



VIDEO INTERVIEW WITH PROF PATRICK WALL FORMER CHAIR EUROPEAN FOOD SAFETY AUTHORITY

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What is your view of GM crops?

Well, genetic engineering – as a scientist and a medical doctor, I view genetic engineering as a technology. So “Is genetic engineering a good thing or a bad thing?” to me is like saying “Is science a good thing or a bad thing?”

So, I think the technology could deliver benefits for society and could deliver benefits for individuals. So the issue for me is how the technology is being used to deliver benefits. And that's the debate I get engaged in, rather than whether it's good or bad.

The EU Commission, EU Parliament and many Member States want EFSA's risk assessment to include social and environmental issues like the increased pesticides used with GM crops. Some want EFSA's to stop approving new GMOs until it implements these reforms.

How does EFSA authorize GMOs today?

Well, EFSA was created because of a chronology of food scares that damaged consumer confidence in the safety of the food chain, in the commitment of the food industry to produce safe food, and in the regulatory agencies' ability to police the food chain. So we had... the two big ones would be the Dioxin scare in Belgium and the BSE crisis, where the citizens were guaranteed that – say, for example – that the beef was safe, and scientists reassured them, and politicians reassured them.

In fact, they were incorrectly reassured. And so EFSA was set up as an independent agency to do risk assessments on all risks across the food chain, with openness and transparency; and they were separated from the risk managers and the regulators.

Now, although EFSA is an independent agency, it actually receives its funding from the Commission. And the founding legislation that set up EFSA mandates that EFSA does its business in a particular way: so EFSA has a series of ten scientific panels; they're populated by independent scientists from outside of

EFSA — they're not on the EFSA executive staff; and these panels range from panels that look at plant protection products [i.e. weedkillers, fungicides, other pesticides etc], that look at animal health and welfare, that look at microbial contamination of the food chain, that look at chemical contamination of the food chain, that look at emerging risks, and that look at GMO.

Now, several of the panels have a role in undertaking risk assessments as the first step in the regulatory process. Whereas some of the panels look at emerging risks and they give an opinion on those risks, others — like [the panels on] plant protection products, materials in contact with food, enzymes that are used in the food chain, health claims — there, an assessment by EFSA is a pre-requisite to entering the approvals process.

So what many people think — that EFSA approves GMOs — EFSA don't approve GMOs. But a favourable risk assessment by EFSA is a pre-requisite to enter into the approvals process.

EFSA itself, as an organisation, the executive staff of EFSA don't give opinions. An "EFSA opinion", in law, is defined as an opinion on one of these independent panels. So scientists are selected by a rigid selection procedure. They have to declare their interests on the EFSA web site to populate the panels, and every few years the scientists turn over. So, basically, on the GMO panel there would be scientists from throughout the European Union who are familiar with the technology. And they do the assessment in a way that's mandated by the Commission. So every GM variety is assessed on a case-by-case basis. So if, for example, a particular maize is approved with a particular trait, and some company submits a dossier with a very similar maize with a first cousin of that original variety, the assessment is undertaken from scratch all over again. There is no allowance made for varieties that are approved in other jurisdictions — they're assessed from scratch by EFSA. So basically, the regulations mandate that things are done in that fashion.

But I'd like to correct the opinion that many people have, that EFSA approve GMs. EFSA don't approve GMs, EFSA just is the first step as the gateway into the approvals process.

Does the European Commission ever pressure EFSA to adopt a particular conclusion, or fast-track a favourable GM opinion?

Well, I mean, there's no panel in the EFSA ten panels that comes under more criticism than the GM panel. And nor is there any panel that comes into, gets as much publicity. Many of the panels — for example, materials in contact with food, or enzymes in the food chain, or flavourings and additives — there's very little publicity associated with them. But the GM debate is so polarised that any decisions by the EFSA panel... There's one group, which is the biotechnology industry, that say that "EFSA is too slow, it's taken eighteen, twenty- four months to approve products that are approved in months in other jurisdictions, they're affecting EU competitiveness."

