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The regulatory challenges for agricultural biotechnology in the EU – workshop summary

On May 23, 2014 the workshop 'Regulatory challenges for agricultural biotechnology in the EU' was arranged within the frame of Mistra Biotech. During the day questions such as; how the EU can move forward on the issues of genetically modified organisms (GMOs) while providing safe and informed decisions to the society, and how the industry and the consumers perceive the issues, where discussed. This is a summary (by Sevasti Chatzopoulou) of what was presented during the day.

All Power Point presentations are available at: www.slu.se/mistrabiotech/regulatoryworkshop

Comparing regulatory styles in food safety: The EU and its major trading partners

Prof. Christopher Ansell, Department of Political Science, Berkeley University, USA

Chris Ansell distinguished nine general trends based on the extensive EU regulatory literature. First, the rise of the EU as a 'regulatory state' and the 'agencification' phenomenon describes the development of a particular form of regulatory agencies. The agencies are important policy making actors and are expected to be independent, in order to be able to make credible commitments and increase their legitimacy. The European Food Safety Authority (EFSA) constitutes such an agencification case. Yet, EFSA differs from the Food and Drug Administration (FDA) in the USA because of FDA's limited competences on the risk assessment and communication. EFSA works through various committees (consisted by scientists and experts) and stakeholders in reaching decisions which exemplifies the networked characterization of the EU agencification.

Second, the development of the EU as a *regulatory leader* in setting regulatory standards with an emphasis on the precautionary approach to risks, which differs among sectors. EFSA promotes these views by actively participating in the international negotiations within the international organisations, e.g. WTO Sanitary and Phytosanitary Measures (SPS rules), and CODEX Alimentarious. Besides, a continuous Europeanisation process creates pressures to upgrade to the highest level of regulatory standards, referred as 'trading up dynamics'. Within this process the EU promotes these standards in the world stage expecting others will follow.

Third, Chris indicated the increasing trend in the EU to follow the American *adversarial legalism* style that relies heavily on formal legal rules that are based on command and control, and are characterized by politically conflictual and contested processes. Although the EU follows a more cooperative and informal style (also China, Japan etc.), there are changes induced by the Europeanisation process that pushes for more integration between countries and creates adversarial legalism.

This does not apply in all cases, but it could be relevant to the EU GMO legal regime that relies more heavily on liability, and has converted to a much more top-down centralized kind of command and control form of regulation. But, this does not necessarily mean that it leads to

litigation (conduct of a lawsuit). The approval of the authorisation for the GMOs formally goes through the regulatory committee (representatives from the member states) based on qualified majority voting. When they cannot reach a decision, the decision goes to the appeal committee. If this committee cannot reach an agreement, the Commission decides, based on EFSA's opinion. This is usually the case with GMOs – thus the system becomes very centralized. One of the effects of the command and control in GMO regulation is related to greater concerns of governance of science based decisions such as transparency, deliberation, and conflict of interest, which also concern the independence of EFSA.

Fourth, responding to rigid and costly command and control regulations, *flexible regulations* proliferated as an alternative, which appear by different names such as principles, performance, management, marketin¬g, information based regulation, responsive regulation, co-regulation, and self-regulation. Flexible regulations allow discretion (freedom to make judgement) on how you create the rule or give discretion on how you implement the rules. The EU General Food law constitutes a set of principles based regulation that is flexible because it sets out broad principles and allows the member states to fill in those principles. The case of the EU hygiene package also constitutes a case of flexible regulation with pre-authorization as co-regulation. The Hazard Analysis and Critical Control Points (HACCP) is another case that is a management based regulation. It decentralizes down to the firm level and gives the firm discretion on how to manage. The result is a reflexive style regulation that is networked and deliberated with an emphasis in upgrading performance through corporatist involvement of interest groups combined with the use of flexibility in implementation.

Fifth the *expansion of auditing and risk based regulation*; drawing on accountancy became the generalized control technology for dealing with regulatory issues. Risk based regulation refers to the emphasis in figuring out which farm poses the greatest risk (food safety issue), and use inspection resources there, rather than inspecting every farm. The Food and Veterinary Office (FVO), the eyes and ears of the Commission, adapt both an auditing strategy and a risk based strategy.

Sixth, the rise of *private regulation via certification regimes* (e.g. forestry, fish, electronics) refers to the emergence of transnational level private bodies that regulate the supply chains (third party auditors or certifiers) for those products that meet certain standards. The use of certification constitutes an important element of the structure of private regulation. The certifiers are the enforcement mechanisms and are typically private but they also present complex mixes of public and private.

