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The Regulation of Agricultural Biotechnology in Poland and the Obstacles to EU Compliance

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Abstract

Transition and accession have necessitated the establishment of a regulatory framework for agricultural crop biotechnology in Poland. This paper examines the theoretical and practical difficulties of complying with EU requirements. The first part of the study utilises evolutionary theory and path dependency to describe how policy makers interpret the requirements of accession through established conceptual models. Secondly the paper examines how accession programmes may alter path dependent trajectory but is simultaneously introducing or importing models which are fundamentally incompatible with national capabilities. Data presents the pre-accession capacity building programmes and the import of German expertise as examples. The final section examines the issue of capacity and in particular, financial capacity, and uses this underlying theme to explore in detail why incompatibilities arise and why EU compliance is presented with certain obstacles.

Introduction

Poland has an economic foundation rooted in its agrarian base and a modern history of advanced biotechnology capability under its former soviet government. A compilation by (Tzotzos and Skyrabin 2000) of known research facilities indicates a likely presence of activity in the agri-biotech sector. The attractiveness of Eastern European countries as a testing ground for large multinationals is also a possibility that has not escaped media reports (ANPED, MURE et al. 2000; Brown 2004). Aside from the capability of hosting agricultural crop biotechnology advances, Poland became formally part of the EU in May 2004. Fulfilling the Copenhagen criteria means obligatory adoption of the vast part of the *Acquis Communautaire*. This necessitates the positioning of a regulatory framework to govern agri-biotech activity which is compatible with EU directives. The need to implement and enforce regulation in the area of agricultural biotechnology is therefore approaching from two directions.

This paper examines the current situation of Poland and its progression towards developing an agri-biotech regulatory framework and the sources of difficulty which may in theory and in practice, limit the extent to which both a successful national strategy and compliance with EU directives is achieved. Specifically, government institutions are examined and the argument is made that many of the difficulties faced are historically embedded in the organisational development of these institutions. Accession both necessitates and catalyses change though the capability for change is affected by certain limited capacities. Section one of this paper utilises evolutionary theory and path dependency to describe how policy makers interpret the requirements of accession through established conceptual models. Section two examines how accession programmes may alter path dependent trajectory but is simultaneously introducing or importing models which are fundamentally incompatible with national capabilities. The third section uses Jänike's definition of capacity to explore in detail these incompatibilities and why EU compliance is presented with certain obstacles. The data for this paper is sourced from an MSc project carried out in September 2005 and uses a comparative grey literature analysis of the main EC directives and Polish national policy documents and data from semi-structured interviews conducted with academic researchers, consultants and policy makers.

Background

There are approximately 2.5 million farms in Poland; however 80% of marketed agricultural produce is produced in only 300,000 farms. The remaining farms are mostly small holder subsistence farms. These farms have a reduced need for credit and are independent of the market. The bigger farms are more dependent on the banking system and are driven to lower the costs of production as far as possible. They therefore have shown an interest in growing GM crops, particularly the herbicide resistant and Bt varieties of maize. This is especially so in the South-West region where the European Corn Borer presents a problem.

There have been some recent reports of the illegal growing of GM canola in the Polish media, but inspections have shown these reports to be unfounded. Research informants have suggested that the majority of voters and politicians don't agree with the growing of GM crops in Poland and this has been followed by 15 out of 17 local government districts in Poland declaring themselves as GM-free. (These GM-free zones do not hold legal status or official recognition and may be simply an expression of opinion, but are important nevertheless). The farming unions as expected, are large and influential though the proportions of subsistence and commercial farmers represented are not known at the time of this study.

Applications and the dossier submitted for approval for the modification, trade or growing of GM crops is passed first to the bureau for GMO's, which checks for accuracy of the technical specifications and completeness of administrative information. The non-confidential parts of the dossier are then placed on the government website for public viewing. It is then passed to the Commission which forwards the dossier along with a recommendation to the Minister of the Environment. Currently nearly all applications are for Class 1 research (contained use) and are submitted by universities and research institutes.

The current act on GMO's is likely to be replaced by a new Law on GMO's. 2005 is an election year and a new parliament will be convened in September. Under Polish law, all acts not passed by the old parliament do not have to be passed by the new one. However, it is hoped that the new law will be accepted and will be in place sometime in 2006.

