The Comparative Regulation of Life Sciences

A Research Agenda

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The Regulation of Life Sciences: Themes for Comparative Analysis

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THE CASE FOR THEMATIC COMPARATIVE ANALYSIS

In his book *Our Posthuman Future. Consequences of the Biotechnology Revolution* (2002), Francis Fukuyama concludes with a major challenge for policy makers: the urgency of substantively regulating emerging biotechnologies in our contemporary society. The author takes an explicitly normative stance, warning against unintended and unforeseen consequences of modern biotechnological innovations in food and medicine. For a time, normative issues of biotechnology were somewhat hidden from arenas in which regulatory policy decisions are made, but they have become more salient in recent years. Governments now face the task of turning all kinds of inputs to the policy process into regulatory packages – and this is a task that within countries and between them is a cause of great concern. Actors with political responsibility, interest organizations, scientific experts, and increasingly also specialists in the assessment of environmental impact, risk, and ethical and legal implications of biotechnology are involved in this regolatory process. As Robert Goodin once noted (1984), however, its not just the 'crazy cases' in need of attention; biotechnology is very much present in our daily life - often invisible, but always significant.

The life sciences are a field in which utilitarian approaches and more sceptical views and a 'new moralism' of traditional values have become particularly salient. Embryo research for example recently generated controversy in the U.S. Senate and in the Italian legislature, where the new pope Benedictus mingled in the discussion over a relaxation of the existing restrictive legislation on assisted reproduction. Since assisted reproductive technologies and genetically modified crops came on the agenda as policy problems in the 1980s, debates over public and private modes of governing these technologies are going on – and they recurred as a source of political dispute. Thus, for this field, the theme of Regulation in an Age of Governance is extremely important. But in contrast to the attention in politics and in the different disciplines involved in regulatory policy making, political scientists are only just beginning to discover the life sciences. The aim of this paper is to bring the two closer together in an agenda for research, presenting themes for comparative analysis. A challenge in this research is to use the complementary knowledge of field studies and more generic theoretical studies in political science. Such knowledge integration can be useful for both empirical

and normative work.

- THEME ONE -

BIOTECHNOLOGICAL INNOVATIONS AND POLICY DESIGN

A first main theme is the social scientific analysis of ongoing technological innovations in the different subfields of the life sciences – what commonly are called the 'green' (agricultural), 'red' (medical) and 'grey' (industrial) biotechnologies. What are the issues in these fields of life sciences, as challenges for regulatory policy? What are the challenges, for policy and for the democratic system at large?

Technological innovations and their uses are promoted and contested by a wide range of actors, and this has resulted in 'wicked' policy problems. Wicked problems involve dispute over values as well as uncertainties about the scientific knowledge status of biotechnological innovations such as those in assisted reproduction, genetic modification of crops, etc.. Given this manifest controversy and the diversity in opportunities for actors to influence policy within countries, also the policy packages are likely to differ between countries. Policy designs in these fields of the life sciences are beginning to be analyzed (see for example: Bleiklie et al, 2004; etc), and initial findings do show that policies differ – depending however on the extent to which international or supranational authority produces policy convergence across countries.

Analyzing Regulation: Policy Design

The systematic comparison of policy design involves the analytical deconstruction of policy. A first approach to such deconstruction is specific to the policy issues, and consists of mapping the degree of automomy of communities of researchers and practitioners to engage in technological innovation, and the degree of access to clients and consumers to the services and products resulting from these innovations. So, this analysis is about the permissiveness or restrictiveness of regulation, and trends over time. Second, regulatory or any type of policy consists of goals, instruments, target groups, and often also a 'policy theory' with causal and normative arguments sustaining the policy choices. While

the life sciences may be identified as a field of regulatory policy, it is important to appreciate the possible variation in forms of such policy across countries and over time. Thus more systematic analysis of policy instruments not only may reveal patterns, but also may indicate some of the causal drivers of the choice of instruments in this field of government intervention.

- THEME TWO –

ANALYZING REGULATORY PROCESSES

A conventional way to analytically decompose the policy process is to distinguish 'stages'. While the implicit suggestion of chronology in the policy cycle may not be adequate, it is none the less useful to consider the different analytical elements such as agenda setting, coalition building and decision making, and implementation. For the life sciences, these distinct elements of the regulatory process have not yet been considered much, and we focus on them here. Specific research subjects relating to the regulatory process include te origins of policy initiatives, variations in policy venues, 'boundary work' between scientific experts and policy makers, and monitoring of rule implementation.

