New Horizons in European Studies

Aston University, 24-25 April 2014

www.uaces.org

The Paralyzed EU Authorization of GMOs: A Fighting with Fear?

Ji Li

Ph.D. candidate in Tilburg University

I. Introduction

The EU authorization of genetically modified organisms (GMOs) is the most strange and controversial area in the whole EU law system: the scientists are seriously distrusted by the general public, the comitology procedure does not work at all, and the authorized GM products are banned by Member States without legitimate reason. But this is not the case in any other field of environmental law, and cannot be explained simply by precautionary principle or political pressure. This phenomenon provokes the author's interest: what is the crux of this predicament?

In this article, the author attempts apply the psychological study on environmental issue—usually called "the laws of fear"—to explore the conundrum. Mainly developed by Paul Slovic and Cass R. Sunstein, this theory revealed some entrenched differences between ordinary people and experts in reading the environmental risks, and how the public's fear may influence the environmental policy.

This article mainly contends for three points. First, the "experts v. ordinary people" scenario is also taking place in the authorization of GMOs and has become the cause of the deadlock. Second, the "science" in GMO regulation is far from "pure numbers", but has already incorporated the public's various concerns. Third, the real problem is not how much risk there is, but how much risk people can accept. Unfortunately, the current legal response actually aggravates people's fear and the EU needs to change its train of thought in this regard.

II. GMOs and Myth

A. What is GMO?

The human beings have been developing new varieties of plants for more than 10,000 years, in the effort to obtain better quality and quantity in harvest.[1] Conventionally scientists use many special means to produce gene mutation or recombination in plants, such as hybridization (within or cross species) and radiation mutagenesis, without knowing what exactly happens at molecular level, and the relevant risks, including ethical perils, are generally accepted by the public. In the 1950s scientists uncovered the double helical structure of DNA, and in the mid-1970s they found the right tool to cut and ligate a piece of DNA segment, thus gradually they developed a way to artificially transfer a gene from one organism to another. This new technology, usually called 'genetic modification' or 'genetic engineering', opened up unlimited possibilities to change the genome of any organism—in fact, transgenes have already been taken from bacteria, viruses, plants, and animals of various type.

In the EU law, GMO is defined as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural

[1] S.R. Parekh, *The GMO handbook: genetically modified animals, microbes, and plants in biotechnology* (Humana Press 2004), at 4.

recombination".[2] Two elements were emphasized in this definition, in order to distinguish GMOs with other sorts of organisms. First, it focuses on the human intervention—a kind of 'engineering manipulation', which is different from a natural process such as bacterial conjugation.[3] Second, not all the 'human intervention' can be defined as 'genetically modified', it only refers to "the insertion of nucleic acid molecules by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism",[4] which are not possible under natural conditions.[5]

The commercial application of GM technology primarily lies in the agricultural sector. GM crops can bring with the farmers and biotech companies appreciable benefits. This includes a higher yields, better quality and easier management measures. In the meantime, GM agriculture also contributes to some health welfare, such as less use of pesticides and lower level of certain toxins.[6]

B. Myth about Possible Risks

Every technical innovation has its potential risks, and this is especially true for GMOs. Operating in the complex biological system, of which we may only have a half-baked knowledge, GMOs may cause many unexpected consequences in theory. First, no one exactly knows what will happen when a new and foreign gene is inserted into a plant genome, the function of related genes may be changed due to the transformed structure in the DNA chain. Second, a new gene probably means a novel protein, which can be toxic or allergic to human or animals. Third, it is very difficult to predict the long-term environmental effects, such as the harm to non-target insects, biological invasiveness and the possibility of gene transfer (into other plants or even human bodies). Fourth, the free-wheeling way of creating new varieties gives rise to a lot of ethical concerns, which regard GM technology as interference with nature order or a sign of human hubris.[7] As these reasons, GM foods or crops are frequently labelled with 'evil seeds' or 'frankenfood' by anti-GMO groups.

While the unlimited creation of new life forms is definitely problematic and dangerous, the biotech industry and the scientific community never go that far. In fact, people have learned a great deal of lesions from 'mad cow disease', both from the regulatory failure and liability cost. First, the biotech industry has developed a series of methods to predict and detect the possible negative effects, like allergic or toxic effects. Second, many controversial techniques in genetic engineering are carefully avoided by the industry and the regulators. For instance, EFSA made a precautionary-based decision in 2004 to phase out antibiotic resistance marker gene (ARMGs) in the EU, even though "there is no evidence that the presence of ARMGs in GM plants has caused any damage".[8] Likewise, Monsanto committed that it will never commercialize sterile seed technology in food crops,[9] even the

---

[2] Article 2(2), Directive 2001/18.