The new law contains several amendments which will impact on regulation and the bureaucracy of GMO's. Under the old law it was the decision of the Polish minister of the environment whether to permit the placing on the market of a GMO. This has become the competence of EU authorities. For class 1 research, no permission is needed according to the new law. The Polish Ministry of Environment need only be notified, a shorter version of the normal dossier submitted, and then the research can commence if the ministry does not protest within two weeks. The issue of co-existence will feature more prominently after some grappling with the EU's perceived lack of guidance in this area. How EU regulations are interpreted and who's if any example is used when the rules on co-existence are settled, will bear on the title of this project, but until the new law is produced and debated on, the effects will be unknown.

The new law will also specify a new structure for the commission and its role in decision making. All 19 members are to be scientists and experts in the plant biotechnology field. The commission will be restricted to providing advice only on the scientific and technical aspects of the dossier. This is a change from the current situation in which the 19 members of the GMO commission include government representatives from public health, agriculture, national defence, economy, transport, science, the environment and a representative from the office of competition and consumer protection. There are seven representatives from 'scientific circles', one member representing entrepreneurs from the biotechnology sector, two from environmental NGOs and one from a consumer organisation. Under the new law other representation from consumer groups, NGO's etc. will give advice via the formation of a second commission or advisory body.

Public notification which currently operates via government website updates under the old law, occurs at the point at which the bureau has received, checked and validated the submission of the dossier. Under the new law, this is to take place later in the process after the science-based commission has given a recommended approval.

To assess how effectively this evolving system addresses the issue of compliance, it is necessary to look further into the historical and practical background of the current and political law.

Poland embarked on a transition process initiated in January 1990. This involved a program of 'deep institutional restructuring' alongside economic reforms which occurred at a rapid pace and in a more radical and comprehensive way than in any other CEE country (Balcerowicz 1994). In this climate authors have argued that retraction of state intervention from science and technology policy was evident. This both as a response to reallocation of priorities where greater attention was given to the urgent state of hyperinflation, shortages, foreign debt etc. and also in concurrence with the attempt to reverse the extremely interventionalist role of the state during the previous socialist regime.

The novelty of the technology might also be considered. The perception of environmental risk and uncertainty surrounding recombinant DNA technology especially in the area of GM crops and seeds, sees an increasingly vociferous call for public engagement and communication between state and non-state actors. This shift in the style of governance (Geels, Elzen et al. 2004) is a requirement which policy makers in former command economies have relatively little experience of.

And so the important question which emerges is; what influences the formation of agri-biotech policy in this environment and what are the implications for EU accession requirements?

1. Historical Embeddedness

An initial answer to this question is that the style of governance follows a trajectory formed from past experiences. In the case of post soviet regimes, the many years of socialist rule create institutions and institutionalised procedures resulting in an in-built inertia and weak capacity for change. Evolutionary theory explains this phenomenon in terms of 'path dependency'.

"Evolutionary theory holds that learning is predominantly local and path dependent. In other words, new learning is built on previously established knowledge bases and it is virtually 'blind' to other learning trajectories. New experiences are interpreted according to established conceptual models, as is the case of policy makers in Central and Eastern Europe."

(Acha and Balazs 1999)

(Von Homeyer 2004), presenting the historical-institutionalist perspective states similarly that institutions are conditioned by the past with earlier events having a more significant influence on institutional developments than later events. A 'positive feedback process' results in the persistence of characteristics unless the regime is 'shocked' in a way which causes these mechanisms to be disrupted.

This idea of path dependent conditioning of institutions presents a problem for the issue of governance of a new technology. Innovation in the biotechnology field is usually accompanied by dynamic adjustments at institutional and social levels (e.g. industrial and science policy shifts, skill and education upgrading). Where this doesn't occur we see an adjustment failure, or what may also be termed as a 'rigidity' (Tzotzos, 2000), with associated consequences. Since advancement and public funding in the area of plant and molecular biotechnology was characteristic of previous socialist soviet policy, familiarity amongst the scientific community exists and so the 'shock' Von Homeyer writes as being required for institutional learning, according to the above theoretical framing, may not occur with respect to the technology itself. Advances may occur without the comprehensive development of new governance mechanisms such as public participation which is perceived as being required by other EU countries and EU level institutions. The requirements for adjustment of governance mechanisms as set by broader EU policy may be interpreted by CEE policy makers based on their previously established conceptual models. The implications for this are two-fold.