And then we have people who are concerned about the technology, and say "look, there are issues that are not being considered."

Now EFSA considers primarily public health, food safety, secondary impact on the environment. But there are other issues that EFSA doesn't consider. There are ethical issues. And some people are against the technology because they think, you know, it's wrong to modify what God created, or they think it's unethical to put trans-species genes like a fish gene into a tomato — they'd say that's wrong and they're against that. But those ethical issues are not considered by EFSA, because it's not in the EFSA mandate to do that.

Then there are people who are against corporations owning the entire food chain, and people who put profit before public health. Again, that's not within EFSA's remit.

So one has to be clear that EFSA's remit is quite narrow. There's a much broader canvas to be discussed when you're talking about GMOs and the application of the technology. I mean, my own opinion is that the technology itself is not inherently good or bad. And could the technology deliver benefits for society? I'm sure it could. There's an argument that the technology could, that we could have crops that would better be able to survive in arid conditions and help third world farmers. Now that's theoretically possible. Now will it happen? Third world farmers are poor. And therefore, unless we have publicly funded research, and third world farmers are given access to the technology and the I.P. [intellectual property], it might never happen. So I wouldn't just rubbish the technology. I mean, as a medical doctor I see where the technology has delivered benefits for society in medicines and cancer treatment, etc. And there are risks and benefits. So you have to weigh up the benefits and the risks.

EFSA only does risk assessments. It doesn't do benefit assessments. So it's not EFSA's role to sell the technology, or sell the benefits of the technology. It only does risk assessments. So I mean, there are areas where — theoretically — the technology could deliver benefits. I mean, as a medical doctor I'm advising people to take three helpings of oily fish per week. So if everybody took three helpings of oily fish, we'd decimate the fish stocks. But like, there is a project here that UCD [University College Dublin] is a partner in it, funded by DG Research, where they've developed a plant — the LipGene project — where they've developed a plant that can produce Omega 3; and Omega 3 is good for your cardio-vascular system, so if people use the plant Omega 3, we could save the fish stocks. So you know, I mean, you can't — that's an example — but you can't judge it in isolation. You have to look at the benefits. And if the benefits only accrue to corporate giants, or to farmers, well then it's understandable that citizens say No.

PART 2/3

Can current scientific knowledge really predict the long-term impacts of genetic modification on the modified organisms, and on the livestock, wildlife, humans and ecosystems in which they are contained?

Science is an evolving subject, and so no scientist can say they that they have complete information, and nobody can say there's absolutely no risk. Of course there's a risk! So therefore you have to assess the risk with all the available information. And that is the key to make sure that all of the information — positive and negative — is submitted. So therefore there is a criticism by many people that dossiers that are submitted to EFSA are only dossiers prepared by the companies. And so, obviously, the companies would present data that are more favourably disposed to their varieties and products. We have in the scientific literature a thing called publication bias — that literature with positive findings is more likely to be published than issues with negative findings. And so we have this all the time with pharmaceutical agents: that if the pharmaceutical agent is funded by a drug company, and there are ten trials and nine of them work and doesn't work, well the nine that work will be published and the one that doesn't work might not be published.

So this is the point about... we probably need much more publicly-funded research. Long-term trials, nobody can forecast the future, so you just sort of make a guesstimate on the balance of probability on the evidence that's at your disposal. That's how you do the assessments.

Now the one thing that's interesting is that on many of the panels in EFSA, they are populated by experts who are comfortable with the technology. And so if you have a lot of molecular scientists who have been playing around with recombinant DNA technology since 1969, it's not a new technology and so many of them use it in their laboratories and their research institutions and they're quite comfortable with it. And so — for them — they wouldn't see the same risks that maybe a citizen would see or someone that wasn't familiar with the technology. It's like, you know, you go to a motorbike convention and ask the motorbike riders "do you think riding a motorbike is dangerous?" They say "no", whereas other people would think they're half crazy! So that's an issue.