Seventh, the greater use of 'soft law' refers to the use of non-legally binding guidelines. Although the general food law allows EFSA to act as a source of soft law, especially in GMO regulation, there has not been any evidence of prominent use of soft law. The coexistence of GM and conventional crops is indicated as soft law in the literature.

Eight, risk assessment via *deliberation and public consultation* involves an exchange of different perspectives and inclusion through active public consultations, or encourages deliberation in order to establish legitimacy. This input is combined with scientific results. In the case of food, EFSA and the Commission have done a lot of efforts to incorporate public consultation, but they basically prioritize science and it is not yet clear what they do with the public input. This has created a tension between public consultation and science.

Ninth and last, the development of *reflexive regulation* is characterized as self-critical and self-correcting, or as creating learning mechanisms where institutions can learn about the risks and how to handle them, and improve their performance over time.

The EU food regulatory framework presents two different regulatory styles. One characterises the GMO regulation and the other broadly characterises the non-GM food. The EU food safety fits pretty well with the nine trends of regulation, especially the regulatory state and agencification, regulatory leader, present ideas of flexibility, auditing, major role emerging from private regulation, and some elements of reflexive but also adversarial legalism. It does not fit so much with soft law unless we consider the private regulation. Moreover, the relation between public consultation and deliberation is unstable as it is reflected in the literature on GMOs. Besides, it is reflexive and self-critical and it has also been characterized as democratic experimentalism. Particularly, Rapid Alert System of Food and Feed (RASFF) has been seen as a success story that is worth exporting to other places (despite its link to the horse meat scandal and to *E. coli*). The US is considering creating a similar mechanism. RASFF allows the transparent exchange of information across countries and helps to promote the ideas of learning between member states.

The FVO is seen as helping the member states and exporting countries to improve their standards through its audit strategy and supported by the skilled people who are involved in the process.

The GMO regulatory framework presents more of a convergence to the American style, i.e. adversarial legalism. However, this does not apply in all cases, but in cases of politically contested regulatory goals (as for GMO), the EU and US systems present some convergence.

New techniques and the GMO-legislation

Dr. Marie Nyman, Swedish Gene Technology Advisory Board

The Gene Technology Advisory Board consists of politicians (one from each of the political parties) and scientists, and gives advice on applications regarding GMOs. Marie talked about new techniques for plant breeding and how they relate to the current legislation. The EU has a common legislation on GMO, and the techniques regarded to result in a GMO are listed in the annexes of the EU directive on genetically modified organisms (2001/18/EC). This directive regulates all GM-animals (except humans), plants, and microorganisms and it applies for experimental purposes but also commercial activities. It is a process based legislation that refers to the techniques used, and it determines if a certain product should be regulated or not. The definition of a GMO and the list of techniques in the annexes is the same today as it was in 1990. This is problematic because science has moved forward and several new techniques have been developed.

According to the legislation a GMO is '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 recombination'. This is a quite narrow definition because basically that would exclude everything except fertilization, although there are many other techniques used in for example plant breeding.

Techniques which are *not* considered to result in genetic modification are *in vitro* fertilisation, natural processes such as: conjugation, transduction, transformation, and polyploidy induction. Methods of genetic modification yielding organisms to be excluded from the Directive (on the condition that they do not involve the use of recombinant nucleic acid molecules) are:

mutagenesis and cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

Previously all the GMOs that have been approved have a DNA sequence that has been integrated in its genome. However, several of the new techniques results in an organism that do not have a foreign DNA incorporated, i.e., the resulting organism does not contain any recombinant nucleic acid.

In one of the new techniques, the cells' own gene repair system is used to modify a gene sequence. An American company (Cibus) has developed this technique (Rapid Trait Development System, RTDS) which results in a precise change in the gene sequence, without altering the rest of the genome or integrating any foreign genetic material. This means that it is not possible to detect if this rapeseed has been altered by conventional methods, RTDS, or spontaneous mutations. One crop variety developed through this technology is an herbicide tolerant rapeseed. This variety is not considered as a GMO in the US, and nor in the UK and Sweden either.

Marie also talked about the governance of the GMO policy. A working group was established by the commission to evaluate eight new techniques in the light of the directives definition of a GMO/GMM, the techniques listed in the annexes and the most recent available scientific data. The group submitted a report to the Commission in January 2012 but there is still no information about any decisions. In the meantime, new techniques are developed.