[3] Bacterial conjugation is the process of transferring genetic material between bacterial cells, through cell-to-cell contact, or a bridge-like channel between two cells, which takes place naturally, without any human intervention.

[4] Annex Ⅰ A, part 1, Directive 2001/18.

[5] Lauren Zeichner, 'Product vs. Process: Two Labeling Regimes for Genetically Engineered Foods and How They Relate to Consumer Preference' 27 Environs: Envtl, L & Pol'y J 467, at 5.

[6] M. Qaim, 'The economics of genetically modified crops' 1 Resource, available at: http://www.annualreviews.org/doi/abs/10.1146/annurev.resource.050708.144203 (last updated on 2014.01.22).

[7] Daniel Gregorowius, Petra Lindemann-Matthies and Markus Huppenbauer, 'Ethical Discourse on the Use of Genetically Modified Crops: A Review of Academic Publications in the Fields of Ecology and Environmental Ethics' 25 Journal of agricultural and environmental ethics 265, at 266.

[8] European Commission, 'Opinion of the scientific panel on genetically modified organisms on the use of antibiotic resistance genes as marker genes in genetically modified plants' 48 EFSA J 1.

[9] Monsanto, 'Myth: Monsanto Sells Terminator Seeds', available online at:

conventional agronomical method produces sterile seeds as well.[10] Third, the final right of choice is at the hands of the consumers, thus the biotech industry normally selects those low-risk and morally acceptable products for commercialization. The best example is the widely used MON810 maize, which contains a novel protein from a microbe that is not toxic or allergic for human beings and most of other animals.

The real crux for understanding the conundrum of GMOs is its difference with conventional breeding methods. If one regards it as dangerous to accurately transfer one gene into a plant, why he accepts the risks of conventional hybridization, which transfers hundreds of genes into a new species in an inaccurate way? If the operation in GM technology is a defiance of nature order, why producing mutagenesis by radiation or chemical is morally accepted? The general public are very concerned about the long-term and unexpected effects of GM crops, and so far we have already cultivated and consumed GM crops for more than 15 years, with vigilant and intensive tests about all the possible impacts, there is no conclusive evidence to date confirming its 'harms'. On the contrary, all the high-profile events where some scientists asserted that they conclusively proved the negative effects of authorized GMOs have been invalidated by the scientific community.[11]

III. The Predicament in the Current EU Authorization of GMOs

The regulation of agricultural biotechnology in the EU is regarded as "one of its most contested policies and a notorious example of a malfunctioning regulatory regime".[12] In particular, the premarket authorization of GM agricultural products (including GM crops, food and feed) has been marked as a tortuous process with serious delays and uncertainties.[13] This is usually attributed to the drastic political divergence among EU Member States on this issue, but how and why does the modern biotechnology become the 'clay pigeon' among all the innovative and risky technologies? This section intends to address this conundrum.

A. A Brief Introduction about the Authorization Procedure of GMOs

The authorization of GMOs is a centralized power enjoyed by the EU. Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms establishes a general obligation to apply for prior authorization for the marketing of all GMOs. Regulation 1829/2003 on Genetically Modified Food and Feed provides a similar obligation for the marketing of GM food or feed or GMOs used in food or feed. Both the Directive and the Regulation explicitly apply the precautionary principle on a case-by-case basis.[14] In addition, it must be mentioned from the outset

---

http://www.monsanto.com/newsviews/pages/terminator-seeds.aspx (last visited on 2014.04.04).

[10] Nigel G Halford, *Genetically modified crops* (Imperial College Press 2011), at 161.

[11] For example, the Séralini Report published in 2012, which asserted that genetically modified maize NK603is poisonous to rats, was invalidated by EFSA and retracted by the publisher of the journal in the end. See European Food Safety Authority, 'Final review of the Séralini et al. (2012a) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in Food and Chemical Toxicology', EFSA Journal 2012; 10(11): 2986. Another good example is the article published in *Nature* in 1999, which claimed that the larvae of monarch butterfly were killed by the pollen of GM corn. At last the author had to admit that this experiment was far from a mature test, but preliminary one. The famous journal *Nature* was accordingly lashed out by the scientific community, since such publication was rushed through probably for headlines and publicity. See ibid, at 142.

[12] Vessela Hristova, 'Recent Developments in EU Biotech Regulation: A Possible Solution to the Deadlock on Authorizations of GM Crops?' (2010) 2 Eur J Risk Reg 151, at 151.

[13] ibid, at 151.