Analyzing Agenda Dynamics: Increments and Shocks

The comparative study of agenda setting is important as it makes clear how, in different countries, images of problems, or of emerging technologies, can be framed positively or negatively. Such images can ensue from deliberate actions of policy entrepreneurs, but they also may result from interactions between policy makers and scientific experts. Such processes are channeled by institutional conditions, and variation in these conditions is a point of comparison that, in the field of the life sciences, has not received much attention (Timmermans 2005). Courts, for example, are very relevant to regulatory issues of life sciences in one country, and hardly relevant in another.

In addition to the different venues available in national systems and in specific policy subsystems, images of regulatory problems and solutions obtain support and become dominant as coalitions are built. Such regulatory policy coalitions may involve not just political actors but also stakeholders from private and other nongovernmental organizations, scientists, and opinion leaders in the media.

Images become authoritative decisions on regulatory policy in arenas where they obtain the necessary support. Thus, this process entails the transfer of images to binding regulation – with the variation in content that appears from analysis of policy design as desctibed in section one of this paper.

One theoretical account for variation across countries in the tone, topic and tempo of the regulatory process is that systems are institutionally induced to different responses. Such differences may be seen in terms of more or less incremental changes. Incremental change, including initiatives for regulatory policy innovation, may be interrupted by larger policy shocks – regulatory breakthroughs. But this may not happen everywhere to the same extent. While the literature on policy styles has indicated differences, this more specific focus on the occurrence of policy punctuations is relatively new in policy analysis (Baumgartner and Jones 1993; 2002). The theory of punctuated equilibrium can be useful for analyzing regulatory policymaking in the field of the life sciences.

Analyzing Boundary Work: Institutional Linkages

While scientific expertise plays a part in most or all fields of policy in Western societies, some areas involve what is called 'regulatory science' (see for example: Jasanoff 1990; Halffman 2003). Regulatory science is applied science, used to feed directly into the regulatory process. This element of regulatory policy making calls for a more focused attention to the links between scientists and policy makers – a link that involves 'boundary work'. Since scientific knowledge is so important to regulation of life sciences, and the input of this knowledge also directly or indirectly shapes policy images, systematic analysis of boundary work is a more specific and useful focus on the regulatory process. This boundary work increasingly involves not only the life sciences per se, but also ethical expertise as well as legal and social knowledge for assessing the impact of biotechnological innovations. Particularly the institutionalization of boundary work in the science-policy nexus is a point for comparative analysis.

Analyzing Implementation: The Monitoring Myth

A final theme for analysis of the regulatory process fits within the recently revitalized attention for implementation – focusing on monitoring and the apparent problems of slippage. Such slippage exists

at the level of supranational regulation being transferred to national regimes, and to implementation of these national regimes. While in all subfields of biotechnology rules for licensing exist, monitoring the packages of regulation appears notoriously difficult. This problem relates to administrative capacities and to the availability of expertise within monitoring agencies. The difficulty of assessing licensing conditions leads to the question to what extent monitoring works – or perhaps is a myth.

- THEME THREE –

LIFE SCIENCES, REGULATION, AND DEMOCRACY

A final cluster of themes relates more directly to normative issues, and deals with the alleged tension between technocracy and democracy in this field of high technology. Comparative analysis not only may enlarge our understanding of the regulatory process, it also may yield clues for lesson drawing – on both process and content of regulation. Normative issues include the question for whose 'good' regulatory policy in this field is – who are the beneficiaries, and what are the distributional effects? Another theme is the democratic legitimation of regulatory policy decisions, and the position of users - as consumers, patients, and citizens. What possibilities for 'voice' exist, and how well, according to calls for voice, do they work?

Policy Effects: Does Regulation Matter?

Even if problems of implementation may not be chronic everywhere, the effects of regulatory policy differ widely. Effects pertain to food companies, the medical profession and organized actors alike, and to users at the end of the chain of production. From a regulatory perspective, the key question of course is to what extent public goals set with regulatory packages are accomplished. This question involves access to services and products flowing from biotechnological innovations, the warrancies to such products and services, and distributional effects.

Democratic Legitimation: Arrangements for Accountability

A final theme is the crossnational examination of venues for 'voice' and influence for citizens, consumers, patients – the endusers of biotechnological innovations. What variation exists across

countries, and what conditions are favorable or unfavorable? These questions relate to the increasing 'process' orientation of governments in many fields of policy making. The crossnational transfer of institutional arrangements for participatory policy making and for producing responsive regulation indicate that democratic legitimation has come under renewed attention. For the life sciences, governments seek to draw lessons that enable them to steer in balance between technological innovation and public support.

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