Firstly the process of change will be slow. Change occurs where a conflict or an experience cannot be made to fit the existing conceptual model, and so policy makers become aware there is a weakness present and an adjustment is made. Secondly the adjustment of institutions will result in locally or nationally-specific characteristics rather than imported models (Acha and Balazs, 1999). The repercussions of this are that EU legislation rather than being directly adopted, will attempt to be integrated or interpreted. The model of governance to include the various stakeholders will not be copied, but will evolve within the country subject to influences from both foreign examples of models and national conditions.

What evidence is there for the retaining of older conceptual models and the following of historically embedded path dependent trajectories? Open coding of the interview data unearthed three examples.

One given was that of Polish research funding, which is still heavily loaded towards public institutes, rather than promoting private industry opportunity or the infrastructure that supports it. The innovation technology push models of the 1950's and 1960's with a focus on the role of academia in the national system of innovation, is possibly still prominent in the thinking of policy makers and is in part retained.

Secondly and with regard to government institutions, power is still very much centralised. The diffusion of GMO policy and power down to a regional level is a heavily debated topic in Poland. It was stated with reference to government administrations:

"It's very hierarchical and not many people have power. The power structure is very different to the civil service here. It's quite paralysing in a way because there's only a few people who can make decisions."

The problem with the government in Poland generally is that the ministries behave very often like independent kingdoms."

"They are also very jealous for power and to share powers with the local governments"

Transparency and accountability in decision making might also be compromised by restricted access to individuals:

"It's a different approach, they're quite protected. And also if you ring someone in Hungary you get secretaries after secretaries after secretaries. You're not allowed to speak to anyone and if you got there, they're all in big high grand closed rooms. They're not nearly as open as here."

As a third example the tax and financial redistribution structures can be examined. These were established under the older soviet regime and have not been restructured in a way that would effectively allow central government to devolve responsibility or its competence in the area of biotechnology regulation. However, regulation at the local or district level is at present not required since there are a very small number of applications and virtually none for deliberate release.

2. The competing influence of accession requirements

The above argument does not completely hold. Adjustments have been made and the predicted path trajectory along which biotechnology regulation might have followed has been at least partially disrupted. Transition and then accession has provided some of Von Homeyers 'shock' requirement. The need to comply with and incorporate the vast majority of the *Acquis Communautaire* has forced the acceptance of external advice through various learning and capacity building programmes. Evidence from the data show these to be highly influential.

The SAPARD was a special accession program for rural development and involved candidate member states writing rural development plans. This programme saw the use of the pre-accession period as a planning period for how environmental policy was to take shape in the years ahead. Trajectories in this field were forced in a new direction by EU financial assistance and foreign expertise.

In addition to SAPARD, the PHARE programme and various other technical assistance programmes occurring between the phases of transition and accession are likely to have been highly influential. These programmes often involved the travelling of Polish academics and policy makers to other countries in order to learn about alternative models of policy making and implementation.

"Part of the Polish research organisation [KBN] went over to NSF in the States – the National Science Foundation. That was some of the research we were looking at. That model as I recall may have been absorbed from an NSF model ... they had a peer review system where they did peer review rankings of the proposals which they leaned from the NSF. So I think there was a lot of transplantation of ideas that were funded by aid programmes and facilitated by analogous policy bodies in western countries."

Descriptions of capacity building programs illustrate the use of imported examples and models. One consultancy's work on capacity building involved the competing use of European rather than American models.

"We give perhaps examples of good practice from member states and how they've managed to implement EU legislation ... Once you can see how other member states have understood what they've been allowed to do with it, then

you needn't reinvent the wheel yourself. So that's what we're trying to do really, is to pass on lessons learnt from member states."

To what extent do such imported EU-compliant models, succeed in establishing a working system for biotechnology regulation? It is argued here that there is a basic incompatibility founded on different conceptual models or understandings of the problem and that Poland's political history prevents the effective use of these models.

One important factor, as part of this basic incompatibility is the difference in approach taken by Poland and the EU to environmental negotiations, recognised by authors such as Paradowski (2003). The particular stance of the EU is noted for its stringent regulation, highly politicized debates and public mistrust of the government, scientists and industry (Bernauer and Meins 2003). This leads to an approach adopted by the EU which has seen an increased emphasis on multi-level governance and the importance of sub-national units of authority (Yoder 2003). This shift from government to governance is described as;

"...a complex process involving the interaction of multiple stakeholders often with different definitions of 'the problem' in numerous forms at different political levels".