Consumers' information processing and decision-making in relation to a biotech label: evidence from an eye-tracking experiment

Prof. Carl Johan Lagerkvist, Department of Economics, Swedish University of Agricultural Sciences

Carl Johan focused on the way we can try to understand what determines people's choice in buying or not buying a product. People act both as citizens and consumers in making those choices, and do not separate their citizen role from the consumer role when making the decisions. Based on data collected through an eye-tracking experimental study, Carl Johan discussed how he investigates what consumers think about GMOs. It is difficult methodologically generate answers to such questions because people have a predetermined conceptualization of the world when they make decisions. Through the eye-tracking tests his research group are trying to understand the unconscious mind that governs and rules human behaviour. He emphasized that measuring what the consumer has on her/his mind is difficult because you only have a window of about 300 milliseconds to capture what is going on. The behaviour of the consumer consists of a grey area that stretches from acquiring and obtaining, to consuming and disposing.

What happens at the time when you are trying to decide to obtain something or not? (Not during the process of consuming something. We consume things even when we do not have access to the real product or the real service.) We are probably not at all (maybe just 10%) aware of what we attend to. But what we attend to then leads us to comprehend, or trying to provide what we have attended to, with a meaning. After that our attitudes, which are at the more analytical level, kicks in: *Do we like what we see, or do we dislike what we see*? This study starts with attention and ends with behaviour, but we do not observe what is going on in-between because we are interested in the extent to which attention leads to behaviour within the narrow window of 300 milliseconds where the unconscious mind reasons with itself.

This study is relevant for biotech policy because it contributes to our understanding about how the consumer views the importance of packaging of food, if he/she notices the information and labelling of food (e.g. health claims, environmental aspects), and if his/her choices as consumer are affected by this information. The experiment works with manipulations of framing and salience to see how these two components together affect the consumer's choice.

Data was collected for both the top down model (implicit measures of attitudes) combined with the salience component (the bottom up). The two models allow testing the most determining factor and how they weigh with each other. In psychology the top-down approach is the mostly used. It measures either explicit or implicit attitudes towards a subject. The combination of the top-down and bottom-up indicates an interaction process between the two perspectives. These two systems operate together and to some extent are very much dependent on each other, so the general discourses about the specific issues are very determining for the outcome. The bottom-up process is a rapid and automatic process governed by the unconscious mind; it is salience independent so you pay attention to what stands out. We filter out if it is irrelevant or not, and then we move from that to the next information set, and filter out what is important or not. This is stimulus driven. The top-down process is the more deliberate way of thinking – voluntary set of information that is typically goal oriented. Your attitudes and your attention play a role here. If you like something, you are more prone to observe it. In a choice or decision making process both of these interact, but have usually been studied separately. Much of the work on consumer preferences goes this direction. It is easy to forget that this bottom up process exists – when deciding for something the consumer has to weigh together these two aspects. The focus of attention or the focus of orientation between these two is slightly subject to a framing effect. By framing something, you can get the balance between these two.

In general, people are more 'loss averse' than 'gain seeking'. They pay more attention to negative outcomes than to positive because the negative outcomes can be more dangerous. Moreover, after a while in the testing process, there can be a learning effect so people react differently to a new label compared to an old one. Thus, time and learning may affect the level of attention.

Do people turn to choosing the product or not? High salience is linked to highly turning into choosing the product because they paid attention. There is an inverse situation between positive and negative. Those in the negative framing were more prone to choose away from the product and the willingness to avoid increases with higher salience. In the positive framing it looks like people were more prone to choose the product. So we can actually persuade people with labelling (e.g. positive framing, information).

The distribution of attention of most choices is made within 180 milliseconds. So people can be induced to buy the product if they are introduced with positive information and high salience label, or scare off people if emphasizing the negative conditioning. Consumers are more likely to notice biotech information if there is salience and it is important to the consumer. When people are not presented with a frame, they do not notice the label.

The regulation of chemicals and GMO - A comparison

Prof. Sven Ove Hansson, Division of Philosophy, KTH, and Department of Crop Production Ecology

Sven Ove compared the chemicals and GMO regulatory frameworks. The chemicals regulations are rather similar across the world, and also the GMO regulation has analogous structure in different countries – to a large extent all depend on science and engineering. The chemical regulation mainly concentrates on what substances should be allowed for production or import, what type of information the company behind the substance has to collect before putting it on the market, what are, if any, the government pre-marketing or post-marketing decisions to be made, and what type of information that should be passed on to consumers and professional users. In addition, there is a supplementary legislation which refers to what happens when certain substances are included in products, and legislation about workplace safety or environmental issues.