I suppose... Could the risk assessment be improved. Of course it could! Of course it could be improved! And it is being improved continuously, and with more and more guidelines. Could it be re-vamped completely? And could there be a completely different procedure required to enter the approvals process into the European Union? Of course it could! But that would be a decision taken by the Commission. If they actually said, look, we want EFSA to do things in a completely different fashion, of course EFSA... EFSA is not independent, in the sense that EFSA does what the legislation mandates it to do. And EFSA doesn't actually make, set its own rules. The ground rules for EFSA are set in the founding regulations of EFSA.

Do you recommend any improvements in the risk assessment process?

Well I say, I would think, you know, publicly-funded research would give people more confidence. I mean, I have no evidence that the corporate companies who submit data submit incomplete data. But there is a huge issue with consumer confidence. And so the consumers would be more confident if we had more publicly-funded research, where the researchers had no vested interests in getting their products over the line. That's one thing.

Basically, perhaps we should have anthropologists or social scientists engaged, and look at the other dimensions to the technology — if you're considering the wider issues like ethical issues etc. But you know, at the moment it's a food safety risk assessment and an environmental risk assessment; but if you were to consider other issues, you would need other disciplines sitting around the table.

Does EFSA carry out risk management as well as risk assessment?

EFSA has no role in risk management. And basically, it just assesses the risk, and that risk assessment is passed on to the risk managers who make the decisions. Now risk managers, they have to take lots of other things into consideration. They have to take in the economic impact of adopting or not adopting the technology; they have to take into account issues like ethical considerations; they have to take into consideration consumer resistance. And so they have a range of other considerations that they think... and so it's at that second stage that a lot of the additional dimensions have to be debated.

So often a risk assessor could say that, in their opinion this product is as safe as its conventional counterpart, whereas the risk managers could say, "Well, look, in our, it's not a priority for us: do we need this product? We don't need this product." You know, and so you could actually have a... so what EFSA does is not necessarily adopted immediately by the risk managers. And so there is another delay, that the biotechnology companies complain about. There are two bottlenecks, they say, in the process. One is the initial step with EFSA, and then there is a much longer bottleneck with the Standing Committee [on Animal Health and the Food Chain] and the Commission. But these things can't be rushed. And basically, people have to have confidence in the process, and if people haven't got confidence in the process, well then the process has to be changed.

How do the GMO approvals processes differ in the USA and Europe?

The EFSA assessment is more comprehensive and it's more onerous [i.e. difficult] than in other jurisdictions. And so in fact, in many of the grain-growing countries, new varieties are being developed, licensed and planted far faster than the EU approvals process. And this is what's happening in that there's two, there's an issue with the EU-approved varieties allowed to be imported into European Union. But there's a lot of GM varieties that are not approved by the European Union because of the time delay in both the EFSA component of the assessment and the Commission component of the approvals process. And so, you know, other jurisdictions remark how stringent the process is in the European Union. And it's interesting that, you know, those people who are very, very, very concerned about the technology say that EFSA is too easy. So there is probably a balance there in the middle somewhere.

The US Food and Drug Administration "deregulates" GMOs based only on the risk assessments provided by the applicant companies...

Yeah, well I mean it's a much faster process, and it's not nearly as onerous, not nearly as onerous, and it's... for a biotech company to get their products approved is much much easier outside of the European Union.

Is the American GMO approvals process trustworthy?

The Americans have confidence in it, but European citizens wouldn't accept that same arrangement. Now, people say "why are we so nervous in the European Union about new technologies?" Well, we had a BSE crisis and we had the Dioxin crisis and basically I think EFSA sees itself as a consumer protection agency — not something to rubberstamp biotechnology dossiers! So we would like to think in EFSA that we are actually acting on behalf of the consumer and that we are actually a protector of the consumer. Now while many consumers believe that, there is a subset that think that EFSA isn't stringent enough. And, I mean, if the assessment process in EFSA has to be modified to try to bring more people on-side, and to give people confidence in the process, so be it.