[14] See article 1 and 4 of the Directive 2001/18, and article 1 of Regulation 1829/2003.

that the EU regulatory system regulates genetic modification as a process, not according to the final product (as the regulatory approach in the United States).[15]

The authorization procedure for GM crops and food/feed is similar. It starts with an application from the 'notifier' to the competent national authority of a Member State. If that authority takes a positive opinion about the GM product concerned, this Member States will inform other Member States via the European Commission. If other Member States or the Commission raises no objections, the authorization will be granted by the competent authority and this is effective throughout the whole Union.[16] If, however, 'reasoned objections' are raised, a special decision-making procedure called 'comitology' will be triggered. According to the latest comitology procedure, the Commission first asks for the opinion from related scientific committees on the possible negative effects mentioned by the objections.[17] If the scientific opinion is favourable to authorize the concerned GM product, the Commission proposes a draft decision to a 'comitology committee' composed of representatives of Member States.[18] If the comitology committee gives a positive opinion, the Commission adopts the decision of authorization. If the comitology committee rejects the Commission proposal or can not reach a decision by qualified majority, the matter is referred to an appeal committee composed of Member States representatives, which shall reconsider the draft and make decision as a higher level of representation.[19] Finally, if the appeal committee is unable to find a decisive opinion, the Commission may adopt the proposal.[20]

In the risk-assessment, all the possible adverse effects on human health and the environment should be examined, including allergic and toxic reaction, flora and fauna, soil fertility, the food/feed chain, animal health and resistance problems in relation to antibiotics. The European regulatory institution especially emphasizes that "it is important not to discount any potential adverse effect on the basis that it is unlikely to occur",[21] therefore, the long-term and cumulative effects should be considered and evaluated as much as possible within the time limit set by law. Generally speaking, the risk-assessment procedure in the EU is regarded as the strictest in the whole world, while it still carries some inherent and inevitable defects. First, one major problem comes from the uncertainty inborn with innovative technology: it is impossible to wait 50 or 60 years to see whether the possible cumulative effects really happen. Hence, the only available method is to evaluate these issues with experience and expertise from scientists, and with data and models developed by the past research in the same or similar area. Second, all the needed information regarding risk-assessment is provided by the developer—biotech companies in the majority of all cases. Basically, this is how science develops, most of times people just review others' work, not repeating everything others has already done. Even though the competent authority like EFSA may ask the Community reference laboratory to carry out independent tests to vindicate the methods and date proposed by the applicants, or to ask a competent Member State authority to carry out the risk-assessment,[22] this is obviously rare case. In all, people in Europe worry about the lack of data and the *ex parte* information provided by the self-interested biotech companies.

---

[15] Jane Matthews Glenn, '" Government Wrongs": Civil liability for Gmo regulation in Canada' (2010) 18 AGRICOLTURA ISTITUZIONI MERCATI 169.
[16] Article 15(1), 15(3) and 19 of the Directive 2001/18.
[17] See article 28 of Directive 2001/18, see also article 5 of Council Decision 1999/486/EC.
[18] Article 30 of Directive 2001/18.
[19] See Rules of procedure for the appeal committee (Regulation (EU) No 182/2011). Adopted by the appeal committee on 29 March 2011, OJ 2011, C 183/13.
[20] Article 6(3) of Regulation (EU) 182/2011.
[21] Communication from the European Commission on the precautionary principle COM(2000) 1, para. 3.
[22] See article 6(3) of the Regulation 1829/2003/EC.

In addition, the authorization process should also take into account 'other legitimate factors', such as socio-economic and ethical impacts, when there is scientific uncertainty in the decision-making. However, some scholars argue that, even the law in paper prescribes so, in reality these factors are discounted by the 'synergistic action' of political divergence among Member States and the comitology procedure as the final solution. As they contended, this situation places the EFSA as the *de facto* decision-maker, which bases its decision exclusively on scientific assessment.[23] This is partly the reason some Member States take a political resistance in the authorization process, or ask for autonomy to ban GMOs after authorization in the central European level.

B. The Paralyzed or Delayed Result

If one only reads statistical number, he/she will surely draw the conclusion that something unusual is happening in the EU GMO authorization procedure. Some of the numbers and facts about GMO authorization are given here, which are extracted from a report published by EuropaBio:[24]

First, some numbers strongly suggests the procrastination of the authorization procedure.

(1) On average, for GM food and feed, it takes 45 month to achieve authorization, while the counterpart time is 25 months for United States, 27 months for Brazil, 30 months for Canada.

(2) It takes 11 months, on average, to put the products to the first vote after receiving the scientific opinion from EFSA, while law only prescribes 3 months.

(3) Every year, twice as many GM products enter the system than exit; almost twice as many product applications are still remaining in the system, than have exited it.

Second, there are also some political actions disguised in the legal procedure identified and complained by the industry:

(1) Some national governments simply vote against all scientific opinions from EFSA, no matter what it is, which suggests a political reason to oppose GMOs.