(Murphy and Chataway 2005)

This preferred mode of governance as taken by the EU requires the ability to engage with multiple stakeholders including publics and NGO's. The data finds that the most influential help came from Germany with the German legal model for GMO's in particular, being used for Poland. Speaking about the PHARE programme;

"It was mainly concentrated on advice of the German experts to the Ministry of the Environment in creating GMO bureaucracy, de-lining the decision making process, training of laboratories... it played quite an important role in establishing the system, bio-safety system in this country."

The use of the German model in particular may have eased the path towards accession and simplified the regulatory harmonisation procedure in the policy area of GMO's. However, research informants suggest it is a particularly "complex system" which is costly to operate in terms of bureaucracy, impacting on both industry and the

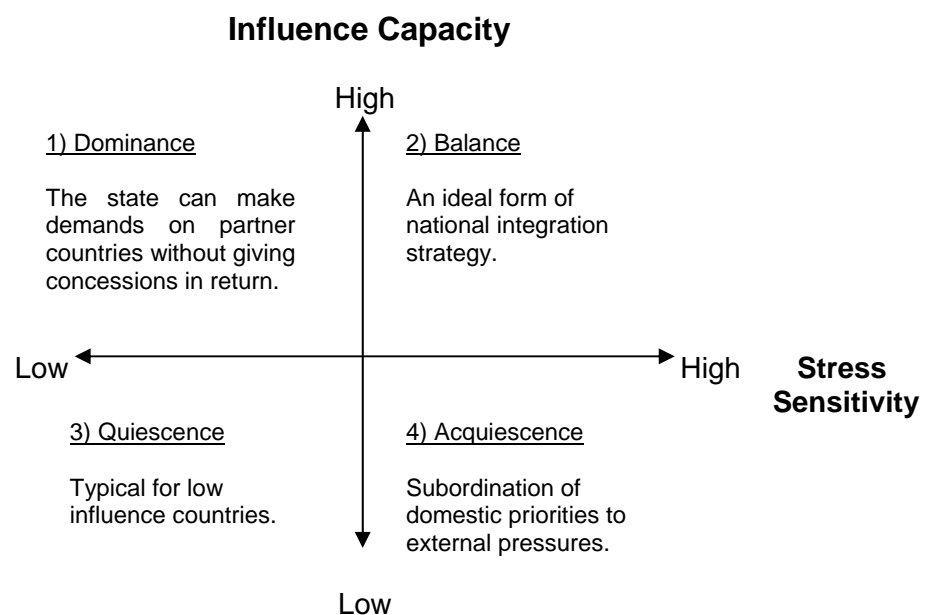
viability of implementing a regulatory structure due to its absorbing significant financial resources.

And so we come to a second important underlying factor in the issue of incompatibility which is capacity.

3. Capacity for change

The ability to implement a complex regulatory system, engage with stakeholders and break from rigidities and path dependencies in order to effect necessary change, requires capacities of various sorts.

The extent of institutional capacity in its various forms can influence the direction policy making will take in the absence of a pre-existing framework. (Jehlicka and Tickle 2004) make a prediction that CEE countries will become passively compliant with EU requirements. This comes from analysing Petersons (1998) general theory of national integration strategies. Four strategies are presented, created by the degree of control a member state has over the external environment, which he terms “influence capacity” (and in this piece of work we take this to be the influence on overarching EU environmental policy making mechanisms). Secondly, the strategies depend on the degree of sensitivity to this external environment and this he terms ‘stress sensitivity’.



Jehlicka and Tickle's prediction that CEE will either follow integration strategies 3 or 4, comes from their observations that CEE countries do not have a strong tradition in environmental policy, the undemocratic character of the harmonisation process laid out in the Copenhagen criteria and the motivation for economic integration with the EU. They also draw on Thorhallsons argument (2000) that integration behaviour is a result of administration size, with small states having insufficient capacity to address all negotiations owing to lack of staff, expertise and other resources. To evaluate their prediction it is possible to investigate certain underlying assumptions – perhaps of influence capacity, two-way communication and to a greater extent, institutional administrative capacity.

To look at institutional capacity in more depth, this investigation will use the argument developed by Jänicke et al (a contributor to the Berlin school of policy analysis). Jänicke argues that the successful implementation of policies does not occur through the sole use of single policy instrument but rather depends on attaining the flexibility to use a combination of multiple tools over time. He suggests that what is most important is the development of institutional capacity to allow this to occur (Andrews 1997). To establish the components of institutional capacity, It is possible to use the following definition of institutional factors:

“Institutional factors include political and legal structures and the rules and norms that produce a framework for interaction. In this area participation, integration, decentralisation and the capacity for strategic planning are seen as particularly important.”