EFSA recommends approvals of GM crops which produce their own pesticide — and GM crops that have absorbed huge doses of weedkiller — based on 3-month feeding studies with only one mammal. Are broader long-term studies not needed?

There are on-going discussions about whether the feeding trials are long enough, and do we need longer studies to give people additional confidence. And that's under discussion at the moment. And that may change.

What do you think about the biotech companies' practice of not disclosing the raw data from their GM risk assessments? Should this data not be published to enable member states and independent scientists to conduct replicable science?

If we want in EFSA to have consumer confidence, we have to be open and transparent. And the public have to understand all, everything that is involved with the process of the risk assessment. And there is

a dilemma, in that when companies submit dossiers, they maintain this is confidential commercial information, and the idea that if this information, if this information were made public their competitors would have access to it. But I think it's in the interest of consumer confidence that as much data as possible is in the public domain, and if scientists want to repeat the trials... But these trials are expensive to run, and so the likelihood that somebody would repeat the trials, you know, is low unless we have public funding.

And I think there should be more publicly-funded research in the area, and that data should be all made public. And the more open and transparent we are, people will understand the process. And if there are flaws, those flaws have to be addressed! And if there are actually consumer concerns about particular issues they have to be addressed. And if particular varieties are a cause of concern, and there are other issues that citizens are worried about, they should be addressed. The thing is that we cannot force-feed European citizens products that they don't want. We live in a democracy. People have a right to have objections. And if people don't want the technology they have a right not to have it.

And so I think the idea of marginalizing sub-sets or some member states who actually are anti the technology, that's wrong. We have to actually be as inclusive as we possibly can.

PART 3/3

What do you think of the demand for mandatory labelling of meat, poultry and dairy produce from livestock fed on GM ingredients — to enable consumer choice and traceability, for post-market monitoring and long-term epidemiological studies?

Well this issue about mandatory labelling — I mean, I think, I'm all for labeling products that contain GMs for consumption. The issue about animals — I don't feel strongly about whether you should label the animals that have eaten the GM products because I feel once the animals have eaten it, that's it, you know.

The biotech companies claim "Americans have been eating GM for years without any problem." Isn't this claim ridiculous without the labelling required for traceability?

The issue of long-term epidemiological studies: you know, one argues that nothing has come to light in the UK or in the US. But if you want to do long-term studies, you have to have case controls, and therefore you have to know, you have to have controls on who didn't eat the product and compare them with those who did. If everybody is eating the products, well then you can't do those kinds of studies. And so we're not geared up to do those kinds of studies.

I, eh, you know, the issue of chronic disease that could be linked to diet — it's a very complex area because there is basically a genetic component to most diseases, there's environmental exposure, there's life-cycle components. And, you know, to tease out from these long-term issues, it's going to be extremely difficult. And that's why we might never be able to do those kinds of studies that people are calling for. And then the biotech industry say, look, these studies are impossible, we're standing in the way of progress. So I think we should do what we can do. And are we currently doing everything that's practically possible? And there are some things that we could do that we're not doing, like more publicly-funded research and longer-term trials on animals. We could do more of those. But long-term trials on humans, I don't think that would be a runner for us.

Should EFSA not require the applicant companies to provide the sequence of trans-genes and the whole genome of their GM crops?

EFSA need to get all of the information from the companies to do comprehensive dossiers. In fact what EFSA does is a thing called a "completeness check" on every dossier. And so they give the companies a list of what they want; but in many of the applications, the clock doesn't start ticking on the EFSA component of the process until the completeness check is finished. And often EFSA has to go back — several times — to the companies to get the complete dossiers, even though the companies know that it's in their own interest to send in a complete dossier. And often the EFSA scientists ask for more information, which requires the companies to do more research. So often we are criticised because of the delay: and, you know, some of the dossiers have been in the process for 24 months, but that's because the complete set of data was not submitted in the first instance, or maybe additional research was required that takes time.