(2) The treatment to GM crops is strikingly poor, which can not be explained by science anyhow. As of January 2014 only one variety of GM crops—MON810 maize is authorized by the EU,[25] while 49 kinds of GM food/feed are approved for commercial release.[26] In the meantime, the number of authorized GM crops is approximately at the same level with that of GM food/feed in other countries.[27] It is generally believed that this is a strategy adopted by the Commission to promote more GM food/feed to be approved.[28] However, given such rigorous method, the renewal of the

---

[23] Floortje Maria Fleurke, 'Unpacking precaution: a study on the application of the precautionary principle in the European Union', at 196-197.

[24] EuropaBio, 'Approvals of GMOs in the European Union', available online at: http://www.europabio.org/approvals-gmos-european-union (last visited on 2014.04.02).

[25] The authorization of Amflora potato was recently annulled by the General Court of the European Union on December 13, 2013, see the General Court of the European Union, Press Release No 160/13, Luxembourg, 13 December 2013, available online at: http://curia.europa.eu/jcms/upload/docs/application/pdf/2013-12/cp130160en.pdf (last visited on 2014.04.05).

[26] European Commission, Health and Consumers, EU Register of Authorized GMOs, available online at: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm (data retrieved on 2014.01.27).

[27] For instance, in the United States this number is 90:90; in Brazil this number is 28:28; in Canada this number is 66:89.

[28] The Commission is currently taking a stand that, as a political compromise, Member States are partly allowed to decide whether to cultivate a type of GM crop in their territory after it achieves authorization from the EU, in order to facilitate the release of GMOs on the market for food/feed purposes. See Sara Poli, 'The Member States' Long and Winding Road to Partial Regulatory Autonomy in Cultivating Genetically Modified Crops in the EU' (2013) 4, European Journal of Risk

authorization for MON810 maize, which has a good safety record anywhere so far, is still suspended since 2007. This long and contested process can only be explained by political reasons.

Finally, some negative consequences are caused by the complex and dysfunctional authorization system:

(1) Trade problems: the delayed procedure may increase the likelihood of presence of non-authorized GMOs in imports, but actually these products are authorized in other countries and are waiting for authorization in the EU for a long time.

(2) Economic costs: the European farmers can not enjoy the higher yields and easier management measures brought by GM crops, and have to pay higher price for the feed.

(3) The EU as a whole will lose competitive advantages and innovative motivations in agricultural biotechnology, due to the regulatory malfunctions in the authorization.

(4) Consumer confidence will be weakened by sensationally negative news resulting from this messy authorization system.

C. The Failed Legal Procedure and Political Theories

There are some political theories or explanations proposed by scholars trying to understand and solve the dilemma in the EU GMO authorization. Comitology procedure, which is specially devised for promoting efficient policy implementation while ensuring a degree of Member State control over the decision-making process, works well in most areas of innovative technologies, yet is solely problematic in the GMO authorization process.[29] The basic and core fact is that EU countries are highly divided on this issue, so never a qualified majority can be achieved either for or against GM product in the commitology committee or the Council.[30] This leads to the fact that the Commission has the final say on GMO authorization, which in turn always agrees on the scientific opinion from the EFSA. EFSA is originally instituted with the explicit purpose to reinforce the public trust in the EU food safety regime after the BSE crisis, where the highly politicized scientific institutions were thought to be responsible for the occurrence of this disaster. The idea of scientists as 'objective' and 'independent' was therefore highlighted in the establishment of EFSA to give European people more confidence upon the decision-making process over technical innovations.[31] However, ironically, in the scenario of GMOs, many people blame EFSA as too much focused on pure science, and ask for more political legitimacy in the decision-making process.

Christoph Klika *et al*. contended that, from the perspective of 'delegation theory', the crux of the matter stems from the incompatibility of the logic of delegation. EFSA is endowed with a function to provide for credit commitment, while the role of comitology procedure is located in reducing the decision-making costs.[32] Vesco Paskalev argued that EFSA as a scientific committee has its own inherent flaws. First, the risk-assessment itself relies too much on the information provided by the applicants who are self-interested. Second, the expertise is context-dependent and subjective as well,

---

Regulation 143, at 144.

[29] Thomas Christiansen and Josine Polak, 'Comitology between political decision-making and technocratic governance: regulating GMOs in the European Union' 2009 EIPAScope 7, at 5.

[30] ibid, at 7.

[31] Grace Skogstad, 'Legitimacy and/or policy effectiveness?: network governance and GMO regulation in the European Union' 10 Journal of European Public Policy 321, at 329-330.