(Murphy, 2001)

A second point Jänicke makes that is also relevant in this study is the situative context. This can either enable or constrain actors as they develop strategies (Murphy 2001). The actors followed in this study are the policy makers and regulators in Polish authority. The particular situative context of Poland in accession may present opportunities, for example the EU's requirement for participation in policy making where the Polish government has less experience. Or the strict legislative requirements and precautionary approach may act as a constraint. The situative context of transition in terms of financial, administrative and other institutional capacities are an added dimension.

If we take public participation and stakeholder engagement as an example, the data shows that stakeholder participation was in the initial stages, extremely poor. Authorities in CEE had difficulties in identifying their audience and finding appropriate methods of communication. A consultant reports that the situation in recent years seems to have improved somewhat;

“After accession, the stakeholder consultation was much better, so they are definitely getting the hang of it. Also the stakeholders are realising that they have a right to be involved.”

The issue of public engagement overlaps with that of communication and the capacity for effective multi-directional communication. With regards to communication between the government of Poland and the EU, communication appears to be at least partially bi-directional. EC officials are available for consultation according to one of the commission members. Another interviewee suggested that the EC does not respond well or quickly enough to the need for clarification of its policy documents. In the pre-accession phase during the Copenhagen summit of 2002, Poland appeared to have some bargaining power. They negotiated for concessions and changes in the common agricultural policy quotas, which they received. However in the general field of environmental agricultural policy it could be said that they were not involved sufficiently (H.Bennett, 2005), lending credence to Jehlicka and Tickles above assumptions.

There are conflicting accounts here. Researchers and consultants working in Poland and CEE countries also report that during the first preparatory stages of accession, communication between government departments was particularly poor. However, this study finds that the way in which the current commission is constructed (despite members views that it doesn't function effectively as a scientific body in weighing evidence), facilitates cross departmental communication in a unique way. There appears to be a small circle of scientists, commission members and commission advisors who are in close contact.

“our department on GMO in the minister on environment, on an everyday basis are in contact. There are also in person, visitors from Brussels, also people from Germany, from Berlin. Majority of us are – I would say in American language ‘friends’, we know each other by first name... The real limit is the money for travel.”

However, there is also no reference in the data which links GMO regulation to other policy areas. An integrated approach to policy making is not seen here, the issue is very much regarded in isolation. This might be reflective of the way the problem is approached by policy makers as a particular cognitive framing but the evidence is too weak to draw a conclusion here.

As suggested by the extract above, that while recognising that stakeholder participation is a new practice and requirement for CEE governments, inexperience as a limiting factor comes secondary to the more crippling issue of financial capacity. Engaging NGO's in government work is highly resource intensive and the funding simply doesn't exist. Limitations in financial capacity are running themes throughout the course of the interviews undertaken.

Lack of financial capacity impacts on other aspects of the regulatory process. Public and reference laboratories responsible for testing and traceability are badly equipped. Detection at the levels specified by EC regulations requires a Real Time PCR¹ machine and also reaction kits which are extremely costly. There are however three established reference laboratories and several operating inspection labs. The scientific community in Poland is increasingly involved with European networks. These networks exchange protocols methods and results and perform ring tests with the same samples across different laboratories. Poland is also an active member of the OECD biotechnology harmonisation working group. This to a certain extent may compensate for some deficiencies, though human capacity in terms of scientific expertise in Poland is by all accounts highly proficient.

In terms of other regulatory aspects the impacts of limited financial capacity are seen again:

“In Berlin in Brandenburg, there are ten persons working in the GMO department – just in one district, district Berlin. In Polish Minister of Environment, we have 5 persons for the entire country. These people are very good. They're young, well educated, they're overloaded with the job.”

“The system is working pretty well, quite effectively with some difficulties of course, for example one of the difficult problems for the department of GMO's

¹ Polymerase Chain Reaction – used to detect particular DNA constructs in a gene sequence

in the Minister of Environment is the problem of paying money to the referee's for their job because of the shortage of money."

Interview transcripts with non-commission interviewees reveal that references to other funding problems were given also in relation to deficient IT in administrative systems, general wage levels for policy makers and the costs of monitoring and reporting.

