INSIGHTS INTO THE BIOTECH POLICY AND EUROPEANS TENDENCY

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Abstract: *The scope of the review is to discuss the evolution of the new biotech policies and strategies at the European level within a global context. Modern biotechnology and their products - genetically modified organisms - are among the main subject of public debate, since their born earlier in '80 years, because the dispute between the opponents the proponents of this technology. However, due to the rapid and visible positive impact in the today agriculture, pharmaceuticals and medicine, the biotech policy is much changing at the EU level and Europeans are accepting more and more the idea of approving these new technologies. Still are under question marks issues related to public information, education and awareness for the biotech domain, as the addressability public group is really small and the European legislation is very strict. However, we may consider that now it is accepted at the EU level that the beneficiary' voice should be listened as they are the direct users of biotech products. These benefits may consist in facilitating or decreasing the work associated with producing crops for example, particularly as regards combating pests. However, developing a study of the advantages of using GMOs cannot be limited to an assessment of the individual benefits for particular users, but also should be considered the collective benefits for society as a whole which includes the environment. This assessment study is a paper review regarding the policies and strategies tendencies at the European Union level through the analysis of other important components of the external relationships. Further these results may ground the future policy at national level regarding the research financing for the biotech domain.*

Key words**:** *modern biotechnology, policy, biotech research*

INTRODUCTION

In the EU policy *a genetically modified organism (GMO) is defined as any 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*". However due to a delay and gap in-between understanding and applying modern biotechnology products and services *„in practice, the legislation currently applies mainly to the deliberate release into the environment of GMOs, for example the cultivation of GM plants such as maize and the import, distribution and industrial processing of GM food and animal feed*". In this respect the main stone corner of the modern biotechnology vision at EU level is *"the precautionary principle in order to protect human health and the environment. Therefore the authorisation of GMOs for deliberate release into the environment requires a thorough environmental and health risk assessment and the authorised GMOs are subject to systematic post-marketing monitoring, labelling and traceability requirements*. The rest of the EU policy is to comply with procedures already in place at EU level. The results of this analysis in a systematic way of the EU today biotech politics supports the research development and financing in this domain.

MATERIAL AND METHODS

Based on published European political statements, strategy and existing legislation at EU level and also based on the analysis of international instruments such as Cartagena protocol on Biosafety and applying Albert Humphrey' SWOT analysis (Strengths, Weaknesses,

Opportunities, and Threats) of the legislation and also Negotiators' terms of references this review was realized. It involves specifying the objective of the proposed project and identifying the internal and external factors that are favorable and unfavorable to achieving that objective.

RESULTS AND DISCUSSIONS

Biotech policy At the EU level it is in place a regulatory framework, maybe the most complete in the worldwide, but still comprising administrative procedures not coherently developed at the member states level and as the authorization procedure for the placing on the market should be developed at the EU level, decision making is difficult to be taken.

At the members states level exists at least two biotech political pools developed for national and international level in accordance with the European Union Treaty. Depending on the member state capacity in getting involved into the political negotiation process at international level it appears that the general approach on modern biotechnology is set out at the EU level. During the last 14 years almost only developed EU countries where deeply involved into the negotiations at the EU and at international level, especially during the negotiations of the Cartagena Protocol on Biosafety. It is already well known that some of the EU countries are not politically open to the modern biotechnology and this attitude can be explained through the involvement of very well trained negotiators for the EU and international levels able to convince the majority about their opinion. Such negotiators are usually working in close cooperation with modern biotechnology's laboratories in their country of origin. In this respect the negotiator capacity is more improved when it is about the technical expertise into the field and the biotech research capacity is a top priority at national level. On the other hand lot of other EU countries came into the negotiation process with lawyers and scientists.

An important momentum in biotech was between 2000 and 2004 when the political expertise expressed against the development of modern biotechnology in Europe was best expressed by certain countries with a clear political message against this technology.

However, later due to the economic boom of the modern biotechnology products and services other developed countries increased their negotiation expertise at the EU and international levels and this expertise was proven to be valuable as today it can be said that at least from the scientific point of view it is generally agreed that the lack of scientific evidences should not be a barrier against the commercialization (WTO - TBT agreement) of these products and the biotech research should be continuously developed.