The US chemicals regulation, the Toxic Substances Control Act (TSCA) from 1976, covers industrial chemicals and chemicals used in households with three major exceptions; the pharmaceutical drugs, food additives, and pesticides. All three exceptions are present all over the world and have special legislations. They are all regulated by what could be called the 'prohibition default' which means that if a pesticide has not been approved by the authorities it cannot be used. The same applies to food additives and pharmaceutical drugs.

In 1976, an inventory list was introduced that distinguished between existing and new chemicals. This distinction has become very strange because a chemical that is used a lot today will be called new, non-existent even though it exists. Existing refers to what was included in the lists at the time. Existing does not refer to the presence in the society but to the fact that someone registered it.

After the introduction of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) EU regulation in 2006, a different distinction between existing and new chemicals followed. The big difference is that the pre-REACH system required much more data for notification of new substances, but no serious attempt was made to catch up with certain existing chemicals.

REACH is for the most part related to registration and evaluation of chemicals, while authorization and restriction is for a small group of chemicals. The big difference is that now everything has to be registered. REACH requires the registration of a large number of substances. There are several deadlines for registration depending on the volume of production. The same criteria apply for old and new substances. For *low volume* (up to 100 tonnes a year) very little is required, and for the lowest group (between 1 and 10 tonnes a year) there is no requirement for toxicological information. Some information is required for *medium volume* substances but it is not very extensive. It does not include chronic toxicity so there is not sufficient information on how the substance should be labelled. At the same time the companies are required to provide an accurate labelling of the substance, which creates tensions between the labelling and the registration requirements. For the *high volume* substances quite a lot of toxicological information is required. While countries outside EU may follow the direction of REACH, there are still big differences. The regulation of chemicals in China and Japan is somewhere between REACH and TSCA. So there are much larger differences in international chemicals legislation than in the legislation for GMOs.

When comparing food crop regulation with chemical regulation, both policy areas deal with complex science issues, namely how health and the environment are influenced. Two big areas

are involved in both cases: toxicology (general toxicology and specifically food toxicology) and ecotoxicology. Food toxicology includes certain issues that do not exist in the chemical case. Besides, chemical toxicology includes issues of chemical activity, explosion, and flammability which are not involved in food. In both cases there are in principle a lot of entities to regulate. There are about 100,000 chemicals in actual use, while the number of crops is much smaller.

Both chemicals and food are related to major public health issues. These issues are rather complex and although we know that we should avoid certain chemicals or foodstuffs, we do not know enough about them. We also have to distinguish between acute and chronic health effects. While acute health effects can often be observed directly, long term toxicity is much more difficult to ascertain because its effects can take decades. Another important distinction is between natural and unnatural, a division which is not easily made. Interestingly, we tend to regard natural products as safer than the ones considered as unnatural even though there are many toxic substances in nature, and plants that can be very toxic. Therefore, common conceptions about what is natural are problematic and can lead to wrong priorities. Both chemicals and food regulations are characterized by conflicts with the industry interests, particularly concerning the documentation requirements of the effects of the entities under the regulatory protection. In both cases regulations can lead to trade barriers, and have done so in both cases (food and chemicals).

Sven Ove stated that the assessment of toxicity based on the *volume* of production and/or *novelty* as criteria are problematic both in the case of chemicals and food. First, volume of production is not a very good predictor because it is a proxy for exposure. In an adequate assessment of risks, two aspects need to be considered: the degree of exposure and the degree of toxicity. The assumption is that if you have a high volume production more people will be exposed to higher degree of toxicity than low volume production, but there is very little research indicating how the relationship between production volume and exposure are related. In general production volume is a bad proxy for exposure as well as for danger. Novelty could be an even worse selection criterion because the new chemicals can be less dangerous due to efforts made to avoid problems and thus make them better than the existing ones.

In the food case a basic criterion is 'genetic modification'. If a product is a GMO it is subject to a very extensive regulation with extensive documentation requirement. For non-GMO it is dramatically different because no such testing is required. Genetic modification is not at all a useful predictor, although it should not be claimed that all GMOs are unproblematic. If you want to produce a toxic plant or a plant that creates environmental problems then the most efficient way could be by genetic modification, similarly if you want to produce a non-toxic plant or one that creates less environmental problems, then GM could be the best method in that case as well. Therefore, other criteria should be developed and used.