The unique situative context of this case reveals further complications in the accession process which prevent regulatory harmonisation but are outside of national control. The path towards EC compliance is complicated by the issue of co-existence which does not have a set of clear rules in EC directives. There are two possibilities for the future with regards to co-existence. One is that it will be written as a special technical directive or amendment by the Ministry of Agriculture. The second possibility is that it will be included in the new Law on GMO. The precautionary principle likewise does not have a legal definition in Europe. The precautionary principle as it is described in the Cartagena protocol is included in the existing law. The importance of overarching international laws and definitions such as the Cartagena protocol and the Aarhus convention are certainly not eclipsed by EU priorities and directives. And with issues such as the precautionary principle, where EU guidelines fall short of providing adequate guidance, interpretation does not diverge too far due to these international agreements.

Conclusion

The evolving system of regulation for agri-biotech in Poland is likely to be highly influenced by Poland's historical and political background. The following of a path-dependent trajectory may create a regulatory framework which complies with EU governance systems with increasing difficulty. Learning structures are theoretically important but more critical are the less tacit infra-structures which support the centralised system of decision making. For example the tax structure which prevents the delegation of authority to local levels, is the result of infrastructures put in place by the previous regime. These infrastructures are difficult and costly to disassemble, but do create an inertia which can also be described as a path-dependent rigidity. It is this which became apparent as a more important factor in this study.

Given this definition of a path dependent rigidity, it is possible to evaluate the competing influence of accession as a factor. The process of transition and accession acted as a catalyst in changing this path trajectory. The 'shock' as described by Von Homeyer (2004) and Fischer (2003) that disrupts inertia and the positive feedback systems, might be seen as being provided by the accession process and the inflexible requirements of EC directives.

A second mechanism by which path dependency may have been disrupted, are the various pre-accession programmes (PHARE, SAPARD etc.) which in part at least, provided expertise and funding for the strengthening of capacities and supporting infra-structure as described above.

A third mechanism involved the import of foreign models and processes by various means such as the travelling and learning of academics and policy makers to other member states and the US. The German model of regulation was highly influential and was provided by German experts in the pre-accession phase. It was implemented however, with outcomes that are not seen as beneficial or appropriate for Poland by members of the commission. (Though it should be noted that the opinions of the scientists in the commission are not entirely representative of general public opinion). There is further demonstrated, a fundamental incompatibility of the use of the German model in the Polish context. The German regulatory system is highly complex and is costly to implement. Poland has neither the funds nor the administrative capacity to implement this model successfully. An added dimension is that the highly stringent and bureaucratic regulations, impose costs on both the state

and the producer which severely limits the possibility of the commercialisation of GM crops in Poland. The paradox which emerges is that due to the stringent nature of this regulatory system, there is currently very little GMO industry and a very small number of applications for experimental release, so allowing the administrative structure which enforces the regulations, to cope and maintain this framework. The system of enforcement, though in place and adequate on paper, has not been tested. With current staff capacity in the GMO bureau, a higher level of applications, along with processing and monitoring requirements would cripple the system. However, new laws at the national level which allow contained use to proceed without permission notification and new regulations at the EU level where the decision of placing on the market is now the competence of the EC, power is drawn away from the national structure and the burden is further reduced.

The ability of the Polish regulatory system to align with EU policy is further compromised by the lack of EU guidance on specific issues such as the precautionary principle, co-existence, public engagement and the perceived lack (by those interviewed) of an EU-model which can be adapted. There are divergent interpretations across EU member states and this suggests that this is not a problem unique to Poland, to post transition, or to post accession countries.

Although state administration in CEE is renowned to be large, that which is dedicated to the management of GMO policy in Poland is quite small. Thorhallsons' (2000) argument that a small administrative capacity would affect integration behaviour by reducing in turn influence capacity, does ring true. This predicts that Poland will follow an acquiescent strategy of passive compliance and to an extent this is seen to be the case. This work does illustrate some of the reasons for this. With a low capacity for negotiation and stakeholder engagement, it is likely that the indigenous development of a national strategy or regulatory framework will be slow to develop. It can be asserted here that the situative context and inexperience with engagement constrains the development of strategies by actors in the Polish system, rather than a limit of capacity in terms of knowledge or scientific regulatory expertise.

Intergovernmental communication does not appear to be a rigidity or barrier currently, though it may have been in the past. It is facilitated by this temporary regulatory structure with commission representatives from across various government departments. Given time, this study would benefit from an observation of changes which will occur after the new law in Poland is established.

The common theme running throughout this work is that of financial capacity. It determines administrative capability in terms of staff number and the capacity for government to engage in national and international negotiation. It also limits EU compliance with regards to monitoring, laboratory testing and public participation.

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