Today at the European Union (EU) level genetically modified plants (GMPs) are considered by the Council Decision taken during December 2008 as a "*subject of public controversy because their advantages for society in general and for agriculture in particular are disputed*". And a question mark was raised too: "*Could a better analysis of these socio-economic aspects clarify these points in the public's perception?*"

Future EU political approaches Based on the today EU legislation, because of the novelty of the subject, the society which is not aware about biotech science should be first informed, educated and after being involved into the decision making process complying also with the Aarhus Convention provisions (Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters). As it is well known, the great producers on modern biotechnology products and services are US, Brazil, Argentina, Canada, and in 1999 EU opposed to these technology on political grounds for couples of years. However, due to new political insights the EU underlined among others the need of increasing cooperation in open investments with the US as it is stated into the 2008 EU-US Summit Declaration which took place in Brdo, Slovenia. A piece of this Brdo

declaration: *Investment policies should be non-discriminatory and provide investors clear guidance on any investment restrictions*.

The today EU policy is recongnizing the followings: [1] EU has adopted a comprehensive legal framework for the authorisation of Genetically Modified Organisms (GMOs) aiming at ensuring a high level of protection of the environment, human and animal health with respect to potential risks of GMOs and taking into account the precautionary principle [2] at the EU political level it is regonized that GMOs give rise to public debates, inlcuding the scientific community and [3] that it is necessary to look for improvement of the implementation of this legal framework in order to better meet the objectives of the EC legislation, taking into consideration the necessity of continuing processing applications without undue delays and respecting the relevant EC international obligations. Such dalys are due today to the risk assessment procedures.

Moreover, in order to bring more confusing elements to the topic some member states are claiming that the social aspects are relevant and attention should be given to these and they are trying to bring a scientific connotation of this which it is a false created problem. Even the socio economic issue should be developed at the EU level, however some of the countries agreed to support the subsidiarity principle. It is very important, at least in the terms how the current legislation is developed at the EU level that this point should be solved at the EU level and not at the member's state level because the authorization procedure is an EU level developed procedure. Romania was acting last year in the favour of such political approach of respecting the state subsidiarity and on our opinion the authorization procedure will encounter the same problems like those developed for the risk assessment procedure and for that we are recommending that this issue should be re-discussed at the political level.

We may add that the case of risk assessment is already solved –at least from conceptual point of view – members states agreeing that this should be developed based on the same guidelines such those already published by the EFSA and already in place in lot of member states and not based on the guidelines developed at national level. It is important to mention that these guidelines are in line with those already in place elaborated by OECD or guidelines of WTO, WHO, FAO or Codex Alimentarius.

Today even the risk assessment should sound scientifically, according to the Directive 2001/18/EC Annex II and Annex III, however due to the very complex applied procedures at country level it is not anymore a scientific item and it is rather the fruit of political debates. We are supporting this analysis support with the case of maize MON810.

Biotech legislation

The delay in developing legislation in the European Community is due especially to the political process of legislation's negotiation for the approval at the EU level and also to the complexity of the process which is time consuming for being fully implemented at national level. We may add that the EU biotech legislation is developing in behind the boost results obtained by the science which grounds gaps between policy and science specific not only for the EU but also for the countries all over the world.

Today it can be said that the EU developed a very impressive legislation that applies at the community level and should be implemented at national level which is developed based on the precautionary principle which is rather a political commitment and it should not be interpreted as an administrative task.

For its political commitment – precautionary principle – which was assumed for the Cartagena Protocol ratification, the EU developed procedures and the members states are today in the position of applying administrative procedures based on this political commitment.

As the risk assessment procedure is not yet completely the same for all biotech product confusion may emerge during the authorization. Thus, for food and feed products the

risk assessment procedure is not applied at the member's states level but at the EU level according to the EFSA guidelines which are not compulsory to be applied any other products by the members states according to the Directive 2001/18/EC.

Even the main principles in the implementing the risk assessment procedure are set out in the annexes of the Directives *and should be scientifically based* however controversial authorizations can be issued depending on the authorities involved in the authorization process (now it is the case of MON810 which is under reauthorization according to the Regulation (EC) 1829/2003 and which first was authorized according to the Directive 2001/18/EC). The lack in any consistency among different legislation acts in the EU represents political debates subjects at the EU level.

Case study – Maize MON810

Maize is an important crop in the European Union (EU) and corn borer infestations can produce considerable yield losses. In Spain for example, the losses in maize production can be as high as 15% in areas of high corn borer pressure and in South Romania up to 10%.