[32] Christoph Klika, Jinhee Kim and Esther Versluis, 'Why Science Cannot Tame Politics:The New EU Comitology Rules and the Centralised Authorisation Procedure of GMOs' (2013) 3 Eur J Risk Reg 327.

different experts may have different conception or judgment toward the same risky behaviour. Third and the most important, an expert body is reluctant to acknowledge the limits of its knowledge, or is inclined to make a fast decision in disregard of some potential and long-term consequences. Consequently, a *de facto* reliance on the EFSA as a scientific institution will lead to systematic deviation from the balance line between scientific and political legitimacy.[33]

In general, these political theories partly revealed the theoretical predicament people have to face: how can we create a regulatory body which is both politically and scientifically correct in the decision-making process with respect to a highly complex biological system? A highly political system failed before, and now a 'pure' scientific body is seriously doubted, then what's next? Should we design a better rule or institution, or shall we simply change the way we read the story? Is it an objective issue, or a subjective one?

D. The Polarized Views in Science

A common feature from all political theories lies in the assumption that a pure political opposition to GMOs is reasonable (because political legitimacy should be separated with scientific legitimacy), or the assumption that different understandings or attitudes towards an uncertain risk should be given the same weight. However, this basis is not true according to existing law-and-psychology studies, and this article aims at challenging this paradigm shared by all political theories concerning GMO regulation.

A good example for such divergence can be observed from the saga of Amflora potato—an extremely contested and controversial GMO authorization event. For example, some Member States expressed their concerns to a study of rats fed on Amflora, some of which exhibited increased number of cysts. To this EFSA responded that: "Thyroid cysts occur commonly in rats, while their frequency varies during ageing……slightly increased incidence ..... in male rats fed on transgenic potato is likely to be due to natural variability and does not trigger a further assessment."[34] Such disagreements also existed in the attitudes towards toxic and allergic of Amflora potato.[35] What is worse, Amflora potato contains an anti-biotic resistance marker gene, which is possible to spread antibiotic resistant traits from Amflora potato into the environment. This became a point of major controversy among the contested parties.

The debate on this issue became more and more heated later on. Some Member States remained unconvinced after several communications with EFSA. In EFSA's opinion, the nptII gene confers resistance to kanamycin, neomycin and several other antibiotics, which were of "limited use in human and veterinary medicine."[36] This statement was based on an earlier scientific opinion on antibiotic resistance, where EFSA classified the ARMG in three groups, placing the nptII in group I--ARMG which are safe to use because: (1) these genes are already widespread in nature anyway; and (2) because they confer resistance to antibiotics which "have no or only minor therapeutic relevance in human medicine and only restricted use in defined areas of veterinary medicine."[37] However, in 2005 the World Health Organisation (WHO) published a report, in which it classified kanamycin and neomycin as "critically important antibacterials."[38] Accordingly, NGOs like Greenpeace expressed their concerns to the Commission, and the latter mandated the European Medicines Agency (EMA) to

---

[33] Vesco Paskalev, 'Can Science Tame Politics: The Collapse of the New GMO Regime in the EU' (2012) 3 European Journal of Risk Regulation, Forthcoming 190.

[34] Amflora Opinion 2005, p. 10. Emphasis added.

[35] Amflora Opinion 2005, p. 11.

[36] EFSA Opinion 2004, p. 13.

[37] EFSA, 'Opinion of the Scientific Panel on GMO on the use of antibiotic resistance genes as marker genes in genetically modified plants' (2004). Hereinafter as 'ARMG Opinion', p. 11.

[38] World Health Organisation, World Health Organisation, 'Critically Important Antibacterial Agents for Human Medicine for Risk Management Strategies of Non-Human Use. Report of a WHO working group consultation' (2005).

opine on the importance of these drugs. In 2007 EMA concluded that kanamycin and neomycin are valuable antibiotics and "cannot be classified as of no or minor importance."[39] Asked again by the Commission, EFSA agreed, in a Statement in 2008, that kanamycin and neomycin are important, but still repeated its original conclusion that nptII is safe to use. EFSA emphasized two reasons for this conclusion: (1) its horizontal transfer (from plants to bacteria) was very unlikely; (2) it was widespread in nature anyway.[40] According to this opinion, the Commission proposed to authorise the Amflora for food and feed use via comitology procedure. The Food Chain Committee failed to reach a qualified majority and the decision was referred to the Council, which also failed to obtain qualified majority. Therefore, the issue was finally taken back to the Commission which adopts the proposal.

From this lengthy saga, one can clearly observe that the political legitimacy still depends on the reason behind that political claim. In other words, a clear and well-stated reason is prerequisite for both political and scientific legitimacy. Hence, a sound scientific reason is still the core of the debate regarding GMOs. In that sense, one can also find that the politically opposite groups, especially between the top experts and the general public, actually interpret the scientific story of GMOs in a totally different way. So, what does this mean? And who are right?

