would in fact amount to a ban on GM crops. The latter would contradict the landmark decision to allow the cultivation of GM crops in the EU. This resolution cannot be openly contradicted by EU member states. Furthermore, member states have different liability regulations for cases where GMO admixtures results in economic damages for non-GM farmers.

Another aspect of the precautionary principle is post-authorisation monitoring. Its objective is to help identify yet unknown risks during the use of GM crops. However, the implementation of post-authorisation monitoring runs up against difficulties: on the one hand it means entering unmapped territory, because there are no guidelines as to what specifically should be observed. On the other hand, in post-authorisation monitoring – as with the initial approval process – it is unclear what the actual risk may be. For example, does a GM plant in a nature reserve already pose a risk, simply because it is not meant to grow there? Or does this GM plant only pose a risk if it causes demonstrable negative ecological effects? Does the potential danger of a horizontal gene transfer suffice, or does this exist only when it has been observed and a plant has gained a fitness advantage, and thus, increased invasivity?

## Coexistence as a confidence-building instrument

At this point, we would like to mention once again one decisive reason for the establishment of the precautionary principle in the EU, this being the low level of

public acceptance of GM plants and food. In view of this political background the question arises of whether the coexistence regulations actually have a calming effect on the public debate and contribute to increased public acceptance.

Generally speaking, the incorporation of a special precautionary philosophy into the regulations of coexistence may be taken by the public as proof of a particularly high standard of safety for GM plants. Alternatively, it may be interpreted as an admission of the particularly high risks in GM crops not present in other forms of plant cultivation.

In any case, the general public can easily gain the impression that coexistence measures primarily serve the purpose of protecting the consumer against known ecological or health risks. This impression is strengthened by the fact that isolation distance rulings are not only discussed in the context of agricultural coexistence. Similar segregation distances are required as buffer zones between GM crops and nature reserves in order to prevent potential risks.<sup>16</sup> Even for citizens with a great interest in the topic, the different purposes of isolation distance rulings and buffer zones are hardly comprehensible.

Furthermore, people may get the impression that any admixture of GM plants and non-GM plants equals an ecological or health risk. Here it is irrelevant whether threshold values are respected or not. In this case, coexistence regulations are falsely perceived as a means of establishing a zero-tolerance limit regarding ecological and health hazards. As emphasised previously, this original objective does not exist. From the perspective of consumers sensitive to risk, the coexistence rules seem to be failing with respect to the alleged protection goal. This in turn might easily lead to an increase both in public and political pressure against the cultivation of GM crops.

Notably, probably not just strict opponents have this risk perception but also average consumers, who have little chance of understanding this complex subject. In extreme cases, uncertain consumers will assume ecological and health risks also for GM plant presences below the threshold values permissible according to the economically oriented coexistence rules.

The view of the general public is of great importance considering the prevailing scepticism of the EU's citizens. The way in which labelling and coexistence are publicly perceived and discussed influences both political debate and decision-making. And, as described above, the precautionary principle and the EU's decision-making system allow sufficient scope for political decisions.

## **Conclusion**

Overall, it has become evident that measures of coexistence and labelling are not appropriate means for solving the fundamental conflict about the use of GM plants. The principle of a basic freedom of choice has its limits even in the case of a labelling system independent of detectability. The same applies to coexistence rules in agriculture, which put into practice the labelling thresholds. By putting these into practice, the economic coexistence of GMO and non-GMO supply chains should be

possible. The additional implementation of the precautionary principle is used as an argument to renegotiate this compromise.

The introduction and design of all measures is based upon political considerations. Scientific expertise plays only a limited role in this process. Other objectives are equally important, such as accommodating the population's widespread scepticism towards GM plants and food.

It is questionable, however, whether the complex labelling and coexistence rules will succeed in increasing the population's sense of safety. The mere existence of threshold values can be perceived as a safety risk by the general public. This holds equally true for labelling thresholds and thresholds for agricultural coexistence. If the initial function of the labelling and coexistence rules conflicts with the objective that is assumed for the general public, then it may even heighten public scepticism.

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