Political and legislative issues

Commission Decision 294/1998 authorized the placing in the market of *Zea Mays* L. line MON 810 for all uses of the product (import, processing into food and feed products and cultivation). On 2 June 1999, Austria informed the Commission of its decision to provisionally prohibit the placing on the market of MON 810 for all uses covered by the consent. Meanwhile, a new Directive on the deliberate release into the environment of genetically modified organisms entered into force (Directive 2001/18/EC). In January 2004, the Commission requested Austria to re-consider its safeguard clause in light of the new legal framework. Austria submitted to the Commission additional information in support of its national safeguard clause. The Commission consulted the EFSA, which concluded, in July 2004, that the information submitted by Austria did not constitute new scientific evidence sufficient to invalidate the environmental risk assessment of maize line MON 810, justifying a prohibition of its use and sale in Austria. Based on this the Commission submitted a draft decision requesting Austria to repeal its provisional safeguard measure. On 24 June 2005, the Council, by qualified majority, rejected the proposal and presented new reasons, requiring further evidence. In November 2005, the EFSA was once more consulted by the Commission and it was, in particular, requested to take account of any further scientific information that had arisen subsequent to the previous scientific opinion. In its opinion of 29 March 2006, EFSA concluded once again that there was no reason to believe that the continued placing on the marked of MON 810 maize was likely to cause any adverse effects for human and animal health or the environment under the conditions of its consent. Therefore, the Commission submitted to the Council a new proposal requesting Austria to repeal the safeguard measures concerning MON 810. On 18 December 2006, the (Environment) Council rejected the Commission proposal, through a decision that refers only to the environmental aspects of the safeguard clause, namely cultivation. The food and feed safety aspects of MON 810 have been assessed by the EFSA, which concluded that this product is unlikely to cause any adverse effects for human and animal health. Under these circumstances, the Commission considered that the proposal should be amended in order to take into account only food and feed aspects of the Austrian prohibition namely the prohibition on import and processing of unprocessed kernels as source materials for further processing or for direct food or feed use. The Commission therefore submits an amended proposal to the Council. Later Hungary, Greece and last year France opposed MON810 and the case is far to be solved at EU political level as these countries developed their negotiation capacity in biotech policy at EU level and not only. However the MON810 authorization is still in place as the dossier was moved form the Directive to the Regulation 1829/2003 by applying the *mutatis mutandis* procedure evoked by

the art. 8 4, during 2005 and a notification for renewing the product according to art. 8.1. was submitted in May 2007. The authorization procedure is on the way and the product may remain on the market according to the Regulation 1829/2003 art 8.1.

Further the Technical Advisory Group (TAG) of EuropaBio's Plant Biotechnology Unit developed monitoring plans for GM crops and in the case of existing Bt maize products, no adverse effects requiring case-specific monitoring have been identified in the environmental risk assessment.

The main conclusion is that as the political debate is not finished yet at the EU level even the scientifically it was proved that MON810 is safe, and barriers are created against the free commercialization of this product which is not in line with the WTO TBT (Technical Barriers to Trade) agreement and for which should be responsible the member state and not the EU – which is another gap in the current EU legislation which is in line with the EU Treaty.

All these data underline some major differences between the EU and the USA GM maize- general approach which is reflected from the political level to the implementation level.

CONCLUSIONS

Never a completely new scientific discovery will receive a satisfactory social acceptance if there are not solved less complicated issues highly depending on politics and society and this is a strong argument for applying in practices the philosophical principles described four centuries ago by Rene Descartes and Francis Bacon which grounded the today modern philosophy. Modern biotechnology is the case here, and this domain is associating new scientific concepts regarding the living world which are now implemented through practical experiences at the highest scientific standards. Even we are living in the XIX century the general public is not ready to cope with the complexity of the domain either from scientific point of view either from technical and political points of views either from all points of view. The modern biotechnology domain is practically living the first 30 years of "ripping as a philosophical concept" because the society needs to develop further and needs to understand more in-between science, technical administrative' issues and politics. This *sine qua non* condition of completely acceptance of the modern biotechnology is however the time passing in the favour of this high level standard science.

Publishing more scientific conclusions regarding the safety of modern biotechnology will ground in time the systematic generalisation and acceptance of it which may be interpreted as a new philosophical concept exactly in the same terms such for any other philosophical concepts initiated from the beginning by the human civilization. At least from this philosophical point of view it is still not surprising to see how a new scientific discovery is the "seed" of new progressive and inductive public debates up to the general acceptance as the politics are deeply involved into the process. This phenomenology research in a systematic way was not discussed nowadays even still it is obvious that modern biotechnology as a concept came into society with revolutionary ideas which shaken from the grounds the oldest concepts on the living world by rigorously applying the principle "*scientia est experiential*" as the single scientific method able can confirm or not the sustainability of this new technology.

Taking into consideration all these issues Romania should take the advantage of this politically created momentum, for the sake of our future generations, in mobilizing funds and supporting politically modern biotechnology research and also being preoccupied in developing the negotiation skills for scientific and technical expertises at the EU and international levels based on the best experienced human resources.

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