IV. A Psychological Reading of the Dilemma

In the late 1980s, the US Environmental Protection Agency (EPA) launched an ambitious project to compare the views of the public and the EPA experts on important environmental issues. The result was surprising and interesting: the two groups sharply diverged on many crucial issues, for example, the public linked some activities with high-risks (like nuclear accidents), while the experts evaluated them as low-risks, and vice versa.[41] Likewise, in some surveys conducted in Europe on consumer and expert attitudes to food risk, a sharp line was also drawn between the two camps, indicating that different conceptions about risks do exist.[42] This intrigued many scholars into groping for the inner mechanisms forming this disparity, and into studying its influence on the decision-making process on environmental issues. In this section, some basic conclusions from a series of psychological studies are introduced, at the same time the author would like to examine whether the same gap exists in the field of GMOs as well.

A. Experts v. Ordinary People: A Tale of Two Perceptions

Modern theories in cognitive psychology and neuroscience agree that human beings understand the risks in two fundamental ways. The 'analytic system', mainly used by experts, uses scientific logic and probability calculus to conduct risk assessment. It is a relatively slow and effortful process, requiring conscious control. The 'experiential system' is fast and intuitive thinking process, and not very accessible to conscious awareness. This system remains in the evolution history as the natural and primary way for human beings to respond to risks, since most of the daily risks must be handled quickly and automatically.[43] This divergence gives rise to two approaches of regulating risks: the *technocratic* and the *populist*. The technocrats emphasize that ordinary people are frequently ill-informed about basic scientific knowledge and urge that the regulators should follow science and evidence, not popular opinion. Populists, on the contrary, tend to distrust experts and to contend that a

---

[39] EMA, 'Committee for Medicinal Products for Veterinary Use And Committee For Medicinal Products For Human Use Presence of the ARMG nptII in GM plants for Food and Feed Uses', at p. 2.

[40] EFSA, 'Statement of the Scientific Panel on GMO on the safe use of the nptII antibiotic resistance marker gene in genetically modified plants' (2007).

[41] Leslie Roberts, 'Counting on Science at EPA', 249 Science 616-618 (1990).

[42] Athanasios Krystallis and others, 'A perceptual divide? Consumer and expert attitudes to food risk management in Europe' 9 Health, Risk & Society 407, at 420.

[43] Paul Slovic and others, 'Risk as analysis and risk as feelings: Some thoughts about affect, reason, risk, and rationality' 24 Risk analysis 311, at 311.

democrat government should follow the will of citizens rather than that of a small group of scientific elite.[44] Furthermore, it is common sense that the decision-making process regarding environmental policy is naturally of political nature, where the two approaches have to be compromised and combined pursuant to certain standard. As a result, we need to have an appreciation of what exactly accounts for the split between experts and ordinary people.

B. Mental Shortcut

a. Heuristics

Psychologists have proposed that people estimate probability or frequency of the risk by some mental strategies, which allow them to reduce these difficult tasks to easier judgments.[45] Usually this mental shortcut is named 'heuristics' by psychologists, referring to rules of thumb which substitute a simple question for a more difficult one.[46] There are two types of heuristics relating to the risk-assessment of GMOs: representativeness and availability.

(a) Representativeness

Basically in the field of new technologies, different sources of activities represent different sorts of risks, which have to be analyzed case by case and in form of probabilistic questions. Nevertheless, ordinary people rely much more on the resemblance between activity A and B to calculate the risk, and this similarity judgment is called 'representativeness'. To put in another way, when activity A (say nuclear accident) is familiar with ordinary people, and they think the probability of risk is X; and when it comes with a new technology B (say GMOs), ordinary people naturally evaluate its risk by its similarity with A. Thus if A is high-risk and is thought to be highly similar with B, then B is high-risk as well.[47] In this process, people tend to predict solely in terms of the favorableness of the description (such as the vividness of the story), and to neglect the reliability of the evidence and the accuracy of this analogy.[48]

A good example can be drawn from a large-scale survey organized by the European Commission about the European citizens' attitudes towards modern biotechnology. (need to be added)

In addition, psychologists also concluded that people's confidence in their prediction mainly depends on the degree of representativeness in their mind, namely the quality of the match between the selected outcome and the input information.[49] If, for instance, MON810 is banned by a Member State, this will greatly enhance their confidence that MON810 is harmful (they will naturally neglect the other side of the controversy). Further, the next time they face another controversy about GMO authorization, the internal consistency in their thinking pattern will contribute a great part to their confidence to draw a similar conclusion, and such unwarranted confidence is called 'the illusion of validity'.[50]

(b) Availability

---

[44] Cass, at 1120.
[45] Paul Ed Slovic, *The perception of risk* (Earthscan Publications 2000), at 13.
[46] Cass, at 1125.
[47] Daniel Kahneman, Paul Slovic and Amos Tversky, *Judgment under uncertainty: Heuristics and biases* (Cambridge University Press 1982), at 4.
[48] ibid, at 8.
[49] ibid, at 9.
[50] ibid, at 9.