What is your view of GMO seed patents?

One thing is the technology, and I say: the technology — is it good or bad? Show me the benefits for society and for individuals, and then we'll judge it! Sometimes the benefits are only for corporate giants — in

terms of increased profits — or for farmers. And obviously there's nothing in it for the consumers. Why should we embrace the technology?

The issue of patents is an issue for — do we want corporate giants to own the entire food chain?

Now, is that an issue of pro- or anti- the technology? It's not got to do with the technology, but it's a question that needs to be addressed. And obviously, you know, for developing world farmers, you know, if they don't have access to the technology, well they're not going to be able to derive any benefits from it.

The other issue is food safety. I'm not actually worried about the food safety issue myself. I don't worry about it. That's my opinion — and I'm not a molecular scientist and I'm not on the assessment panel of EFSA — that's my personal opinion.

The environmental issues: cross-pollination of the environment is an issue, and that has to be addressed. And for those countries that have very small landmass, there's no way they can segregate GM crops from conventional crops or from organic crops, and so the likelihood of cross pollination exists.

What should European member states do if they want to keep GM crops out of their countries, or if they want EFSA to implement transparent and acceptable risk assessments?

Several member states wish to be GM[-free], and they're entitled to be GM[-free]. But several of the member states that wish to be GM[-free] aren't worried about food safety or public health issues: they may be worried about cross-contamination of the environment, or they may not want it because it doesn't fit the image of their country. I mean, if you want to be into eco-tourism and you're anti-intensive farming, GM crops don't fit that.

So basically, you know, countries are entitled to their opinion. But I think one has to be careful that people don't scaremonger. I mean, if your grounds for being anti-GM is that "it doesn't fit our image, we're into eco-tourism, GM doesn't fit", fair enough. You know, it's important to be open and transparent with your reasons for being against the technology. Or "I'm against corporate giants owning the food chain, full stop". Well, fair enough! If that's your reason, that's your reason and you should articulate that as your reason.

Should such countries then lobby the Commission instead of EFSA?

People like to blame EFSA for lots of things, but EFSA only does what it was set up to do. And if the Commission wishes EFSA to carry out its risk assessments in a different fashion, or if they want to abolish the panels and do risk assessments in-house, I mean EFSA will respond to what the Commission wants it to do.

But EFSA is a resource for all EU citizens. And so it's a consumer protection agency — that's why it was set up. We mustn't forget the reason for EFSA being, it's separated from the Commission because it has got nothing to do with risk management. It just assesses the risk and then it passes that over to the Commission in all of the areas, and the Commission makes the decision: is this an acceptable risk for EU citizens, or is it not? EFSA doesn't make that judgement.

What is the best GMO strategy for the future of Irish food and farming?

Well in Ireland we have a unique small country; it's an island; we're potentially the bread-basket of Europe. And Irish farmers have a high cost-base. So Irish farmers need to have a serious look and see how can we differentiate ourselves in a global market place from other countries that have economies of scale, maybe cheaper labour and cheaper energy. And we don't get an informed debate in Ireland about whether, if we were a GM-free Ireland, would this give us a competitive advantage for the farmers? The debate is quite polarised.

And I would like to see for us in Ireland to start looking at the pros and cons of being GM-free as opposed to being just another intensive farming country. And can we deliver a competitive advantage to Irish farmers by being GM-free?

Irish farmers have to survive. And so if there's an economic advantage in being GM-free, and that economic argument is presented to farmers, farmers will consider it. At the moment the debate is too polarised and we don't even get into the discussion. Farmers are told if they don't go forward with the technology, they're going to lose out, and be left behind, and they will be commercially non-viable. Well, we haven't had a proper debate!