When judging the frequency or probability of an event, people tend to retrieve information from their memory, where the more vivid or frequent experience will increase the subjective probability. In other words, the easier people can find an instance in their memory, the higher risk they will evaluate about an event.[51] This heuristics is called 'availability'. For example, a group of people who see a house burning is very likely to have higher subjective probability of fire accidents than the group reading about a fire in the local paper.[52] In another classical experiment, people generally thought that words started with a *k* are more than words with a *k* in the third position, because the former is easier to come to mind. But in fact, the latter is twice as many as the former in the whole English vocabulary.[53]

Availability is a useful clue in daily life for assessing probability of accidents, because instances of large classes can be reached better and faster than instances from less frequent classes,[54] thus it is an economic and effective strategy under normal conditions.[55] However, availability can also lead to systematic errors in terms of both excessive fear and neglect.[56] For instance, in a study people tend to think the number of death from accidents is higher than the number of death from diseases, whereas the opposite is true (diseases actually take about 15 times as many lives). At the same time, participants significantly overestimated highly publicized causes of death, like tornado, cancer, homicide, while, on the contrary, they underestimated the number of death from strokes, asthma, diabetes, etc. They even mistakenly believed that more people died from homicide than from suicide.[57] Consequently, psychologists suggest that highly publicized events make people fearful of statistically small risks.[58] Besides, it is also proved that public officials are prone to use availability heuristics as well (no less than ordinary people in this regard).[59]

In the area of GMOs, similar result was found in some empirical studies. For instance, in a survey in Sweden, the public rated personal GM food risk as no. 12 in a context of 46 types of hazards, while experts rated it as no. 45. The public rated general GM food risk as no. 21, while experts rated as smallest of all 46 risks.[60] Generally speaking, experts were much more positive than members of the public in almost all respects, likewise, different demographic strata had similar views.[61]

Here it is not intended to argue which side is right or wrong, but to debunk the fact that people are still confused by the innate psychological gap in perceiving the risk--no exception for GMOs. In other words, it is possible that people are fearful of GMOs because this issue is intensively hyped, rather than its objective risks, upon the assumption that the previous model (developed in other fields of environmental risks) can still be applied to the area of GMOs, which will be discussed in the sections below.

(c) Intuitive Toxicology

Another heuristic model established by psychologists is called 'intuitive toxicology', which refers to the fact that human beings rely on their senses of sight, taste and smell to detect harmful food and

---

[51] Slovic, at 13-14.
[52] Kahneman, Slovic and Tversky, at 11.
[53] Slovic, at 14.
[54] Kahneman, Slovic and Tversky, at 11.
[55] ibid, at 20.
[56] Cass, at 1126.
[57] Slovic, at 106-109.
[58] Cass, at 1127.
[59] Timur Kuran and Cass R Sunstein, 'Availability cascades and risk regulation' Stanford Law Review 683, at 691-703.
[60] Lennart Sjöberg, 'Genetically modified food in the eyes of the public and experts' 10 Risk Management 168, at 176.
[61] ibid, at 188.

to assess the dangers in certain activity.[62] Even though it is not clear yet what identifiable heuristics are at work in intuitive toxicology, it is clear that people use mental shortcuts in judging risks and that these shortcuts lead to errors.[63]

First, many people seem to believe that risk is an "all or nothing" matter, namely something is either safe or dangerous, and there is no middle ground.[64]

Ordinary people expressed their agreement with such statements by popularities or even majorities, while toxicologists disagreed by overwhelming majorities.[65] Why? It is generally connected with 'certainty effect', which finds that people overweight outcomes that are considered certain, compared to outcomes that are merely probable.[66] In the meantime, many people appear to hold a 'zero-risk' mentality in some respects of accidents, i.e. believing that it is possible and advisable to eliminate risk entirely.[67]

Second, the laypeople are also of the opinion that products of human activities are more dangerous than products of natural processes, which is also called the 'benevolence of nature'.[68] An obvious example is the following statement in the same survey:

"Natural chemicals, as a rule, are not as harmful as man-made chemicals".[69]

Here about 45% of the ordinary people agreed or strongly agreed with this statement, while the majority (about 86%) of the experts totally disagreed with it.[70] And it must be noted that the concept of 'benevolence of nature', or the 'balance of nature',[71] has been powerfully challenged or overturned by scientists in the past 40 to 50 years.[72] Natural food may also be dangerous, so is organic food.[73] Besides, ironically, many ways by which our pre-industrial ancestors altered the environment are appreciated by us and regarded as 'natural',[74] so maybe the real problem is how to fit the human activities with the nature.

C. Emotions

It is no doubt that we human beings have emotions, and psychologists have confirmed that sometimes strong emotions will influence people's judgment to risks. In Paul Slovic's words, the perceived risk is dependent on "intuitive and experiential thinking, guided by emotional and affective process".[75]

---

[62] Slovic, at 285.
[63] Cass, at 1128.
[64] ibid, at 1128-1129.
[65] ibid, at 290.
[66] Daniel Kahneman and Amos Tversky, 'Prospect theory: An analysis of decision under risk' Econometrica: Journal of the Econometric Society 263, at 265.
[67] For instance, a study conducted in the United States proved that jurors, as good citizens and laypeople, are more probable to have zero-risk mentality than judges, which will lead to systematic errors. Please see W Kip Viscusi, 'Jurors, Judges, and the Mistreatment of Risk by the Courts' 30 The Journal of Legal Studies 107.
[68] Cass, at 1129.
[69] Slovic, at 297.
[70] ibid, at 297.
[71] The 'balance of nature' refers to the belief that the nature undisturbed by humans will remain constant and is the most desirable.
[72] For a criticism of the paradigm that nature produces the best environment and products for all creatures, please see Daniel B Botkin, 'Adjusting Law to Nature's Discordant Harmonies' 7 Duke Envtl L & Pol'y F 25.
[73] For an analysis of the toxins in natural food and organic food, please see James Paddock Collman, *Naturally Dangerous: surprising facts about food, health, and the environment* (University Science Books 2001), at 29-33.
[74] Botkin, at 31.
[75] Slovic, at xxxi.

Affect refers to the experience of feeling or emotion, which is rapid and to some extent unconscious.[76] When affect plays a lead role in the decision-making process, it is also called 'affect heuristic', referring to the mental shortcut that replaces a thorough and complex assessment with a quick and efficient substitute.[77] The most striking instance is people's tendency to say that highly risky activities carry low benefits, or highly beneficial activities come with low risks.[78] This is pretty odd because the nature of the gains from a hazardous activity is qualitatively different from the nature of the risks, but why don't people frequently think that an activity is both highly risky and beneficial, or both low in benefit and danger?[79] Paul Slovic suggested that the 'affect' comes first in people's mind and then directs judgments regarding both risks and benefits, forming an emotional, all-things-considered reaction to certain activity.[80]

The same phenomenon was also observed in GM products. In the survey in Sweden, the public showed a clear attitude that GM food comes with low utility, high risk, and is morally unacceptable. On the contrary, experts found its risks to be low, and that it is morally acceptable. The experts' position with respect to its utility is a little bit complex. They thought GM food should be used more and said that its utility was relatively low. However, it must be mentioned that they rated all technologies as very useful, and that their assessment was partly because GM food was a new technology and was yet to be more widely used in Sweden then.[81]

V. A Brief Analysis on the Possible Solutions

A. Who Are Right?

As the conclusion of this article, it is very interesting to note which side is right, and on what condition. The statistical data shows that according to our past experience, for most of times, experts are right in their judgment about uncertain risks from an innovative technology, while the laypeople's ideas still have their own value. For example, sometimes the minority group from the whole population needs special care, and the lay people are more sensitive in this respect. Thus the basic conclusion from law-and-psychology studies is that a successful regulation system should combine the two systems together, but with different weight. This reminds us with the precautionary principle applied in the EU, and it seems to suggest that the current provision is all right: the authorization process is primarily science-based, with full consulting with the Commission's European Ethics Group. In the meanwhile, ethical or socio-economic considerations, if difficult to clearly stated or reasoned, can not be fully applied as an independent criteria, thus their roles should be relatively minor.

B. Possible Solutions

Psychologist also discussed many solutions to the conundrum of risk regulation, especially when the event is highly sensitive and publicized. In addition to the normally methods like increasing the public participation, two points are particularly important in the future.

---

[76] Cass, at 1144.
[77] Slovic, at 414.
[78] ibid, at 415-416.
[79] ibid, at 415.
[80] Cass, at 1137.
[81] Sjöberg, at 181.

First, a natural reaction in the EU countries is that with more pressure or fear, there should be more regulatory measures in certain area. However, historical data have told us this is just wrong. For a highly publicized event, the more regulation, the more fear people will feel. So the scale and degree of regulation should be limited to its best extent, which is usually defined by law-and-economic approach.

Second, liability law should play a more important role in addressing a complicated issue like GMOs, probably because it is easier to rationally decide the factual situation and to let people know what is really happening, rather than only listening to the biased stories.

In all, facing such a contested and polarized situation, it is still meaningful to attempt to find a relatively objective approach to draw the conclusion. Many myths will resolve themselves if the general public have access to and understand a particular technology, and this will surely happen to GMOs in the future, with the assistance of liability law.